PERFORMRx℠

Drug Information Update

January 2019

TABLE OF CONTENTS

NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
PALM OIL/HYALURONATE SODIUM	SPRAY	SI PHARMACEUTIC	ENTTY
MESALAMINE	1,000 mg SUPP. RECT	MYLAN GREENSTONE LLC	CANASA
PIMECROLIMUS	1% CREAM	ACTAVIS PHARMA OCEANSIDE PHARM	ELIDEL
CINACALCET HCL	30 MG, 60 MG, 90 MG TABLET	ACTAVIS PHARMA SLATE RUN PHARM	SENSIPAR
BACLOFEN	10,000 MCG/20 ML VIAL; 40,000 MCG/20 ML VIAL; 20,000 MCG/20 ML VIAL	MYLAN INSTITUTI	GABLOFEN
LIDOCAINE HCL	0.5 MG PEN INJECTR	SA3, LLC	ZINGO
ALBUTEROL SULFATE	90 MCG HFA AER AD	TEVA	PROAIR
ALBUTEROL SULFATE	90 MCG HFA AER AD	PRASCO LABS	VENTOLIN
HALOBETASOL PROPIONATE	0.05% FOAM	MAYNE PHARMA	LEXETTE

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
AGTS TX NEUROMUSC TRANSMISSION DIS,POT-CHAN BLKR	FIRDAPSE	AMIFAMPRIDINE PHOSPHATE	10 MG TABLET	New Entity
THYROID HORMONES	TIROSINT	LEVOTHYROXINE SODIUM	175, 200 MCG CAPSULE	New Strength
RIFAMYCINS AND RELATED DERIVATIVE ANTIBIOTICS	AEMCOLO	RIFAMYCIN SODIUM	194 MG TABLET, DR	New Entity
INSULINS	TRESIBA	INSULIN DEGLUDEC	100 UNIT/ML SUB-Q INJECTION, VIAL	New Dosage Form
HUMAN MONOCLONAL ANTIBODY COMPLEMENT(C5) INHIBITOR	ULTOMIRIS	RAVULIZUMAB-CWVZ	300 MG/30 ML IV SOLUTION, VIAL	New Entity
EYE ANTI-INFLAMMATORY AGENTS	YUTIQ	FLUOCINOLONE ACETONIDE	0.18 MG INTRAOCULAR IMPLANT	New Strength
INTERLEUKIN-6 (IL-6) RECEPTOR INHIBITORS	ACTEMRA ACTPEN	TOCILIZUMAB	162 MG/0.9 ML SUB-Q PEN INJECTOR	New Dosage Form
IMMUNOSUPPRESSANT-INTERFERON GAMMA INHIBITOR, MAB	GAMIFANT	EMAPALUMAB-LZSG	10 MG/2 ML, 50 MG/10 ML IV SOLUTION, VIAL	New Entity
THROMBOPOIETIN RECEPTOR AGONISTS	PROMACTA	ELTROMBOPAG OLAMINE	12.5 MG ORAL POWDER PACKET	New Dosage Form
ANTIMIGRAINE PREPARATIONS	EMGALITY SYRINGE	GALCANEZUMAB-GNLM	120 MG/ML SUB-Q INJECTION	New dosage form
ESTROGENIC AGENTS	DIVIGEL	ESTRADIOL	0.75 MG/0.75 G TRANSDERMAL GEL	New Strength
ANTICOAGULANT REVERSAL AGENT FOR FACTOR XA INHIB.	ANDEXXA	FACTOR XA,INACTIVATED-ZHZO	200 MG IV SOLUTION FOR RECONSTITU-TION, VIAL	New Strength
ANTI-ARTHRITIC AND CHELATING AGENTS	D-PENAMINE	PENICILLAMINE	125 MG TABLET	New Strength (unapproved drug for use in drug shortage)

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTIMALARIAL DRUGS	KRINTAFEL	TAFENOQUINE SUCCINATE	150 MG TABLET	New Strength

NEW INDICATIONS (EXISTING DRUGS)

LYNPARZA®

December 19, 2018

AstraZeneca and Merck & Co., Inc., (Merck: known as MSD outside the US and Canada) today announced that the US Food and Drug Administration (FDA) has approved LYNPARZA for use as maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to 1st-line platinum-based chemotherapy. Patients with gBRCAm advanced epithelial ovarian, fallopian tube or primary peritoneal cancer are selected for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

Source: AstraZeneca and Merck & Co., Inc.

KEYTRUDA®

December 19, 2018

Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved KEYTRUDA, Merck's anti-PD-1 therapy, for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC), based on the results of the Cancer Immunotherapy Trials Network (CITN)'s CITN-09/KEYNOTE-017 trial. In this Phase 2 trial of 50 patients with recurrent locally advanced or metastatic MCC who had not received prior systemic therapy for their advanced disease, KEYTRUDA monotherapy demonstrated an objective response rate of 56 percent (95% CI, 41-70), with a complete response rate of 24 percent (95% CI, 13-38) and a partial response rate of 32 percent (95% CI, 20-47). This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Source: Merck

ADACEL®

January 14, 2019

The U.S. Food and Drug Administration has approved the expanded use of Adacel® (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis (Tdap) Vaccine Adsorbed) to include repeat vaccination to help protect against tetanus, diphtheria and pertussis. It is now the first and only Tdap vaccine in the U.S. approved for a repeat dose in people 10 through 64 years of age 8 years or more after the first vaccination. Adacel is also the only Tdap vaccine available in a syringe made without natural rubber latex, which may help reduce risk to patients with an allergy.

Source: Sanofi

CABOMETYX®

January 14, 2019

Exelixis, Inc. (NASDAQ:EXEL) today announced that the U.S. Food and Drug Administration (FDA) approved CABOMETYX® (cabozantinib) tablets for patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. HCC is the most common form of liver cancer and the fastest-rising cause of cancer-related death in the U.S.

Source: Exelixis, Inc.

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Fluoroquinolone Antibiotics: Safety Communication - Increased Risk of Ruptures or Tears in the Aorta Blood Vessel in Certain Patients

[Posted 12/20/18]

ISSUE: FDA review found that fluoroquinolone antibiotics can increase the occurrence of rare but serious events of ruptures or tears in the main artery of the body, called the aorta. These tears, called aortic dissections, or ruptures of an aortic aneurysm can lead to dangerous bleeding or even death. They can occur with fluoroquinolones for systemic use given by mouth or through an injection.
BACKGROUND: Fluoroquinolone antibiotics are approved to treat certain bacterial infections and have been used for more than 30 years. They work by killing or stopping the growth of bacteria that can cause illness. Without treatment, some infections can spread and lead to serious health problems (see List of Currently Available FDA-Approved Systemic Fluoroquinolones).
RECOMMENDATION: Healthcare professionals should:
• Avoid prescribing fluoroquinolone antibiotics to patients who have an aortic aneurysm or are at risk for an aortic aneurysm, such as patients with peripheral atherosclerotic vascular diseases, hypertension, certain genetic conditions such as Marfan syndrome and Ehlers-Danlos syndrome, and elderly patients.
• Prescribe fluoroquinolones to these patients only when no other treatment options are available.
• Advise all patients to seek immediate medical treatment for any symptoms associated with aortic aneurysm.
• Stop fluoroquinolone treatment immediately if a patient reports side effects suggestive of aortic aneurysm or dissection.
Patients should: • Seek medical attention immediately by going to an emergency room or calling 911 if you experience sudden, severe, and constant pain in the stomach, chest or back.
• Be aware that symptoms of an aortic aneurysm often do not show up until the aneurysm becomes large or bursts, so report any unusual side effects from taking fluoroquinolones to your health care professional immediately. • Inform your health professional before starting an antibiotic prescription, if you have a history of aneurysms, blockages or hardening of the arteries, high blood pressure, or genetic conditions such as Marfan syndrome or Ehlers-Danlos syndrome.
• Not stop the antibiotic without first talking to your health care professional.
Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:
• Complete and submit the report Online: www.fda.gov/MedWatch/report
• Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Source: U.S. Food and Drug Administration (FDA)

Torrent Pharmaceuticals Limited Issues Voluntary Nationwide Recall of Losartan Potassium Tablets, USP

[Posted 12/20/18]

Torrent Pharmaceuticals Limited is voluntarily recalling 2 lots of Losartan potassium tablets, USP to the consumer level due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited. The impurity detected in the API is N-nitrosodiethylamine (NDEA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.

To date, Torrent Pharmaceuticals Limited has not received any reports of adverse events related to this recall.

Losartan is used to treat hypertension, hypertensive patients with Left Ventricular Hypertrophy and for the treatment of nephropathy in Type 2 diabetic patients. Patients who are on Losartan should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.

The products subject to recall are listed below and packaged in bottles. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products.

NDC	Manufacturer	Product Description	Lot/Batch	Expiration Date
13668-115-30	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,30count bottles	BO31C016	04/2019
13668-115-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,90count bottles	BO31C016	04/2019
13668-115-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DK3C005	04/2019

Losartan potassium tablets, USP were distributed nationwide to Torrent's wholesale distributor, repackager and retail customers. Torrent Pharmaceuticals Limited is notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Torrent is arranging for return of all recalled products to Qualanex. Instructions for returning recalled products are given in the recall letter. Consumers with

medical questions regarding this recall or to report an adverse event can contact Torrent Pharmaceuticals Limited at:

• 1-800-912-9561 (live calls received 8:00 am – 5:00 pm Eastern Time, voicemail available 24 hours/day, 7 days/week). • Medinfo.Torrent@apcerls.com
• Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
Any general questions regarding the return of this product should be directed to Qualanex at 1-888-280-2040 (live calls received 8 am - 9:00 pm Eastern Time).
Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.
• Complete and submit the report Online: www.fda.gov/medwatch/report.htm
• Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Source: U.S. Food and Drug Administration (FDA)

Terrific Care, LLC. / Medex Supply Dist, Inc. issues Nationwide Recall of CoaguChek Test Strips

[Posted 12/20/18]

This announcement clarifies information included in Terrific Care, LLC's press release issued on 12/19/2018

On 12/19/2018, Terrific Care, LLC. / Medex Supply Dist, Inc. initiated a nationwide recall of Roche CoaguChek test strips distributed directly to U.S. consumers by Terrific Care, LLC. / Medex Supply Dist, Inc. This recall only includes CoaguChek test strips distributed directly to U.S. consumers by Terrific Care, LLC. / Medex Supply Dist, Inc via its website/phone calls/facsimile of All Catalog/REF Numbers that DO NOT END IN 160.
The products distributed by Terrific Care, LLC / Medex Supply Dist, Inc. have been found to inaccurately report high INR test results. Patients taking warfarin who receive inaccurate INR results above their target therapeutic range may be at risk for inappropriate therapeutic measures such as a warfarin dose reduction, interruption of warfarin use, or administration of vitamin K.
All Catalog/REF Numbers that DO NOT END IN 160

Product	Catalog/REF Numbers	Affected Lot Numbers
CoaguChek XS Test Strips (All varieties sold by Terrific Care LLC. dba Medex Supply)	All Catalog/REF Numbers that do NOT end in 160 (see ex. image below)	27216700 through 33449899

This recall is related to the recent Roche Diagnostics Recall, the manufacturer of CoaguChek meters and test strips. The CoaguChek test strips distributed by Terrific Care LLC./Medex Supply Dist. Inc. include Catalog/REF numbers that were not included in the recent Roche recall because these items were not distributed by Roche Diagnostics in the United States.

Terrific Care, LLC. / Medex Supply Dist, Inc. began distributing impacted products between 12/27/2017 through 12/15/2018 directly to consumers via courier service. Terrific Care, LLC. / Medex Supply Dist, Inc. voluntarily recalled product after becoming aware of consumer complaints.

Actions Required:
Immediately stop using all CoaguChek XS Test Strips listed above and purchased directly from Terrific Care LLC. dba MedEx Supply.

Returns:
• Please send an E-Mail to RMA@medexsupply.com or call a customer service specialist at 888-433-2300 between the hours of 9:00 am - 5:00 pm, Monday - Thursday
• Return impacted strips directly to Terrific Care LLC. 61 Willet Street Passaic, NJ 07055-1971
Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.
• Complete and submit the report Online: www.fda.gov/medwatch/report.htm
• Regular Mail or Fax: Download form www.fda.gov/medwatch/report.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Source: U.S. Food and Drug Administration (FDA)

Aurobindo Pharma USA, Inc. Initiates Voluntary Nationwide Consumer Level Recall of 80 Lots of Amlodipine Valsartan Tablets USP, Valsartan HCTZ Tablets, USP and Valsartan Tablets USP, Due to the Detection of NDEA (N-Nitrosodiethylamine) Impurity

[Posted 12/31/18]

Aurobindo Pharma USA, Inc. is conducting a voluntary recall of 80 lots of Amlodipine Valsartan Tablets USP, Valsartan HCTZ Tablets, USP and Valsartan Tablets USP to the consumer level due to the detection of trace amounts of an unexpected impurity found in the finished drug product. The impurity detected in the finished drug product is N-nitrosodiethylamine (NDEA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification. To date, Aurobindo Pharma USA, Inc. has not received any reports of adverse events related to this recall. Amlodipine Valsartan Tablets USP, Valsartan HCTZ Tablets, USP and Valsartan Tablets USP are indicated to control high blood pressure and for the treatment of heart failure. Patients who prescribed Amlodipine Valsartan Tablets USP, Valsartan HCTZ Tablets, USP and Valsartan Tablets USP should

continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.

Amlodipine Valsartan Tablets USP, Valsartan HCTZ Tablets, USP and Valsartan Tablets USP were distributed nationwide to Aurobindo Pharma USA, Inc. wholesale, distributor, repackager and retail customers. Aurobindo Pharma USA, Inc. is notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Aurobindo Pharma USA, Inc. is arranging for return of all recalled products to Inmar/CLS Medturn. Instructions for returning recalled products are given in the recall letter.
Consumers with medical questions regarding this recall or to report an adverse event can contact Aurobindo Pharma USA, Inc. at: Consumers with medical questions regarding this recall or to report an adverse event can contact Aurobindo Pharma USA, Inc. at:
• 1-866-850-2876 Option 2
• pvg@aurobindousa.com
Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
Any general questions regarding the return of this product please contact Inmar\CLS-Medturn at 1-877-208-2407 or email rxrecalls@inmar.com (live calls received 9 am -5:00 pm Eastern Time).
Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.
• Complete and submit the report Online: www.fda.gov/medwatch/report.htm
• Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Source: U.S. Food and Drug Administration (FDA)

Torrent Pharmaceuticals Limited Expands Voluntary Nationwide Recall of Losartan Potassium Tablets, USP

[Posted 01/03/2019]

Torrent Pharmaceuticals Limited is expanding its voluntary recall from 2 lots of Losartan potassium tablets USP to a total of 10 lots, to the consumer level due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited. Torrent is only recalling lots of losartan-containing products that contain N-nitrosodiethylamine (NDEA) above the acceptable daily intake levels released by the FDA.

NDEA is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.
To date, Torrent Pharmaceuticals Limited has not received any reports of adverse events related to this recall.
Losartan is used to treat hypertension, hypertensive patients with Left Ventricular Hypertrophy and for the treatment of nephropathy in Type 2 diabetic patients. Patients who are on Losartan should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.
Losartan potassium tablets, USP were distributed nationwide to Torrent's wholesale distributor, repackager and retail customers. Torrent Pharmaceuticals Limited is notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Torrent is arranging for return of all recalled products to Qualanex. Instructions for returning recalled products are given in the recall letter.
Consumers with medical questions regarding this recall or to report an adverse event can contact Torrent Pharmaceuticals Limited at:
• 1-800-912-9561 (live calls received 8:00 am – 5:00 pm Eastern Time, voicemail available 24 hours/day, 7 days/week). • Medinfo.Torrent@apcerls.com
Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
Any general questions regarding the return of this product should be directed to Qualanex at 1-888-280-2040 (live calls received 8 am - 9:00 pm Eastern Time).
Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.
• Complete and submit the report Online: www.fda.gov/medwatch/report.htm
• Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Source: U.S. Food and Drug Administration (FDA)

Lupin Pharmaceuticals, Inc. Issues Voluntary Recall of Ceftriaxone for Injection USP, 250mg, 500mg, 1g and 2g

[Posted 01/05/2019]

Lupin Pharmaceuticals, Inc. is voluntarily recalling 5 lots of Ceftriaxone for Injection, USP, 250mg, 10 lots of Ceftriaxone for Injection, USP, 500mg, 24 lots of Ceftriaxone for Injection, USP, 1g and 3 lots of Ceftriaxone for Injection, USP 2g, to the hospital/physician level. The products have been found to contain visual grey particulate matter in reconstituted vials.

Improper piercing and use of a needle greater than 21 gauge (larger internal diameter), while reconstituting the vial, can push rubber flecks into the solution. There were no grey flecks seen prior to the reconstitution of the vials and the issue was identified upon standard visual inspection prior to patient administration.

If injected, this product (containing rubber particulate matter from the stopper) could cause vein irritation/phlebitis or pulmonary embolic events that could result in permanent impairment of body function or damage to body structures, such as the lungs and vascular system. In addition, as ceftriaxone can be administered intramuscularly, the use of the product may result in local muscle inflammation and/or abscesses.

Ceftriaxone for Injection, USP, is used as a sterile, semi-synthetic, broad-spectrum cephalosporin antibiotic for intravenous or intramuscular administration. It is used to reduce the development of drug-resistant bacteria and maintain the effectiveness of ceftriaxone sodium and other antibacterial drugs Ceftriaxone for Injection, USP, should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria. To date, the Company has not received any reports of adverse events related to the recalled lots.

Ceftriaxone for Injection, USP, is packaged in a glass vial, in pack of 10, containing 10 vials in a carton, with NDC 68180-611-10, 68180-622-10, 68180-633-10, 68180-644-10 and as single pack containing one glass vial in a carton with NDC 68180-611-01, 68180-622-01, 68180-633-01.

Ceftriaxone for Injection, USP, 250mg, Ceftriaxone for Injection, USP, 500mg, Ceftriaxone for Injection, USP, 1g and Ceftriaxone for Injection, USP, 2g were distributed Nationwide to Wholesalers / Drug chains.

Lupin Pharmaceuticals Inc. is notifying its distributors by phone and through recall notification and is arranging for return of all recalled product lots.

Hospitals / Physicians that have Ceftriaxone for Injection, USP, which are being recalled should stop using and return to Genco Pharmaceuticals Services “a subsidiary of FedEx Supply Chain” 6101 North 64th Street, Milwaukee, WI 53218, Tel: (855) 838-5786.

Questions regarding this recall can be made by contacting GENCO Pharmaceutical Services at 1-855-838-5786 Monday – Friday 7:30 am to 6:00 pm EST. For reimbursement, please have the recalled lots returned to GENCO, the lot number can be found on the side of the vial. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

• Complete and submit the report Online:www.fda.gov/medwatch/report.htm

• Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration

Source: U.S. Food and Drug Administration (FDA)

Sun Pharmaceutical Industries, Inc. Issues Voluntary Nationwide Recall of Vecuronium Bromide for Injection Due to the Presence of Particulate Matter Identified as Glass

[Posted 01/08/2019]

Sun Pharmaceutical Industries, Inc. (SPII), a wholly owned subsidiary of Sun Pharmaceutical Industries, Ltd. is voluntarily recalling three lots of Vecuronium Bromide for Injection, 10 mg (lyophilized powder), and one lot of Vecuronium Bromide for Injection, 20 mg (lyophilized powder) to the hospital level. The Vecuronium Bromide for Injection has been found to contain particulate matter identified as glass.
The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening. To date, SPII has not received any reports of adverse events related to this recall.
Vecuronium Bromide for Injection is used as an adjunct to general anesthesia, to facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation and is packaged in a glass vial; ten vials per carton. Vecuronium Bromide for Injection should be administered by or under the supervision of experienced clinicians and must be reconstituted prior to use. The affected Vecuronium Bromide for Injection, include the following:

Product Name	Lot Number	NDC Number
Vecuronium Bromide for Injection, 20 mg	JKS0400A	47335-932-44 [carton]
Vecuronium Bromide for Injection, 10 mg	JKS0443A	47335-932-44 [carton]
Vecuronium Bromide for Injection, 10 mg	JKS0444A	47335-932-44 [carton]
Vecuronium Bromide for Injection, 10 mg	JKS0477A	47335-932-44 [carton]

The product can be identified by vial or carton labeled as Vecuronium Bromide for Injection containing the specific Lot Number and Expiration Dates mentioned above.
This product was distributed nationwide to wholesale customers and medical facilities.
On January 3, 2019, SPII notified its distributors and customers through its 3rd party, Recall Coordinator (Inmar Inc.), via FedEx standard overnight shipping and has arranged for return via prepaid FedEx Ground shipping of all recalled products. Distributors and medical facilities that have Vecuronium Bromide for Injection, which is being recalled, should stop using and return it to place of purchase or as directed in the recall notification.
Consumers with questions regarding this recall can contact SPII by calling 1-800-406-7984 Monday through Friday between 8:00 am to 5:00 pm EST or e-mailing drug.safetyUSA@sunpharma.com.
Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.

• Complete and submit the report Online: www.fda.gov/medwatch/report.htm

• Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Source: U.S. Food and Drug Administration (FDA)

Prinston Pharmaceutical Inc. issues Voluntary Nationwide Recall of Irbesartan and Irbesartan HCTZ Tablets Due to detection of a Trace Amount of Unexpected Impurity, N- nitrosodiethylamine (NDEA) in the Products

[Posted 01/18/2019]

Prinston Pharmaceutical Inc., dba Solco Healthcare LLC., has initiated a voluntary recall of one (1) lot of Irbesartan and seven (7) lots of Irbesartan HCTZ Tablets to the consumer level due to the detection of trace amount of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals.

Prinston is only recalling lots of Irbesartan-containing products that contain N- nitrosodiethylamine (NDEA) above the acceptable daily intake levels released by the FDA.

N-nitrosodiethylamine (NDEA) is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.

To date, Prinston Pharmaceutical Inc. has not received any reports of adverse events related to this recall.

Irbesartan and Irbesartan HCTZ are used to control high blood pressure and for the treatment of heart failure. Irbesartan in combination with amlodipine plus hydrochlorothiazide is used to control high blood pressure.

Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on Irbesartan should continue taking their medication, until their pharmacist provides a replacement, or their doctor prescribes a different medication that treats the same condition as the risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative treatment.

The product subject to recall are listed below and packaged in bottles. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products.

Prinston's Irbesartan and Irbesartan/HCTZ tablets were distributed nationwide to wholesale, distributor, repackager and retail customers. Prinston Pharmaceutical Inc. dba Solco Healthcare LLC. is notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Prinston Pharmaceutical Inc. dba Solco Healthcare LLC. is arranging for return of all recalled products. Instructions for returning recalled products are given in the recall letter.

Retail pharmacies in possession of any unused products: Irbesartan Tablets, 300 mg/90 ct. and Irbesartan-HCTZ Tablets, 300mg/12.5mg, 150mg/12.5mg, in 30 and 90 ct. within the above expiry dates should immediately return the product by following the instructions below:
•Immediately examine your inventory and quarantine product subject to recall.
•Immediately discontinue use and distribution of the identified lot numbers. A credit memo will be issued covering the quantity of your product returned.
Return products to:
Eversana
Attn: Returns Department C/O Solco Healthcare 4580 S. Mendenhall,
Memphis, TN 38141
Note: A return label will be provided to you, free of charge. For the call tag, contact customer service via email customerservice@solcohealthcare.com; fax 1-866-931-0709. Wholesalers: No call necessary, just send debit memo via email or fax to customerservice@solcohealthcare.com; fax 1-866-931-0709
Solco is notifying its distributors and customers by letter and email and is arranging for return of all recalled products. Pharmacies and wholesalers that received the impacted products will receive a letter as well as a copy of this press release with their recall notification information.
Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this product.
Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.
•Complete and submit the report Online: www.fda.gov/medwatch/report.htm
•Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.
This Product Recall is being made with the knowledge of the United States Food and Drug Administration (FDA).
Source: U.S. Food and Drug Administration (FDA)

UPDATED: Torrent Pharmaceuticals Limited Issues Voluntary Nationwide Recall of Losartan Potassium Tablets, USP and Losartan Potassium and Hydrochlorothiazide Tablets, USP

[Posted 01/22/2019]

Torrent Pharmaceuticals Limited is expanding its voluntary recall from 10 lots of Losartan potassium tablets USP to include 6 lots of Losartan potassium and hydrochlorothiazide tablets, USP, to the consumer level due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited.
The impurity detected in the API is N-nitrosodiethylamine (NDEA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per international Agency for Research on Cancer (IARC) classification. Torrent is only recalling lots of losartan containing products that contain Nitrosodiethylamine (NDEA) above the acceptable daily intake levels released by the FDA.
To date, Torrent Pharmaceuticals Limited has not received any reports of adverse events related to this recall. Losartan is used to treat hypertension, hypertensive patients with Left Ventricular Hypertrophy and for the treatment of nephropathy in Type 2 diabetic patients. Patients who are on Losartan should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their

pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.
Patients who are on losartan potassium and hydrochlorothiazide tablets, USP should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment.
The products subject to recall are listed below and packaged in bottles. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products. Losartan potassium tablets, USP were distributed nationwide to Torrent's wholesale distributor, repackager and retail customers. Torrent Pharmaceuticals Limited is notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Torrent is arranging for return of all recalled products to Qualanex. Instructions for returning recalled products are given in the recall letter.
Consumers with medical questions regarding this recall or to report an adverse event can contact Torrent Pharmaceuticals Limited at:
• 1-800-912-9561 (live calls received 8:00 am – 5:00 pm Eastern Time, voicemail available 24 hours/day, 7 days/week). • Medinfo.Torrent@apcerls.com
Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
Any general questions regarding the return of this product should be directed to Qualanex at 1-888-280-2040 (live calls received 8 am - 9:00 pm Eastern Time).
Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.
• Complete and submit the report Online: www.fda.gov/medwatch/report.htm
• Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.
Source: U.S. Food and Drug Administration (FDA)

STUDIES AND RECENT TOPICS

FDA hails 2018 as bumper year for drug development successes
December 13, 2018

The FDA has hailed 2018 as a standout year for drug development and approvals, both in terms of the quantity and quality of activity. With the FDA approving 55 new molecular entities (NMEs) over the first 11 months of the year, 2018 has eased past 1996 to become the busiest year ever. Perhaps more importantly, the FDA thinks there are plenty of important drugs in the class of 2018.

Source: fiercebiotech.com

Lilly's Taltz beats out AbbVie's megadrug Humira in psoriatic arthritis showdown
December 18, 2018

What's a surefire way to get noticed in any field? Beat out a behemoth. And that's what Eli Lilly's Taltz has just done in psoriatic arthritis (PsA). Monday, the Indianapolis drugmaker said its anti-inflammatory player had topped AbbVie's Humira, the world's best-selling drug, in a study of PsA patients who hadn't yet been treated with a biologic. At week 24, patients treated with Taltz showed more symptom improvement than those who'd taken the megablockbuster.

Source: fiercepharma.com

FDA panel backs prescribing overdose reversal drug with opioids
December 18, 2018

An advisory panel to the U.S. Food and Drug Administration on Tuesday narrowly recommended prescribing the opioid overdose reversal drug, naloxone, along with addictive painkillers. The panel voted 12-11 in favor of labeling changes for opioids that recommend co-prescribing the overdose antidote, concluding a two-day discussion on ways to make the potentially life-saving drug readily available.

Source: reuters.com

Levothyroxine Associated With Increased Mortality in Patients with Heart Failure
December 19, 2018

Treatment with levothyroxine in patients with heart failure is associated with a higher risk for all-cause mortality, cardiovascular death, and major adverse cardiac events, according to findings published in The Journal of Clinical Endocrinology & Metabolism.

Source: endocrinologyadvisor.com

Data on safety, effectiveness of common acne drug unreliable, some researchers say
December 21, 2018

Isotretinoin, a drug for severe chronic acne, has long been linked to miscarriages, birth defects and other serious problems, but a research review suggests much of data on the drug's safety, effectiveness and side effects may be unreliable.

Source: Reuters Health

Some Diabetes Drugs Linked to Higher Heart Risks
December 21, 2018

Two common classes of type 2 diabetes drugs may lower blood sugar levels, but new research suggests those same drugs might boost the risk of heart attack, stroke and heart failure.
The drug classes in question are sulfonylureas and basal insulin. Sulfonylureas cause the body to release more insulin. They're taken orally and have been used since the 1950s. Basal insulin is given as an injection, and it's engineered to be released slowly throughout the day.

Source: healthday.com

FDA casts shadow on hemp win, calling CBD products illegal
December 22, 2018

The hemp industry still has work ahead to win legal status for hemp-derived cannabidiol, or CBD oil, as an ingredient in food or dietary supplements despite the big farm bill President Donald Trump signed this week designating hemp as an agricultural crop.
CBD oils have become increasingly popular in lotions, tinctures and foods, but their legal status has been murky and the Food and Drug Administration has sent warning letters to some companies making health claims for CBD.

Source: apnews.com

More Evidence That Abuse of Xanax, Valium is on the Rise
December 27, 2018

About one in every five people who take Valium, Xanax and other benzodiazepines are misusing the potentially addictive medication, U.S. survey data show.

The statistics also revealed that benzodiazepine use among adults is more than twice as high as previously reported, with nearly 13 percent using the drugs within the past year.

Source: healthday.com

Doctors still prescribing testosterone to men with heart disease, despite risks
December 28, 2018

Despite warnings that supplemental testosterone may raise the risk of stroke and heart attack, doctors continue to prescribe the hormone off-label to men with cardiovascular disease, a U.S. study finds.

After poring over 10 years of prescription data, researchers found that men with heart disease were no less likely than those without it to receive a testosterone prescription despite warnings from the Food and Drug Administration (FDA) in 2014 that the hormone might increase cardiovascular risk, researchers reported in JAMA Internal Medicine.

Source: reuters.com

Abatacept reduced infections in RA patients

January 02, 2019

Patients with RA who initiated abatacept had significantly lower risk of hospitalized infection, compared with those who initiated a tumor necrosis factor inhibitor (TNFi), based on data from more than 11,000 matched pairs of patients.

Source: mdedge.com

Women See Greater Benefit From Daily Dapsone Gel for Facial Acne

January 04, 2019

Once-daily dapsone gel, 7.5% is tolerable and effective for the treatment of facial acne in both men and women regardless of baseline lesion count, according to a study published in the Journal of Drugs in Dermatology.

Source: dermatologyadvisor.com

Alteplase Impedes Progression of Poststroke Ischemic Brain Lesions

January 04, 2019

According to class II evidence presented in a meta-analysis published in Neurology, intravenous alteplase, a recombinant tissue plasminogen activator, effectively prevents or delays the progression of poststroke ischemic brain lesions on computed tomography (CT) imaging and brain magnetic resonance imaging (MRI).
Source: neurologyadvisor.com

When Medicine Makes Patients Sicker

January 04, 2019

ANN ARBOR, Mich. — Despite the jackhammer-like rhythm of a mechanical ventilator, Alicia Moreno had dozed off in a chair by her 1-year-old's hospital bed, when a doctor woke her with some bad news: The common stool softener her son, Anderson, was given months earlier had been contaminated with the bacterium Burkholderia cepacia.

Source: khn.org

Extreme Temperatures May Pose Risks to Some Mail-Order Meds

January 10, 2019

Take a look at your prescription bottles. Most say “Store at room temperature” or “Keep refrigerated.” But what happens when drugs are delivered by mail? Were those instructions followed as the medicine wended its way from the pharmacy to your doorstep?

Source: khn.org

Smartphones Could Boost OTC Drug Utilization and Numbers of Rx-To-OTC Switches, Too

January 10, 2019

Some time this year, the U.S. Food and Drug Administration (FDA) is expected to formally propose a plan that would limit the need for patients to obtain a prescription from a doctor for certain drugs that currently have prescription-only status. Instead, patients would be permitted to use their smartphone to answer a set of questions to determine their medical need for certain medications. Ideally, this self-selection process would determine for the patient whether use of an over-the-counter (OTC) drug is appropriate. If deemed appropriate, patients would be provided with a code or ticket to use to pick up the medication at the pharmacy.

Source: Forbes.com

How a 'regulatory dead zone' may be holding up copycat insulin

January 14, 2019

The insulin market has increasingly attracted scrutiny from politicians, regulators and patient groups, as prices ramp higher for the hormone that millions of diabetics depend on to stay alive.
Food and Drug Administration head Scott Gottlieb has advocated for greater competition in the pharmaceutical industry as a means of bringing down drug costs. But, for insulin, changing legal rules have effectively created a "regulatory dead zone," hindering generic drugmakers filing applications for copycat versions of the biologic drug.

Source: biopharmadive.com

Fragile pharmaceutical supply chain increases costs, compromises care

January 15, 2019

The increasing frequency of drug shortages has injected some complexity into how Ochsner Health Systems manages supply scarcities.
It has pharmacy experts across the system that are constantly calling wholesalers and suppliers to get a hint of what drug may soon be in short supply. Ochsner has a phone call twice a week with its pharmacy, supply chain, chief nursing and chief operating officers to identify the next problem, said Dr. Robert Hart, executive vice president and chief medical officer for Ochsner Health

Source: modernhealthcare.com

Metronidazole Successful for Mild C difficile in Patients Under 65

January 16, 2019

Investigators from the Providence Veterans Affairs Medical Center conducted a 2-pronged study using the national cohort of veterans in order to guide clinicians in identifying patients who may be considered for metronidazole therapy. The investigators found patients who had their first episode of mild C difficile infection between 2010 and 2014 and looked at the factors that led to success, which they defined as the absence of all-cause mortality or recurrence 30 days after treatment.

Source: mdmag.com

New $1 birth control patch works in seconds, lasts for a month, researchers claim

January 16, 2019

Unlike some contraceptive patches on the market that require the user to continuously wear them, the patch's backing can be discarded once the microscopic needles break off into the skin, say researchers. In early testing of the patches on rats, the study found the patch — which contained 100 microneedles —was able to deliver a therapeutic amount of the drug for more than a month with one application

Source: usatoday.com

Grassley to test GOP on lowering drug prices

January 21, 2019

Sen. Chuck Grassley (R-Iowa) is giving Republicans an early test on their commitment to lowering drug prices.
Legislation sponsored by the Senate Finance Committee chairman and Democratic Sen. Amy Klobuchar (Minn.) would allow people to buy prescription drugs from approved pharmacies in Canada.

Source: thehill.com

U.S. top court rejects Helsinn over anti-nausea drug patent in win for Teva

January 22, 2019

WASHINGTON (Reuters) - The U.S. Supreme Court on Tuesday refused to revive Swiss drug company Helsinn Healthcare S.A.’s patent on the lucrative anti-nausea drug Aloxi in a victory for Teva Pharmaceutical Industries, which launched a generic version of it last year.

Source: reuters.com

RECALLS

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drug	Lubrisine eye drops (polyethylene glycol 400 0.4% and Propylene glycol 0.3%), 30 ML bottle, Manufactured and Distributed by: Results RNA, LLC, 1272 S 1380 W., Orem, UT 84058, UPC 7 92382307234	Class I	All Lots	Lack of Sterility Assurance and Incorrect/Undeclared excipient: Product was found to contain undeclared colloidal silver	Results RNA, LLC 1272 S 1380 W Orem, UT 84058-4911
Drug	Phenylephrine HCl, 1 mg in Sterile Water for Injection, QS 10mL Injectable Solution, 1 mg/10 mL incorrectly labeled as (10 mcg per mL), 10 mL syringe, Rx only, Avella of Houston, 9265 Kirby Dr., Houston, TX 77054, (877) 794-0404; NDC: 42852-802-61.	Class I	Lot: 11/01/18 8847 80261S, BUD: 03/31/19	Labeling: Label Error on Declared Strength: Label incorrectly lists concentration as "10 mcg per mL" rather than the correct concentration of "100 mcg per mL".	Advanced Pharma Inc.
Drugs	Ceftriaxone for Injection USP, 250 mg, packaged in a) one Single Use Vial (NDC 68180-611-01) and b) 10 Single Use Vials per box (NDC 68180-611-10); Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., 111 South Calvert Street, Baltimore, Maryland 21202; Manufactured by: Lupin Limited, Mandideep 462 046 INDIA.	Class I	Lot #: a) C600142, Exp 08/19; b) C600136, Exp 08/19; C600182, Exp 09/19, C700147, Exp 05/20; C700207, Exp 09/20 Additional lots added 12/19/2018 - C600142, C700147 and C700207	Presence of Particulate Matter: Product complaints received of grey flecks, identified as shredded rubber particulate matter from the stopper observed in reconstituted vials.	Lupin Pharmaceuticals Inc.
Drugs	Ceftriaxone for Injection USP, 500 mg, packaged in a) one Single Use Vial (NDC 68180-622-01) and b) 10 Single Use Vials per box (NDC 68180-622-10); Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., 111 South Calvert Street, Baltimore, Maryland 21202; Manufactured by: Lupin Limited, Mandideep 462 046	Class I	Lot #: a) C600173, Exp 08/19; C600218, Exp 09/19; b) C600126, C600127, C600137, C600143, Exp 08/19; C600219, Exp 09/19; C700146, Exp	Presence of Particulate Matter: Product complaints received of grey flecks, identified as shredded rubber particulate matter from the stopper observed in reconstituted vials.	Lupin Pharmaceuticals Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	INDIA.		05/20; C700208, C700209, Exp 09/20.		
Drugs	Ceftriaxone for Injection USP, 1 g, packaged in a) one Single Use Vial (NDC 68180-633-01) and b) 10 Single Use Vials per box (NDC 68180-633-10); Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., 111 South Calvert Street, Baltimore, Maryland 21202; Manufactured by: Lupin Limited, Mandideep 462 046 INDIA.	Class I	Lot #: a) C600110, Exp 05/19; C600130, Exp 08/19; C700113, Exp 03/20; C700143, Exp 05/20; b) C600106, C600108, Exp 05/19; C600128, C600138, Exp 08/19; C600174, C600179, C600180, C600181, Exp 09/19; C700108, C700109, C700110, C700111, C700112, Exp 03/20; C700129, C700130, C700131, C700132, C700138, C700142, C700145, Exp 05/20	Presence of Particulate Matter: Product complaints received of grey flecks, identified as shredded rubber particulate matter from the stopper observed in reconstituted vials.	Lupin Pharmaceuticals Inc.
Drugs	Ceftriaxone for Injection USP, 2 g, packaged in 10 Single Use Vials (NDC 68180-644-01) per box, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., 111 South Calvert Street, Baltimore, Maryland 21202; Manufactured by: Lupin Limited, Mandideep 462 046 INDIA, NDC 68180-644-10.	Class I	Lot #: C600109, Exp 05/19; C600129, C600135, Exp 08/19	Presence of Particulate Matter: Product complaints received of grey flecks, identified as shredded rubber particulate matter from the stopper observed in reconstituted vials.	Lupin Pharmaceuticals Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Vecuronium Bromide for Injection 10 mg*, *1mg/mL when reconstituted to 10 mL Lyophilized, 10 x 10 mg vials, Rx only, Manufactured by: Sun Pharmaceutical Industries Ltd. Halol-Baroda Highway Halol-389 350, Gujarat, India. Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512 NDC 47335-931-40 [vial] NDC 47335-931-44 [carton]	Class I	Lot #: JKS0443A, JKS0444A, JKS0477A, EXP 03/2019	Presence of Particulate Matter: Foreign matter identified as glass detected in Vecuronium Bromide for Injection.	Sun Pharmaceutical Industries, Inc.
Drugs	Vecuronium Bromide for Injection 20 mg* *1mg/mL when reconstituted to 20 mL Lyophilized, 10 x 20 mg vials, Rx Only, Manufactured by: Sun Pharmaceutical Industries Ltd. Halol-Baroda Highway Halol-389 350, Gujarat, India. Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512 NDC: 47335-932-40 [vial] 47335-932-44 [carton]	Class I	Lot #: JKS0400A, EXP 03/2019	Presence of Particulate Matter: Foreign matter identified as glass detected in Vecuronium Bromide for Injection.	Sun Pharmaceutical Industries, Inc.
Drugs	Dyural-40 Injection Kit, 1 Dose, Single Use Only, Rx only, Distributed by Enovachem Pharmaceuticals, Torrance, CA 90501, NDC 76420-0750-01	Class I	Lot #: 050518X5, 051618X1, Exp 1/31/19; 052318X4, Exp 5/1/19; 052318X5, 062818X1, 072518X3, 072718X1, 080318X2, 091818X2, Exp 5/31/19; 082318X4, 083118X1, 090518X4, 091818X4, Exp 6/30/19; 091818X3, Exp 7/31/19;	Labeling: Not elsewhere classified - The kits include Sodium Chloride, USP, 0.9% which was recalled by the manufacturer due to the product insert incorrectly stating stoppers do not contain latex. The stoppers contain natural rubber latex	Ascleme d USA Inc. dba Enovach em

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			091818X5, 092418X1, 092818X4, 101018X3, 101018X5, Exp 8/31/19; 102418X5, Exp 9/30/19		
Drugs	Dyural-80 Injection Kit, 1 Dose, Single Use Only, Rx only, Distributed by Enovachem Pharmaceuticals, Torrance, CA 90501, NDC 76420-0755-01	Class I	Lot # 050918X1, 051618X10, 051818X4, Exp 12/31/18; 071718X2, Exp 2/28/19; 061118X8, Exp 5/1/19; 051518X4, 051818X5, 052118X4, 052118X5, 052918X7, 061118X9, 061118X10, 061418X2, 061518X1, Exp 5/31/19; 061518X2, 061918X2, 062518X2, 062718X1, 062718X2, 062818X3, 062818X4, 070918X1, 071018X5, 071118X4, 071118X5, 072018X6, 072418X3, 072418X4, 072518X2, 073018X4, 073018X8, 080218X3, 080718X7,	Labeling: Not elsewhere classified - The kits include Sodium Chloride, USP, 0.9% which was recalled by the manufacturer due to the product insert incorrectly stating stoppers do not contain latex. The stoppers contain natural rubber latex	Ascleme d USA Inc. dba Enovach em

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			080918X3, 083018X2, 083118X2, 083118X5, 090518X5, Exp 6/30/2019; 090518X6, 090718X2, 090718X3, 090718X5, 091118X7, 091318X5, 091918X1, 092718X1, 092718X2, 092818X3, 100518X6, 101118X3, 101518X2, 101618X7, 101618X8, 101818X3, 101918X1, 102318X1, 103118X1, 103118X2, Exp 7/31/2019; 103118X3, 110618X1, 110818X1, Exp 9/30/2019		
Drugs	Lubrisine eye drops (polyethylene glycol 400 0.4% and Propylene glycol 0.3%), 30 ML bottle, Manufactured and Distributed by: Results RNA, LLC, 1272 S 1380 W., Orem, UT 84058, UPC 7 92382307234	Class I	All Lots	Lack of Sterility Assurance and Incorrect/Undeclared excipient: Product was found to contain undeclared colloidal silver	Results RNA, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Nevirapine Extended Release Tablets, 400 mg, 30-count bottle, Rx Only, Manufactured by: Cipla Ltd. Verna Goa, India, Manufactured for: Cipla USA Inc. 9100 S Dadeland Blvd., Suite 1500 Miami, FL 33156, NDC 69097-403-02	Class II	Lot #: GG80257, Exp. 12/2019	Failed Dissolution Specifications.	Cipla Limited L129 - 146 S - 103 - 105 S - 107 - 112 L147 - L147/1/2/3 L147/A Vasco Da Gama
Drug	Nitrofurantoin Oral Suspension, USP, 25mg/5mL, 230 mL bottle, Rx only, Manufactured by: Novel Laboratories, Inc., Somerset, NJ 08873; Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, MD 21202, NDC 43386-450-11.	Class II	Lot #: S700038, S700044, S700059, S700065, Exp 28-Feb-19; S700410, S700427, Exp 30-Jun-19; S700617, S700619, Exp 31-Aug-19; S700813, S700815, S700869, Exp 31-Oct-19; S700871, S700873, Exp 30-Nov-19; S700875, S701073, Exp 31-Dec-19.	Subpotent Drug: Expansion of June 2018 recall of lots S700065 and S700619 due to below specification results for assay.	LUPIN SOMERSET
Drugs	OZURDEX (dexamethasone intravitreal implant) 0.7 mg), 1 single-use plastic applicator contained within carton, Rx only, Allergan Inc Irvine, CA 92612, NDC 0023-3348-07	Class II	E78689, exp. date 06/21/2019 E78726, exp. date 06/29/2019 E78729, exp. date 07/01/2019 E78894, exp. date 08/09/2019 E79157, exp. date 09/05/2019 E79233, exp. date 09/15/2019 E79366, exp. date 10/06/2019 E79891, exp. date	GMP Deviations: A silicone particulate was noted in Ozurdex.	Allergan, PLC.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			12/07/2019 E80122, exp. date 01/18/2020 E80216, exp. date 02/06/2020 E81080, exp. date 05/09/2020 E81083, exp. date 05/22/2020 E81273, exp. date 05/31/2020 E81344, exp. date 06/21/2020 E82526, exp. date 12/11/2020 E82638, exp. date 12/20/2020 E82738, exp. date 01/18/2021 E82741, exp. date 01/23/2021 E82847, exp. date 01/29/2021 E82852, exp. date 02/01/2021 E83029, exp. date 02/26/2021 E83364, exp. date 04/18/2021		
Drugs	Estradiol Vaginal Inserts, USP, 10 mcg, Rx only, packaged in a) 8 count (NDC 68462-711-71) and b) 18 count (NDC 68462-711-88) cartons, Manufactured by: Glenmark Pharmaceuticals, Ltd., Colvale, Goa India, Manufactured for: Glenmark Pharmaceuticals, Inc., USA Mahwah, NJ	Class II	Batch numbers: a) 20180393, exp. date 01/31/2020, 20180424, exp. date 02/29/2020, 20180425, exp. date 02/29/2020, 20180427, exp. date 02/29/2020; b) 20180338, exp. date 12/31/2019, 20180386, exp. date 01/31/2020	Defective Delivery System: Customer complaints of malfunctioning plunger of the applicator	Glenmark Pharmaceuticals Inc., USA

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose, 2000 mL UltraBag container bag, Rx only; Baxter Healthcare Corporation, Deerfield, IL 60015; Product Code 5B9766, NDC 0941-0424-52.	Class II	Lot #: Y281477, Expiry: 02/2020	Lack of Assurance of Sterility: Confirmed customer complaints for leaks on the tubing.	Baxter Healthcare Corporation
Drugs	Cefdinir for Oral Suspension USP, 125mg/5mL, packaged in a) 60mL (NDC 68180-722-20), b)100mL (NDC 68180-722-10), Rx Only, Manufactured for: Lupin Pharmaceuticals Inc. Baltimore, MD 21202; Manufactured by: Lupin Limited Mandideep 462 046 INDIA	Class II	a) Lot #: F700329, F700330, F700328, Exp. January 2019; F700544, F700545, F700668, F700669, F700670, Exp. March 2019; F700958, Exp. April 2019 b) Lot #: F700327, F700392, F700393, Exp. January 2019; F700546, F700547, F700664, Exp. March 2019; F700967, Exp. April 2019, F701106, F701107, F701108, F701109, Exp. May 2019.	CGMP Deviations: Product complaints received indicating reconstituted suspension was observed to be thick.	Lupin Pharmaceuticals Inc.
Drugs	Cefdinir for Oral Suspension USP, 250mg/5mL, packaged in a) 60mL (NDC 68180-723-20), b)100mL (NDC 68180-723-10), Rx Only, Manufactured for: Lupin Pharmaceuticals Inc. Baltimore, MD 21202; Manufactured by: Lupin Limited Mandideep 462 046	Class II	a) Lot #: F700343, F700344, F700345, F700346, F700347,F700376, F700377, F700415, F700146,F700417, F700418, Exp. Jan	CGMP Deviations: Product complaints received indicating reconstituted suspension was observed to be thick.	Lupin Pharmaceuticals Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	INDIA		2019; F700419, F700420, F700492, F700493,F700508, F700665, Exp. February 2019; F700784, Exp. April 2019; b) Lot #: F700324, F700325, F700326, Exp. January 2019; F700618, F700619, F700620, Exp. February 2019.		
Drugs	0.9% Buffered Lidocaine HCl (buffered in 8.4% Sodium Bicarbonate) a.) 1 mL in 3 mL BD Syringe, 10 per carton, b.) 0.9% Buffered Lidocaine HCl (buffered in 8.4% Sodium Bicarbonate) 5 mL in 5 mL BD Syringe, 10 per carton Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX77478.	Class II	Service Code 2K2466 and 2K2470 183320004S, 183330008S, 183340002S, 183340003S, 183300004S, 183310007S, 183370041S, 183310043S, 183370042S, 183320003S, 183380007S, 183250013S, 183250014S, 183320005S, 183330009S, 183370007S, 183390044S, 183400006S, 183410003S	Subpotent	PharMEDium Services, LLC.
Drugs	Cidofovir Injection 375mg/5mL (75mg/mL) vial injection. 5 mL vials, Rx only, Mfd by: Emcure Pharmaceuticals Ltd., Hinjawadi, Pune, India Mfg. for : Heritage Pharmaceuticals	Class II	Lot #: VCIA082, Exp. MAY 2020; VCIA083, VCIA084, Exp. JUNE 2020	Lack of Assurance of Sterility: complaints received about dried powder on the outside of bottle	Heritage Pharmaceuticals, Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Inc. NDC 23155-0216-31				
Drugs	infants* IBUPROFEN, Concentrated Ibuprofen Oral Suspension, USP (NSAID), 50 mg per 1.25 mL, Dye-Free Berry Flavor, 0.5 FL OZ (15 mL) bottle, Distributed by Wal-Mart Stores, Inc., Bentonville, AR 72716, NDC 49035-125-23, UPC 0 78742 02016 7.	Class II	Lot #: 00717009A, Exp 02/19; 00717015A, Exp 04/19; 00717024A, Exp 08/19	Superpotent Drug: recalled lots may have higher concentration of ibuprofen.	Tris Pharma Inc.
Drugs	Human Chorionic Gonadotropin 3000 IU, Rx only, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054 1-844-263-6843 --- NDC: 69699-1738-10	Class II	Lot: 10292018:21 Exp. 3/31/2019	Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.	Pharm D Solutions, LLC
Drugs	Omnipaque (iohexol) Injection, 180mgI/mL, 20 mL Single-Dose Vial, packaged in 10 x 20 mL Vials per carton, Rx only, Distributed by GE Healthcare Inc., Marlborough, MA 01752 U.S.A.; Manufactured by GE Healthcare AS, Oslo, Norway; NDC 0407-1411-20.	Class II	Lot #: 14301544, Exp 21Sep21	Defective Container: vial defect was identified that could potentially impact the container closure and result in a lack of sterility assurance and/or the potential for glass particles.	GE Healthcare Inc. Life Sciences
Drugs	Monsel's (Ferric Subsulfate) Solution, 8 mL amber glass bottle, packaged as one dozen bottles with applicators per box, Rx only, Gordon Laboratories, Upper Darby, PA 19082, NDC 10481-0112-8.	Class II	Batch #: 579602, 579604, 579606, Exp 12/18; 579609, Exp 04/19.	Superpotent Drug: contains higher levels of Iron than labeled.	Gordon Laboratories

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Estradiol Tablets, USP, 2 mg, 100-count bottle, Rx Only, Distributed by: Epic Pharma, LLC Laurelton, NY 11413, NDC 42806-089-01	Class II	Lot #: 18103A, Exp 6/20	Presence of foreign tablet/capsule: A single foreign tablet was found in pharmacy dispensed bottle of 30 Estradiol 2 mg tablets.	Epic Pharma, LLC
Drugs	Fentanyl Citrate 2 mcg per mL (100 mcg per 50 mL) and Ropivacaine HCl 0.1% in Sodium Chloride 0.9%, Injection, 50 mL total volume in a 60 mL BD Syringe, Rx Only, PharMEDium Services, LLC. 913 N. Davis Ave. Cleveland, MS 38732 NDC 61553-644-75.	Class II	Lot: 183220013C Exp. 12/19/2018	Sub-potent	Pharmedium Services, LLC
Drugs	Fentanyl Citrate 2 mcg per mL (200 mcg per 100 mL) and Ropivacaine HCl 0.2% in Sodium Chloride 0.9%, Injection, 100 mL total volume in a 150 mL Intravia Bag, Rx Only, PharMEDium Services, LLC. 913 N. Davis Ave. Cleveland, MS 38732. NDC 61553-148-48	Class II	Lot: 183230004C Exp. 02/17/2019	Sub-potent	Pharmedium Services, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Levoxyl (levothyroxine sodium tablets, USP) tablets 112 mcg, 100-count bottle, Rx Only, Distributed by Pfizer Inc. New York, NY 10017, NDC 60793-855-01	Class II	Lot #:18A18, Exp. 01/2020	Superpotent Drug.	Pfizer Inc.
Drugs	Infants' Ibuprofen, Concentrated Ibuprofen Oral Suspension, USP, (NSAID), 50 mg per 1.25 mL, Dye-Free Non-Staining Berry Flavor, 0.5 FL OZ (15 mL) bottle, Distributed by Family Dollar Services, Inc., 10301 Monroe Road, Matthews, NC 28105, NDC 55319-250-23, UPC 0 32251 03374 2.	Class II	Lot #: 00717024A, Exp 08/19	Superpotent Drug: recalled lots may have higher concentration of ibuprofen.	Tris Pharma Inc.
Drugs	Infants' Ibuprofen, Concentrated Ibuprofen Oral Suspension, USP, (NSAID), 50 mg per 1.25 mL, Dye Free, Non-staining Berry Flavor, 0.5 FL OZ (15 mL) bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 39338 3.	Class II	Lot #: 00717024A, Exp 08/19	Superpotent Drug: recalled lots may have higher concentration of ibuprofen.	Tris Pharma Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Nevirapine Extended Release Tablets, 400 mg, 30-count bottle, Rx Only, Manufactured by: Cipla Ltd. Verna Goa, India, Manufactured for: Cipla USA Inc. 9100 S Dadeland Blvd., Suite 1500 Miami, FL 33156, NDC 69097-403-02	Class II	Lot #: GG80257, Exp. 12/2019	Failed Dissolution Specifications.	Cipla Limited
Drugs	Oxybutynin Chloride Tablets, USP, 5 mg, 500-count bottle, Rx only, Mfd. By: KVK-Tech, Inc., Newtown, PA 18940, NDC 10702-201-50	Class II	Lot #: 15079A, Exp 10/20	Labeling: Wrong bar code	KVK-Tech, Inc.
Drugs	curaplex Epi Safe Administration and Training Kits # 8600-01100. Kit contains 2 Epi Safe Administration Kit (8600-01101) and 1 Epi Safe Training Kit (8600-01102), Rx Only. Distributed by Sarnova HC, LLC's family of companies: Bound Tree Medical, LLC, Cardio Partners, Inc., Emergency Medical Products, Inc. & Tri-anim Health Services, Inc. 5000 Tuttle Crossing Blvd, Dublin, OH 43016	Class II	Lot # ASM0018348, EXP 12-31-2018	Labeling: Incorrect or Missing Lot and/or Exp date: vials of epinephrine within kit 8600-01100 expired on December 2018, but the outer kit label has an expiration date of January 2020. In addition, device component (syringe) may lack 510(k) clearance.	Bound Tree Medical, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Olmesartan Medoxomil and Hydrochlorothiazide Tablets, 40 mg/25 mg, packaged in a) 30-count bottle (NDC 0093-7617-56), b) 90-count bottle (NDC 0093-7617-98), Rx only, Manufactured In Israel By: Teva Pharmaceutical, IND. LTD., Jerusalem, 9777402, Israel, Manufactured For: Teva Pharmaceutical USA, INC., North Wales, PA 19454	Class II	Lot #: a) 49O005, 49O006, 49O007, 49O010, Exp 02/2019; b) 49O005, 49O009, 49O010, Exp 02/2019	Failed dissolution specifications	Teva Pharmaceuticals USA
Drugs	EEMT HS (esterified estrogens and methyltestosterone) 0.625 mg/1.25 mg, tablets,100-count bottle, Rx only, Manufactured By: Syntho Pharmaceuticals, Inc., Farmingdale, NY 11735, Distributed By: Creekwood Pharmaceutical, Inc., Birmingham, AL 35242, NDC 15310-020-01	Class II	Lot #: S16E01, Exp 05/18	CGMP deviations: Lots were recalled due to sub-potency and cGMP violations.	Syntho Pharmaceuticals, Inc.
Drugs	EEMT (esterified estrogens and methyltestosterone) 1.25 mg/2.5 mg, tablets,100-count bottle, Rx only, Manufactured By: Syntho Pharmaceuticals, Inc., Farmingdale, NY 11735, Distributed By: Creekwood Pharmaceutical, Inc., Birmingham, AL 35242, NDC 15310-010-01	Class II	Lot #: S16E02, Exp 05/18	CGMP deviations: Lots were recalled due to sub-potency and cGMP violations.	Syntho Pharmaceuticals, Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Amlodipine and Valsartan Tablets USP 5 mg/160 mg, 30-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-737-30	Class II	Lot # VESA17013-A, exp. 10/2019 Lot # VESA17014-A, exp. 10/2019 Lot # VESA18001-A, exp. 12/2019 Lot # VESA18002-A, exp. 12/2019	CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.	Aurobindo Pharma USA Inc.
Drugs	Amlodipine and Valsartan Tablets USP 10 mg/160 mg, 30-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-739-30.	Class II	Lot # VFSA17008-A, exp. 10/2019 Lot # VFSA17010-A, exp. 10/2019 Lot # VFSA18002-A, exp. 01/2020 Lot# VFSA18003-A, exp. 01/2020 Lot # VFSA18007-A, exp. 03/2020 Lot # VFSA18008-A, exp. 03/2020 Lot # VKSA17008-A, exp. 05/2019 Lot # VFSA17009-A, exp. 10/2019 Lot # VKSA17014-A, exp. 10/2019 Lot # VKSA17015-A, exp. 10/2019 Lot # VKSA17016-A, exp. 10/2019 Lot # VKSA17017-A, exp. 10/2019 Lot # VKSA18002-A, exp. 01/2020 Lot # VKSA18004-A, exp. 01/2020	CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.	Aurobindo Pharma USA Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Amlodipine and Valsartan Tablets USP 5 mg/320 mg, 30-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-738-30.	Class II	Lot # VMSA17012-A, exp. date 11/2019 Lot # VMSA17013-A, exp. date 11/2019 Lot # VMSA17014-A, exp. date 11/2019 Lot # VMSA17015-A, exp. date 11/2019 Lot # VMSA17016-A, exp. date 11/2019 Lot # VMSA17017-A, exp. date 11/2019	CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.	Aurobindo Pharma USA Inc.
Drugs	Amlodipine and Valsartan Tablets USP 10 mg/320 mg. 30-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-740-30.	Class II	Lot # VKSA18005-A, exp. date 03/2020 Lot # VKSA18001-A, exp. date 01/2020	CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.	Aurobindo Pharma USA Inc.
Drugs	Valsartan and Hydrochlorothiazide tablets USP 320mg/12.5 mg, 90-count bottle, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-550-90.	Class II	Lot # HRSA17033-A, exp. date 10/2020 Lot # HRSA17034-A, exp. date 10/2020 Lot # HRSA17035-A, exp. date 10/2020 Lot # HRSA17036-A, exp. date 10/2020 Lot # HRSA17037-A, exp. date 10/2020	CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.	Aurobindo Pharma USA Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Valsartan and Hydrochlorothiazide tablets USP 160mg/12.5 mg, 90-count bottle, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-548-90.	Class II	Lot # HTSA17033-A, exp. date 10/2020 Lot # HTSA17034-A, exp. date 10/2020 Lot # HTSA17035-A, exp. date 10/2020 Lot # HTSA17036-A, exp. date 10/2020 Lot # HTSA17040-A, exp. date 10/2020 Lot # HTSA17041-A, exp. date 11/2020 Lot # HTSA17042-A, exp. date 11/2020 Lot # HTSA17043-A, exp. date 11/2020 Lot # HTSA17037-A, exp. date 10/2020 Lot # HTSA17039-A, exp. date 10/2020	CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.	Aurobindo Pharma USA Inc.
Drugs	Valsartan and Hydrochlorothiazide tablets USP 320 mg/25 mg, 90-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-551-90.	Class II	Lot # HTSB17049-A, exp. date 08/2020 Lot # HTSB17054-A, exp. date 10/2020 Lot # HTSB17055-A, exp. date 10/2020 Lot # HTSB17056-A, exp. date 10/2020 Lot # HTSB17057-A, exp. date 10/2020 Lot # HTSB17058-A, exp. date 10/2020 Lot # HTSB17059-A, exp. date 10/2020 Lot # HTSB17060-A, exp. date 10/2020	CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.	Aurobindo Pharma USA Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			Lot # HTSB17062-A, exp. date 10/2020 Lot # HTSB17066-A, exp. date 10/2020 Lot # HTSB17067-A, exp. date 11/2020 Lot # HTSB17068-A, exp. date 11/2020 Lot # HTSB17069-A, exp. date 11/2020 Lot # HTSB18001-A, exp. date 12/2020 Lot # HTSB18002-A, exp. date 12/2020 Lot # HTSB18003-A, exp. date 12/2020 Lot # HTSB18004-A, exp. date 12/2020 Lot # HTSB18005-A, exp. date 12/2020 Lot # HTSB18006-A, exp. date 12/2020 Lot # HTSB18007-A, exp. date 12/2020 Lot # HTSB17063-A, exp. date 10/2020 Lot # HTSB17064-A, exp. date 10/2020 Lot # HTSB17065-A, exp. date 10/2020 Lot # HTSB18029-A, exp. date 03/2021		

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Valsartan and Hydrochlorothiazide tablets USP 80 mg/12.5 mg, 90-count bottle, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-547-90.	Class II	Lot # HVSA17011-A, exp. date 11/2020 Lot # HVSA17012-A, exp. date 11/2020 Lot # HVSA18001-A, exp. date 12/2020	CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.	Aurobindo Pharma USA Inc.
Drugs	Valsartan and Hydrochlorothiazide tablets USP 160 mg/25 mg, 90-count bottle, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-549-90.	Class II	Lot # HVSB17023-A, exp. date 08/2020 Lot # HVSB17036-A, exp. date 11/2020 Lot # HVSB17037-A, exp. date 11/2020 Lot # HVSB17038-A, exp. date 11/2020 Lot # HVSB17039-A, exp. date 11/2020 Lot # HVSB17040-B, exp. date 11/2020 Lot # HVSB18001-A, exp. date 12/2020 Lot # HVSB18002-A, exp. date 12/2020 Lot # HVSB18003-A, exp. date 12/2020 Lot # HVSB18004-A, exp. date 12/2020	CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.	Aurobindo Pharma USA Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Valsartan tablets USP 320 mg, 90-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-573-90.	Class II	Lot # VUSD17008-A, exp. date 07/2019 Lot # VUSD17009-A, exp. date 09/2019	CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.	Aurobindo Pharma USA Inc.
Drugs	Cephalexin for Oral Suspension USP, 250mg/5mL, 200 mL (when mixed), Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland, Manufactured by: Lupin Limited, Mandideep, India ---- NDC 68180-0124-02	Class II	lot # F602820, Expiry December 2019	CGMP Deviation; manufacturing batch record could not be located	Lupin Pharmaceuticals Inc.
Drug	Temozolomide Capsules, 20 mg, packaged in a a) 5-count (NDC 43975-253-05) and b) 14 count (NDC 43975-253-14) bottles, Rx only, Mfd, by: Stason Pharmaceuticals, Inc., Irvine, CA, Dist. By: Amerigen Pharmaceuticals, Lyndhurst, NJ	Class III	a) Lot # 18B005 A and b) Lot # 18B005 B, exp 02/2020	Failed Dissolution Specifications	Amerigen Pharmaceuticals Inc.
Drug	Temozolomide Capsules, 180 mg, packaged in a 14 count bottles, Rx only, Mfd, by: Stason Pharmaceuticals, Inc., Irvine, CA, Dist. By: Amerigen Pharmaceuticals, Lyndhurst, NJ ---- NDC 43975-256-14	Class III	Lot # 18E031, exp 05/2020	Failed Dissolution Specifications	Amerigen Pharmaceuticals Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Aprepitant Capsules, USP 40 mg, 1 capsule Unit Blister Pack, Rx Only, Manufactured in India for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430. UPC 368462583401. NDC 68462-583-40	Class III	Lot: 17180918, EXP June 2020	Shortfill: Aprepitant capsules 40 mg is being recalled due to customer reports of missing capsule in the blister pack.	Glenmark Pharmaceuticals Inc., USA
Drugs	NYSTATIN Oral Suspension, USP 500,000 Units/5mL, unit dose 5ml cups, packaged in a) 50 unit dose cups (10x5ml unit dose cups per tray, 5 trays per case) NDC 66689-037-50; b) 100 unit dose cups (10x5ml unit dose cups per tray, 10 trays per case) NDC 66689-037-99. Rx Only, Manufactured by more...	Class III	Lots: a) 505300 Exp. Dec 2018; 522200 Exp. Apr 2019; 534400 Exp. Jul 2019; 539000 Exp. Aug 2019; 543400 Exp. Sep 2019; b) 523600, 522200X Exp. Apr 2019; 535500 Exp. Jul 2019; 540700 Exp. Aug 2019; 543300 Exp. Sep 2019; 550100 Exp. Oct 2019.	Failed Impurities/Degradation Specifications: Out of specification for impurities.	VistaPharm, Inc.
Drugs	Advanced Protection Sunscreen spf 30 (Octinoxate 7.5%, Octisalate 5%, Oxybenzone 6%), 4.5 Oz/127.5 g tube.	Class III	Lot #: 131965, Exp 12/2018; 127426 Exp. 01/2019; 129045, 130424 Exp. 06/2019; 130432 Exp. 10/2019; 131870 Exp. 06/2019; 132648, Exp. 03/2020; 133732 Exp. 04/2020; 134400 Exp. 02/2020; 135345 Exp. 08/2020	Subpotent Drug: Out of specification for percentage of active pharmaceutical ingredients.	CBI Laboratories, Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Options Rx Anti-Oxidant Oil-Free Sunscreeen (Octinoxate 7.5%, Octisalate 5%, Oxybenzone 6%), 4.5 oz./128 g tube, Mfg. For Credentials Skincare Fort Worth, TX 76155	Class III	Lot #: 129114 Exp. 06/2019; 131927,133239 Exp. 03/2020; 126292, Exp.01/2019.	Subpotent Drug: Out of specification for percentage of active pharmaceutical ingredients.	CBI Laboratories, Inc.
Drugs	Curaplex Epi Safe Kit, Rx Only, contains: 1mL Vial of Epinephrine, 1 Epi-Safe Syringe, 1 Safety needle, 2 Alcohol Prep Pads,1 Adhesive Dressing, 1 Insert. Distributed by Sarnova, HC. LLC's family companies: Bound Tree Medical. LLC, Cardio Partners, Inc., Emergency Medical Products, Inc. & Tri-amin Health Services, Inc. 5000 Tuttle more...	Class III	LOT # ASM0020274 Exp 5/31/2018	Labeling: Incorrect or missing Lot and/or Exp Date: The Kit is incorrectly labeled as expiring May 2018 however the correct expiration date is May 2019. In addition, device component (syringe) lacks 510(k) clearance.	Bound Tree Medical, LLC
Drug	Cyclosporin liquid 0.2%, RX, plastic dropper bottle, dry eye, 10/24/18 Cyclosporin liquid 0.5%, RX, plastic dropper bottle, dry eye, 7/27/18 Cyclosporin liquid 1%, RX, plastic dropper bottle, dry eye, 7/19/18 Cyclosporin liquid 0.05%, RX, plastic dropper bottle, dry eye, 10/12/18-11/2/18 Cyclosporin liquid 2%, RX, plastic dropper bottle, dry eye, 8/17/2018-10/17/18	Not Yet Classified	10042018@10 exp 3/2/19, 07272018@2 exp 1/23/19, 07192018@12 exp 1/15/19, 11022018@18 exp 3/2/19, 10122018@30 exp 3/2/19, 08172018@7 exp 2/13/19, 09202018@16 exp 3/2/19, 10172018@32 exp 3/2/19,	Lack of Assurance of Sterility	Hiers Enterprises, LLC dba Northwest Compounding Pharmacy 1350 Ne Stephens St Ste 42 Roseburg, OR 97470-6410

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drug	Epinephrine liquid 1:1000, RX, glass vial, various, 10/10/18-10/22/18	Not Yet Classified	10102018@13 exp 1/8/19, 10222018@33 exp 1/20/19,	Lack of Assurance of Sterility	Hiers Enterprises, LLC dba Northwest Compounding Pharmacy
Drugs	Glutathione liquid, 100mg/ml Glutathione liquid, 200mg/ml	Not Yet Classified	10292018@17 exp 1/27/19, 10092018@5 1/7/19,	Lack of Assurance of Sterility	Hiers Enterprises, LLC dba Northwest Compounding Pharmacy
Drugs	HCG liquid, 1000u/ml, RX, glass vial, various, 10/16/18	Not Yet Classified	10162018@22 exp 1/14/19	Lack of Assurance of Sterility	Hiers Enterprises, LLC dba Northwest Compounding Pharmacy
Drugs	Hydroxyprogesterone liquid, 250mg/ml, RX, glass vial, pregnancy retention 10/25/18	Not Yet Classified	10252018@24 exp 3/31/19,	Lack of Assurance of Sterility	Hiers Enterprises, LLC dba Northwest Compounding Pharmacy
Drugs	Lidocaine gel 2%, RX, plastic dropper, analgesic 10/22/18 Lidocaine liquid 1%, RX, glass vial, analgesic, 10/22/18	Not Yet Classified	10222018@15 exp 1/20/19, 10222018@40 exp 1/20/19	Lack of Assurance of Sterility	Hiers Enterprises, LLC dba

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
					Northwest Compounding Pharmacy
Drugs	Lidocaine/Epinepherine liquid1%/1:1000, RX, glass vial, analgesic, 8/7/18	Not Yet Classified	08072018@30 exp 2/3/19	Lack of Assurance of Sterility	Hiers Enterprises, LLC dba Northwest Compounding Pharmacy
Drugs	MIC B vitamin liquid 25/50/50/1/1/1mg/ml RX glass vial, health support, 10/29/18 MIC Ba vitamin liquid 25/50/50/1/1/100/250/20mg/ 1.5ml, RX, glass vial, health 10/19/18	Not Yet Classified	10292018@15 exp 1/31/19, 10192018@8 exp 2/28/19	Lack of Assurance of Sterility	Hiers Enterprises, LLC dba Northwest Compounding Pharmacy
Drugs	Methocarbamol liquid 100mg/ml, RX, glass vial, muscle relaxer, 10/8/18-10/31/18	Not Yet Classified	10082018@34 exp 1/6/19, 10312018@27 exp 1/29/19	Lack of Assurance of Sterility	Hiers Enterprises, LLC dba Northwest Compounding Pharmacy
Drugs	Testosterone Cypionate liquid 200mg/ml, RX, glass vial, HRT, 10/1/18	Not Yet Classified	10012018@54 exp 3/30/19	Lack of Assurance of Sterility	Hiers Enterprises, LLC dba Northwest Compounding

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
					Pharmacy
Drugs	Vitamin B12 liquid 1000mcg/ml, RX, glass vial, health support, 10/16/18 Vitamin B12a liquid 1000mcg/ml, RX, glass vial, health support, 10/18/18	Not Yet Classified	10162018@28 exp 1/14/19 10182018@38 exp 1/16/19	Lack of Assurance of Sterility	Hiers Enterprises, LLC dba Northwest Compounding Pharmacy
Drugs	Absorica (Isotretinoin) Capsules 30 mg USP, 30 capsules (3x10 Prescription Packs) Rx only, Manufactured by: Galephar Pharmaceutical Research Inc. Humacao, PR 00792, Distributed by: Sun Pharmaceutical Industries Inc. Cranbury, NJ 08512, UPC 310631117313, NDC 10631-117-31 (carton) NDC10631-117-69 (prescription pack)	Not Yet Classified	Lot: 17F28AA, Exp 1/2020	Subpotent Drug: Isotretinoin content results were lower than the specification limit obtained during routing product monitoring.	Sun Pharmaceutical Industries, Inc.

*Please refer to FDA website for further information at: http://www.fda.gov/Safety/Recalls/default.htm

CURRENT DRUG SHORTAGES

Sincalide Injection

December 19, 2018

Reason for the Shortage
•Bracco Diagnostics has Kinevac injection on shortage due to a supply disruption.
•There are no approved alternatives to Kinevac for the labeled indications.

Estimated Resupply Dates
•Bracco has Kinevac on backorder and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=277

Methylphenidate Extended-Release Oral Suspension and Chewable Tablets

December 19, 2018

Reason for the Shortage
•Tris Pharma has Quillivant XR available.
•Tris Pharma did not provide a reason for QuillChew ER chewable tablet shortage.

Estimated Resupply Dates
•Tris Pharma has QuilliChew ER 40 mg chewable tablets in limited quantities. The company estimates additional product will be available in mid-January 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=373

Hepatitis B Vaccine (Recombinant)

December 19, 2018

Reason for the Shortage
•Merck has Recombivax HB on shortage due to increase in global demand.
•GlaxoSmithKline has Engerix B available.
•GlaxoSmithKline discontinued Engerix B pediatric vials in October 2017.

Estimated Resupply Dates
•Merck has Recombivax HB adult formulation vials and syringes on back order and the company estimates this will continue through 2019.
•Merck has Recombivax HB pediatric/adolescent formulation syringes and pediatric/adolescent vials on back order and the company estimates this will continue through mid-2nd quarter 2019. Merck's limited supply is being allocated to the CDC to ensure use is in accordance with their clinical guidance.
•Merck has Recombivax HB dialysis formulation 40 mcg/mL on back order and the company estimates this will continue through 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=320

Furosemide Tablets

December 19, 2018

Reason for the Shortage
•Major discontinued furosemide tablets in early-2018.
•Mylan did not provide a reason for the shortage.
•Hikma states the shortage is due to manufacturing delays.
•Sandoz discontinued furosemide tablets in late-August 2017.
•Teva discontinued furosemide tablets in June 2018

Estimated Resupply Dates
• Hikma has furosemide 20 mg tablets in 100 count unit dose packs, 40 mg tablets in 100 count unit dose packs, 40 mg tablets in 100 count bottles, and 40 mg tablets in 1000 count bottles on allocation. There are short-dated 80 mg tablets in 100 count unit dose packs available with an expiration date of November 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=339

Doxorubicin Injection

December 19, 2018

Reason for the Shortage
•Hikma did not provide a reason for the shortage of Adriamycin.
•Teva has doxorubicin solution for injection on shortage due to increased demand
•Fresenius Kabi did not provide a reason for the shortage.
•Caraco has discontinued doxorubicin solution for injection 25 mL and 100 mL vials
•Pfizer has doxorubicin on shortage due to manufacturing delays
•Sagent discontinued doxorubicin solution for injection in late-2017.
•Mylan Institutional did not provide a reason for the shortage of doxorubicin lyophilized powder for injection
•Athenex has doxorubicin available.
•FDA was allowing temporary importation of doxorubicin lyophilized powder for injection 50 mg vials. These vials were manufactured for Hospira UK Limited. The labeling as well as bar coding for the imported product is different from the US version. FDA has the Dear Healthcare Professional Letter linked on their website. The letter includes a link to both the US and United Kingdom package inserts to help explain the differences in labeling and packaging. The link to the letter is http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM507498.pdf. Ordering can be done directly with Hospira Customer Care at 877-946-7747.

Estimated Resupply Dates
•Athenex has doxorubicin 2 mg/mL 25 mL vials available with short expiration dating of March 2019. The 100 mL vials also have short expiration dating of April 2019.
•Fresenius Kabi has doxorubicin 5 mL, 10 mL, and 25 mL vials available with short-expiration dating (< 9 months).
•Mylan Institutional has doxorubicin lyophilized powder 10 mg vials on back order and the company cannot estimate a release date. The 50 mg vials are on back order and the company estimates a release date of late-April 2019.

•Hikma has Adriamycin 2 mg/mL 5 mL vials and 50 mg vials on back order and the company estimates a release date of January to February 2019. The 25 mL vials are on back order and the company estimates a release date in January 2019
•Sagent has doxorubicin 2 mg/mL 5 mL, 10 mL, and 25 mL vials on back order and the company cannot estimate a release date
•Teva has doxorubicin 2 mg/mL 25 mL vials (NDC 00703-5046-01) on intermittent back order and the company will allocate these as they become available. The 5 mL vials (NDC 00703-5043-03) and 10 mL (NDC 45963-0733-57) vials are available with short expiration dating

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=108

Ceftriaxone Sodium Injection

December 19, 2018

Reason for the Shortage
•Apotex has ceftriaxone available.
•Fresenius Kabi states the reason for the shortage was increased demand.
•Pfizer has ceftriaxone injection on shortage due to increased demand and manufacturing delays.
•Sagent states the reason for the shortage is manufacturing delay.
•Sandoz has ceftriaxone available.
•Hikma states the reason for the shortage is manufacturing delay
•Wockhardt has discontinued their ceftriaxone presentations

Estimated Resupply Dates
•Baxter has ceftriaxone premixed bags on allocation.
•Lupin has all ceftriaxone presentations on allocation.
•Hikma has ceftriaxone 500 mg vials on back order and the company cannot estimate a release date. The 1 gram vials are on intermittent back order and the company is releasing supplies as they become available. The 250 mg vials are on back order and the company estimates a release date of January 2019.
•Sagent has ceftriaxone 2 gram vials on back order and the company estimates a release date of January 2019. The 1 gram vials are on allocation. The 500 mg vials are available with short expiration dating (April 2019).

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=86

Phenytoin Sodium Injection

December 20, 2018

Reason for the Shortage
•Hikma did not provide a reason for this shortage.
•X-Gen Pharmaceuticals discontinued their phenytoin sodium presentations in April 2017.

Estimated Resupply Dates
•Hikma has phenytoin sodium 50 mg/mL 2 mL and 5 mL vials available.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=406

Morphine Sulfate Immediate-Release Tablets

December 20, 2018

Reason for the Shortage
•Hikma did not provide a reason for the shortage.

Estimated Resupply Dates
•Hikma has all morphine immediate-release tablets on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=504

Meropenem Injection

December 20, 2018

Reason for the Shortage
•Amneal did not provide a reason for the shortage.
•AuroMedics did not provide a reason for the shortage.
•Pfizer has meropenem injection on shortage due to manufacturing delays.
•Sagent has suspended manufacturing meropenem at this time.

Estimated Resupply Dates
•Amneal has meropenem 500 mg and 1 gram vials on allocation.
•AuroMedics has meropenem 1 gram vials on intermittent back order and the company estimates a release date of late-December 2018.
•Pfizer has Merrem 500 mg vials (NDC 00310-0325-20) and 1 gram vials (NDC 00310-0321-30) on back order and the company cannot estimate a release date. Pfizer has generic meropenem 500 mg and 1 gram vials on back order and the company estimates a release date of 2019.
•Sagent has meropenem 500 mg vials and 1 gram vials on back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=475

Amiodarone Injection

December 20, 2018

Reason for the Shortage
•Baxter has Nexterone premixed bags on shortage due to manufacturing delays.
•Mylan Institutional did not provide a reason for the shortage.
•Hikma did not provide a reason for the shortage; however, the 50 mg/mL, 3 mL 10 count presentation was discontinued in December 2018.

Estimated Resupply Dates
•Auromedics has amiodarone 50 mg/mL 9 mL and 18 mL vials on back order and the company estimates a release date of late-January 2019.
•Sagent has amiodarone 50 mg/mL 3 mL vials available with short expiration dating of February 2019
•Hikma has amiodarone 50 mg/mL 3 mL vials on back order and the company estimates a release date of late-December 2018 to early-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=374

Thiothixene Capsules

December 21, 2018

Reason for the Shortage
•Mylan did not provide a reason for the shortage
•Mylan is the sole supplier of thiothixene.

Estimated Resupply Dates
•Mylan has thiothixene 1 mg, 2 mg, 5 mg, and 10 mg capsules in 100 count bottles on back order and the company estimates a release date of late-January 2019 for the 1 mg and 5 mg capsules, late-January to early-February 2019 for the 2 mg capsules, and early-February 2019 for the 10 mg capsules.
•Mylan Institutional has thiothixene 2 mg, 5 mg, and 10 mg capsules in 100 count unit-dose blister packs on back order and the company estimates a release date of late-February to early-March 2019 for the 2 mg and 5 mg capsules and mid-March 2019 for the 10 mg capsules.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=418

Recombinant Zoster Vaccine (Shingrix)

December 21, 2018

Reason for the Shortage
•GlaxoSmithKline has Shingrix on shortage due to high demand for the product.

Estimated Resupply Dates
•GlaxoSmithKline has recently provided customers with allocation estimates for 2019. Allocations may be as low as 25% of past use.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=427

Pyridoxine Hydrochloride Injection

December 21, 2018

Reason for the Shortage
•Fresenius Kabi had pyridoxine on shortage due to manufacturing delays. They are the sole suppliers of pyridoxine injection.

Estimated Resupply Dates
•Fresenius Kabi has pyridoxine 100 mg/mL 1 mL vials available. Check wholesaler for inventory.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=450

Metoprolol Injection

December 21, 2018

Reason for the Shortage
•Alvogen has metoprolol injection available
•American Regent is not currently marketing metoprolol injection
•Athenex has metoprolol injection available
•Baxter did not provide a reason for the shortage

•Fresenius Kabi has metoprolol injection on shortage due to increased demand
•Mylan Institutional acquired metoprolol injection from Sagent. They discontinued metoprolol injection in March 2018
•Pfizer has metoprolol injection on shortage due to manufacturing delays
•Hikma did not provide a reason for the shortage

Estimated Resupply Dates
•Alvogen has metoprolol 1 mg/mL 5 mL vials on back order and the company cannot estimate a release date.
•Baxter (formerly Claris) has metoprolol 1 mg/mL 5 mL vials on back order and the company estimates a release date of April 2019.
•Fresenius Kabi has metoprolol 1 mg/mL 5 mL vials on back order and the company estimates a release date of early-February 2019.
•Hikma has metoprolol 1 mg/mL 10 mL vials on back order and the company cannot estimate a release date. The 5 mL vials are on back order and the company estimates a release date of January 2019
•Pfizer has metoprolol 1 mg/mL 5 mL Carpuject syringes on back order and the company estimates a release date of 1st quarter 2020. The 1 mg/mL 5 mL ampules are on back order and the company estimates a release date of 2019. The 1 mg/mL 5 mL vials are on back order and the company estimates a release date of 1st quarter 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=363

Methadone Injection

December 21, 2018

Reason for the Shortage
•Akorn did not provide a reason for the shortage.
•Mylan Institutional has methadone injection available.

Estimated Resupply Dates
•Akorn has methadone injection on back order and the company estimates a release date of January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=358

Flumazenil Injection

December 21, 2018

Reason for the Shortage
•Baxter did not provide a reason for the shortage.
•Hikma did not provide a reason for the shortage.
•Mylan Institutional did not provide a reason for the shortage

Estimated Resupply Dates
•Mylan Institutional has flumazenil 0.1 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of late-January 2019 for the 5 mL vials and cannot estimate a release date for the 10 mL vials.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=490

Dorzolamide 2% and Timolol 0.5% Ophthalmic Solution

December 21, 2018

Reason for the Shortage
•Akorn has dorzolamide and timolol ophthalmic solution on shortage due to manufacturing delays.
•Sandoz did not provide a reason for the shortage.
•Teva discontinued dorzolamide and timolol ophthalmic solution in April 2018.
•Bausch Health has dorzolamide and timolol ophthalmic solution on shortage due to manufacturing delays.

Estimated Resupply Dates
•Akorn has Cosopt 2%/0.5% ophthalmic solution in 10 mL bottles on back order and the company cannot estimate a release date.
•Bausch Health has dorzolamide 2% and timolol 0.5% ophthalmic solution in 10 mL bottles on back order and the company estimates a release date of mid-January 2019
.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=360

Lorazepam Injection

December 22, 2018

Reason for the Shortage
•Bedford discontinued lorazepam injection in May, 2011.
•Hikma has product on shortage due to manufacturing delays.
•Pfizer has product on shortage due to increased demand and manufacturing delays. Pfizer discontinued 4 mg/mL 10 mL vials in December 2017.
•Akorn has not provided a reason for the shortage.
•Amphastar has product available.

Estimated Resupply Dates
•Hikma has lorazepam 2 mg/mL 1 mL vials on allocation. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of January 2019. The 2 mg/mL 10 mL vials are on back order and the company estimates a release date in January to February 2019.
•Hikma has Ativan 2 mg/mL 1 mL and 4 mg/mL 1 mL vials on back order and the company estimates a release date of late-December 2018 to early-January 2019. Ativan 2 mg/mL 10 mL vials are on back order and the company estimates a release date of January to February 2019
•Pfizer has lorazepam 2 mg/mL 10 mL vials on back order and the company estimates a release date of January 2019. The 2 mg/mL 1 mL Carpuject syringes are available in limited supply. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of 1st quarter 2019. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 1st quarter 2020.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=87

Famotidine Injection

December 22, 2018

Reason for the Shortage
•Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
•Hikma did not provide a reason for the shortage.
•Pfizer launched famotidine injections in March 2012.
•Mylan Institutional acquired famotidine injections from Pfizer on December 6, 2013
•Fresenius Kabi did not provide a reason for the shortage.
•Baxter has famotidine premixed bags available.

Estimated Resupply Dates
•Fresenius Kabi has famotidine 20 mL vials on back order and the company estimates a release date of early-January 2019. Check wholesalers for inventory.
•Mylan Institutional has famotidine 2 mL vials on back order and the company estimates a release date of mid- to late-February 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=166

Dopamine Hydrochloride Injection

December 22, 2018

Reason for the Shortage
•American Regent is not marketing dopamine injection.
•Baxter had dopamine on shortage due to manufacturing delays.
•Pfizer states the shortage is due to manufacturing delays. The dopamine 200 mg/250 mL and 400 mg/500 mL premixed bags were discontinued in August 2017.

Estimated Resupply Dates
•Pfizer has dopamine 40 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of 2nd quarter 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=246

Butorphanol Tartrate Injection

December 22, 2018

Reason for the Shortage
•Pfizer has butorphanol injection on shortage due to manufacturing delays.

Estimated Resupply Dates
•Pfizer has butorphanol 1 mg/mL 1 mL vials on back order and the company estimates a release date of 1st quarter 2019. The 2 mg/mL 2 mL vials are on back order and the company estimates a release date of January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=414

Aminophylline Injection

December 22, 2018

Reason for the Shortage
•Pfizer has aminophylline injection on shortage due to manufacturing delays

Estimated Resupply Dates
•Pfizer has aminophylline 25 mg/mL 10 mL and 20 mL vials are on back order and the company estimates a release date of 1st quarter 2019 for the 10 mL vials and January 2019 for the 20 mL vials.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=407

Metoclopramide Injection

December 24, 2018

Reason for the Shortage
•Pfizer had metoclopramide injection on shortage due to increased demand.
•Teva had metoclopramide injection on shortage due to increased demand
•Fresenius Kabi has metoclopramide injection on shortage due to increased demand.

Estimated Resupply Dates
•Fresenius Kabi has metoclopramide 5 mg/mL 2 mL syringes on back order and the company estimates a release date of 1st quarter 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=338

Etomidate Injection

December 24, 2018

Reason for the Shortage
•American Regent is not currently marketing etomidate.
•AuroMedics has etomidate available.
•Hikma has etomidate available.
•Mylan did not provide a reason for the current shortage.
•Par Sterile Products discontinued etomidate in early 2015.
•Pfizer has Amidate on shortage due to manufacturing delays. Pfizer discontinued etomidate ampules in October 2016
•Sagent is no longer marketing etomidate.
•Zydus has etomidate available.

Estimated Resupply Dates
•Hikma has all etomidate 2 mg/mL presentations available, but with short expiry of November 2019.
•Mylan Institutional has etomidate 2 mg/mL 10 mL and 20 mL vials on back order and the company estimates a release date of late-January 2019.
•Pfizer has Amidate 2 mg/mL 20 mL LifeShield syringes on back order and the company cannot estimates a release date of 1st quarter 2020.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=147

Temazepam Capsules

December 26, 2018

Reason for the Shortage
•Ascend did not provide a reason for the shortage.
•Major has temazepam on shortage due to manufacturing delays.
•Mylan has temazepam on shortage due to manufacturing delays.
•Sun Pharma has temazepam on shortage due to manufacturing delays.
•Teva did not provide a reason for the shortage.
•Mallinckrodt has Restoril capsules available.

Estimated Resupply Dates
•Ascend has temazepam 15 mg capsules in 100 count and 30 mg capsules in 100 count on back order and the company estimates a release date of mid-January 2019.
•Major has temazepam 7.5 mg capsules in 30 count unit-dose packs and 100 count bottles on back order and the company estimates a release date of mid-January 2019.
•Mylan has temazepam 15 mg capsules in 100 count bottles, 22.5 mg capsules in 30 count bottles, and 30 mg capsules in 100 count bottles on back order and the company estimates a release date of late-April 2019 for the 15 mg and 30 mg capsules and late-January 2019 for the 22.5 mg capsules.
•Mylan Institutional has temazepam 15 mg capsules in 100 count unit-dose packs on back order and the company cannot estimate a release date. The 30 mg capsules in 100 count unit-dose packs are on back order and the company estimates a release date of early-January 2019.
•Teva has temazepam 30 mg capsules in 100 count and 500 count on back order and the company estimates a release date of early-January 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=503

Sufentanil Injection

December 26, 2018

Reason for the Shortage
•Akorn had Sufenta injection on shortage due to increased demand for the product.
•Hikma stopped marketing sufentanil injection in October 2018.
•Pfizer had sufentanil injection on shortage due to manufacturing delays.

Estimated Resupply Dates
•All marketed presentations are available.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=376

Proparacaine Hydrochloride Ophthalmic Solution

December 26, 2018

Reason for the Shortage
•Akorn, Bausch Health, and Sandoz did not provide a reason for the shortage.

Estimated Resupply Dates
• Akorn has proparacaine 0.5% ophthalmic drops on allocation.

•Bausch Health has proparacaine 0.5% ophthalmic drops on back order and the company estimates a release date of early-January 2019

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=489

Polyvinyl Alcohol (Artificial Tears) Ophthalmic Solution

December 26, 2018

Reason for the Shortage
•Akorn did not provide a reason for the shortage.
•Altaire is not currently marketing polyvinyl alcohol 1.4% ophthalmic solution.
•Major did not provide a reason for the shortage
•Ocusoft did not provide a reason for the shortage.
•Rugby did not provide a reason for the shortage

Estimated Resupply Dates
•Major has Liquitears ophthalmic drops on back order and the company cannot estimate a release date.
•Akorn has Artificial Tears Solution ophthalmic drops on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=451

Penicillin G Procaine Injection

December 26, 2018

Reason for the Shortage
•Pfizer had penicillin G procaine on shortage due to manufacturing delays.
•Pfizer is the sole supplier of penicillin G procaine.

Estimated Resupply Dates
•Pfizer has penicillin G procaine 600,000 unit/mL 1 mL and 2 mL syringes available.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=240

Olanzapine Intramuscular Injection

December 26, 2018

Reason for the Shortage
•American Regent did not provide a reason for the shortage
•Lilly has Zyprexa intramuscular injection available.
•Sandoz has olanzapine injection available.

Estimated Resupply Dates
•American Regent has olanzapine 10 mg vials for intramuscular injection on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=492

Octreotide Injection

December 26, 2018

Reason for the Shortage
•Fresenius Kabi has octreotide available.
•Hikma did not provide a reason for the shortage.
•Mylan Institutional has octreotide available.
•Sagent has octreotide available.
•Sun Pharma did not provide a reason for the shortage.
•Teva has octreotide available
•Novartis has Sandostatin available. The 200 mcg/mL 5 mL vials were discontinued in early-2018.

Estimated Resupply Dates
•Hikma has octreotide 1000 mcg/mL 5 mL vials on back order and the company estimates a release date of January 2019. The 100 mcg/mL 1 mL vials, 500 mcg/mL 1 mL vials, and 200 mcg/mL 5 mL vials are available with a short expiration date of March 2019.
•Sun Pharma has all octreotide presentations on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=229

Multiple Vitamins for Infusion

December 26, 2018

Reason for the Shortage
•Pfizer states the shortage is due to manufacturing delays.
•Baxter has all presentations fully available at this time.

Estimated Resupply Dates
•Pfizer has M.V.I. Adult 2 X 5 mL Dual vials on back order with an estimated release date of January 2019. The M.V.I. Adult 2 X 50 mL vials and Pediatric 5 mL vials are on back order and the company estimates a release date of 4th quarter 2019. There is limited short-dated product available for all 3 presentations.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=69

Methylene Blue

December 26, 2018

Reason for the Shortage
•Akorn has methylene blue on shortage due to manufacturing delays
•American Regent has recently launched an FDA approved presentation, ProvayBlue and product is available.

Estimated Resupply Dates
•Akorn has methylene blue 10 mg/mL 1 mL vials on back order and the company cannot estimate a release date. There are short-dated 10 mL vials available with an expiration date of August 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=47

Methocarbamol Tablets

December 26, 2018

Reason for the Shortage
•Bayshore, Solco, Virtus, Hikma, and Endo did not provide a reason for the shortage.
•Camber states the shortage is due to an API shortage
•Par discontinued methocarbamol tablets in July 2018.

Estimated Resupply Dates
•Camber has all methocarbamol presentations on back order and the company cannot estimate a release date.
•Hikma has methocarbamol 750 mg tablets in 500 count on back order and the company estimates a release date in January 2019. Methocarbamol 500 mg and 750 mg tablets in 100 count are on back order and the company cannot estimate a release date.
•Solco has all methocarbamol presentations on allocation.
•Virtus has all methocarbamol tablets on back order and the company cannot estimate a release date.
•Endo has Robaxin 500 mg and 750 mg tablets in 100 count on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=423

Indocyanine Green

December 26, 2018

Reason for the Shortage
•Akorn had IC-Green on shortage due to manufacturing delays.
•Hub has indocyanine green available.

Estimated Resupply Dates
•Akorn has IC-Green 25 mg kits on allocation.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=324

Hypromellose Ophthalmic Solution

December 26, 2018

Reason for the Shortage
•Akorn has hypromellose ophthalmic solution on shortage due to lack of raw materials.
•HUB Pharmaceuticals has hypromellose ophthalmic solution on long-term back order and did not provide a reason.
•Altaire did not provide a reason for the shortage.

Estimated Resupply Dates
•Akorn has Gonak 2.5% ophthalmic solution 15 mL bottles on back order and the company estimates a release date of 1st quarter 2019.
•HUB Pharmaceuticals has Goniovisc 2.5% ophthalmic solution 15 mL bottles on long-term back order and the company cannot estimate a release date.
•Ocusoft has Goniosoft 2.5% ophthalmic solution 15 mL bottles on back order and the company cannot estimate a release date.
•Altaire has Goniotaire on back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=466

Hydralazine injection

December 26, 2018

Reason for the Shortage
•Akorn has product on back order due to increased demand.
•American Regent is not currently marketing hydralazine injection.
•Fresenius Kabi did not provide a reason for the shortage.
•X-Gen did not provide a reason for the shortage.

Estimated Resupply Dates
•Akorn has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of 1st quarter 2019.
•Fresenius Kabi has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of early-January 2019. Check wholesalers for inventory.
•X-Gen has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of mid-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=431

Gentamicin Sulfate Ophthalmic Ointment

December 26, 2018

Reason for the Shortage
•Akorn has Gentak ophthalmic ointment on shortage due to manufacturing delays.
•Gentamicin ophthalmic solutions are not affected by this shortage.

Estimated Resupply Dates
•Akorn has Gentak 3.5 gram tubes on back order and the company estimates a release date in 1st quarter 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=412

Fluorescein Sodium Ophthalmic Strips

December 26, 2018

Reason for the Shortage
•Hub has Bio-Glo on shortage because demand exceeds supply.
•Akorn did not provide a reason for the shortage.

Estimated Resupply Dates
•Akorn has Ful-Glo 0.6 mg strips on back order and the company estimates a release date of 1st quarter 2019. The 1 mg strips are on allocation.
•Hub has Bio-Glo 1 mg strips on intermittent back order and the company is releasing supplies as they become available.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=362

Dorzolamide Ophthalmic Solution

December 26, 2018

Reason for the Shortage
•Akorn has dorzolamide ophthalmic solution on shortage due to manufacturing delays.
•Merck did not provide a reason for the shortage.
•Sandoz did not provide a reason for the shortage.
•Teva discontinued dorzolamide ophthalmic solution in April 2018.
•Bausch Health had dorzolamide ophthalmic solution on shortage due to manufacturing delays.

Estimated Resupply Dates
•Akorn has dorzolamide 2% ophthalmic solution on allocation.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=359

Diltiazem Hydrochloride Injection

December 26, 2018

Reason for the Shortage
•Akorn states the reason for the shortage was increased demand due to market conditions. They are not currently producing the 25 mL vials in 10 count.
•Pfizer states the reasons for the shortage is manufacturing delays and increases in demand.
•Hilkma has diltiazem injection on shortage due to manufacturing delays caused by increased demand due to current market conditions.

Estimated Resupply Dates
•Akorn has diltiazem 5 mg/mL 5 mL, 10 mL, and 25 mL vials on allocation.
•Hikma has diltiazem 5 mg/mL 10 mL and 25 mL vials on back order and the company estimates a release date of January 2019.
•Pfizer has 100 mg ADD-Vantage vials on back order and the company estimates a release date of January 2019. The 5 mg/mL 5 mL and 10 mL vials are also on back order and the company estimates a release date of 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=26

Diltiazem Extended-Release Capsules (Twice-Daily Dosing)

December 30, 2018

Reason for the Shortage
•Mylan did not provide a reason for the shortage.

Estimated Resupply Dates
•Mylan has diltiazem extended-release 60 mg, 90 mg, and 120 mg capsules in 100 count bottles on back order and the company estimates a release date of early-February 2019.
•Mylan Institutional has diltiazem extended-release 60 mg, 90 mg, and 120 mg capsules in 100 count unit-dose packs on back order and the company estimates a release date of mid-March 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=496

Diclofenac 0.1% Ophthalmic Solution

December 26, 2018

Reason for the Shortage
•Akorn did not provide a reason for the shortage.
•Rising pharmaceuticals discontinued diclofenac ophthalmic solution.
•Sandoz did not provide a reason for the shortage.

Estimated Resupply Dates
•Akorn has diclofenac 0.1% ophthalmic solution on long-term back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=395

Ciprofloxacin Ophthalmic Solution

December 26, 2018

Reason for the Shortage
•Akorn did not provide a reason for the shortage.
•Novartis has Ciloxan available.
•Sandoz has ciprofloxacin ophthalmic solution available.

Estimated Resupply Dates
•Akorn has ciprofloxacin ophthalmic solution on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=443

Calcium Gluconate Injection

November 30, 2018

Reason for the Shortage
•American Regent is not currently marketing calcium gluconate.
•Fresenius Kabi has calcium gluconate available.

Estimated Resupply Dates
•Fresenius Kabi has calcium gluconate 100 mg/mL 100 mL vials on back order and the company estimates a release date of mid-December 2018. Check wholesalers for inventory.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=150

Cidofovir Injection

December 26, 2018

Reason for the Shortage
•Heritage did not provide a reason for the shortage.
•Mylan Institutional did not provide a reason for the shortage.

Estimated Resupply Dates
•Heritage has cidofovir 75 mg/mL 5 mL vials on back order and the company cannot estimate a release date.

•Mylan Institutional has cidofovir 75 mg/mL 5 mL vials on back order and the company estimates a release date of mid-February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=486

Calcitriol Injection

December 26, 2018

Reason for the Shortage
•Akorn did not provide a reason for the shortage.
•American Regent has not had product for several years.

Estimated Resupply Dates
•Akorn has calcitriol 1 mcg/mL 1 mL ampules on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=464

Buspirone Tablets

December 26, 2018

Reason for the Shortage
•Accord did not provide a reason for the shortage.
•Mylan did not provide a reason for the shortage.
•Teva did not provide a reason for the shortage.

Estimated Resupply Dates
•Accord has buspirone 5 mg tablets in 100 count and 500 count, 10 mg tablets in 100 count and 500 count, 15 mg in 100 count, and 30 mg in 60 count on back order and the company estimates a release date of mid-January 2019. The 15 mg tablets in 60 count are on back order and the company estimates a release date of late-December 2018.
•Mylan Institutional has buspirone 5 mg, 10 mg, 15 mg, and 30 mg tablets in 100 count unit-dose packs on back order and the company estimates a release date of early-January 2019.
•Mylan has all buspirone presentations in bottles on long-term back order and the company cannot estimate a release date.
•Teva has buspirone 5 mg tablets in 100 count and 500 count on back order and the company estimates a release date of early-January 2019. The 10 mg tablets in 100 count and 500 count are on back order and the company estimates a release date of early-January 2019. There are short-dated 15 mg tablets in 100 count available with an expiration date of November 2019. The 15 mg tablets in 500 count are on back order and the company estimates a release date of early-January 2019. The 30 mg tablets in 60 count and 500 count are on back order and the company estimates a release date of early-January 2019.
•Zydus has all buspirone presentations on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=465

Amyl Nitrite Inhalation

December 26, 2018

Reason for the Shortage
•James Alexander has amyl nitrite inhalation on shortage because they are in the process of serializing the product.

Estimated Resupply Dates
•James Alexander has amyl nitrite inhalation on back order and the company estimates a release date in February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=505

Alcohol Dehydrated Injection (Ethanol)

December 26, 2018

Reason for the Shortage
•Akorn states the back order is due to manufacturing delays.
•Flon Laboratories has dehydrated alcohol 1 mL and 5 mL vials available through Morris and Dickson and direct orders. The customer service number is 877-358-4342. It is being marketed by MHC Pharma, LLC.

Estimated Resupply Dates
•American Regent has dehydrated alcohol 1 mL and 5 mL ampules on back order and the company cannot estimate a release date.
•Akorn has dehydrated alcohol 5 mL vials on allocation.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=274

Albuterol Inhalation Solution

December 26, 2018

Reason for the Shortage
•Akorn has albuterol inhalation solution on shortage due to manufacturing delays.

Estimated Resupply Dates
•Akorn has albuterol 0.5% inhalation solution 20 mL bottles on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=470

Mepivacaine Injection

December 27, 2018

Reason for the Shortage
•Fresenius Kabi did not provide a reason for the shortage.
•Pfizer states the reason for the shortage is manufacturing delays.

Estimated Resupply Dates
•Fresenius Kabi has 1.5% Polocaine-MPF 30 mL vials on back order and the company estimates a release date of mid-February 2019. The 2% Polocaine-MPF 20 mL vials are on back order and the

company estimates a release date of late-January 2019. The 1% Polocaine 50 mL vials are on back order and the company estimates a release date of late-February to early-March 2019. There are short-dated 2% Polocaine 50 mL vials available with an expiration date of <3 months. Check wholesalers for inventory.
•Pfizer has 2% Carbocaine 20 mL preservative-free vials, 2% Carbocaine 50 mL multiple-dose vials, 1% Carbocaine 30 mL preservative-free vials, 1% Carbocaine 50 mL multiple-dose vials, and 1.5% Carbocaine 30 mL preservative-free vials on back order and the company estimates a release date of 1st quarter 2020.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=331

Melphalan Tablets

December 27, 2018

Reason for the Shortage
•Apo-Pharma did not provide a reason for the shortage.

Estimated Resupply Dates
•Apo-Pharma has melphalan 2 mg tablets on long-term back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=472

Mepivacaine Injection

December 27, 2018

Reason for the Shortage
•Fresenius Kabi did not provide a reason for the shortage.
•Pfizer states the reason for the shortage is manufacturing delays.

Estimated Resupply Dates
•Fresenius Kabi has 1.5% Polocaine-MPF 30 mL vials on back order and the company estimates a release date of mid-February 2019. The 2% Polocaine-MPF 20 mL vials are on back order and the company estimates a release date of late-January 2019. The 1% Polocaine 50 mL vials are on back order and the company estimates a release date of late-February to early-March 2019. There are short-dated 2% Polocaine 50 mL vials available with an expiration date of <3 months. Check wholesalers for inventory.
•Pfizer has 2% Carbocaine 20 mL preservative-free vials, 2% Carbocaine 50 mL multiple-dose vials, 1% Carbocaine 30 mL preservative-free vials, 1% Carbocaine 50 mL multiple-dose vials, and 1.5% Carbocaine 30 mL preservative-free vials on back order and the company estimates a release date of 1st quarter 2020.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=331

Melphalan Tablets

December 27, 2018

Reason for the Shortage
•Apo-Pharma did not provide a reason for the shortage.

Estimated Resupply Dates

•Apo-Pharma has melphalan 2 mg tablets on long-term back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=472

Diphenhydramine Injection

December 27, 2018

Reason for the Shortage
•Fresenius Kabi has diphenhydramine injection on shortage due to increased demand
•Hikma did not provide a reason for the shortage.
•Mylan did not provide a reason for the shortage.
•Pfizer has diphenhydramine injection on shortage due to manufacturing delays.

Estimated Resupply Dates
•Fresenius Kabi has diphenhydramine 50 mg/mL 1 mL vials on back order and the company estimates a release date of mid-January 2019. The 50 mg/mL 1 mL syringes are on back order and the company estimates a release date of 1st quarter 2019. Check wholesalers for inventory.
•Hikma has diphenhydramine 50 mg/mL 1 mL vials on allocation
•Mylan Institutional has diphenhydramine 50 mg/mL 10 mL vials on back order and the company estimates a release date of mid-January 2019.
•Pfizer has diphenhydramine 50 mg/mL 1 mL vials on back order and the company estimates a release date of 1st quarter 2020.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=456

Carbidopa and Levodopa Extended-Release Tablets

December 27, 2018

Reason for the Shortage
•Accord has discontinued carbidopa and levodopa 25 mg/100 mg extended-release tablets. The 50 mg/200 mg tablets are on shortage due to problems obtaining active ingredient.
•Sun Pharma had carbidopa and levodopa extended-release tablets on shortage due to increased demand.
•Merck had Sinemet CR on shortage due to increased demand.
•Mylan did not provide a reason for the carbidopa and levodopa extended-release tablet shortage.

Estimated Resupply Dates
•Accord has carbidopa and levodopa 50 mg/200 mg extended-release tablets on allocation.
•Mylan has carbidopa and levodopa 25 mg/100 mg extended-release tablets in 100 count unit-dose packs on back order and the company estimates a release date of mid-February 2019. The carbidopa and levodopa 50 mg/200 mg extended-release tablets in 100 count unit-dose packs are on back order and the company estimates a release date of late-February to early-March 2018. The 50 mg/200 mg extended release tablets in 100 count bottles are on back order and the company estimates a release date of late-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=349

Trifluoperazine Tablets

January 3, 2019

Reason for the Shortage
•Mylan did not provide a reason for the shortage.
•Upsher-Smith did not provide a reason for the shortage.

Estimated Resupply Dates
•Mylan has trifluoperazine 1 mg, 2 mg, 5 mg, and 10 mg tablets in 100 count bottles on back order and the company estimates a release date of mid- to late-February 2019 for the 1 mg tablets, early- to mid-January 2019 for the 2 mg tablets, mid-January 2019 for the 5 mg tablets, and late-January 2019 for the 10 mg tablets. The 1 mg, 2 mg, 5 mg, and 10 mg tablets in 100 count unit-dose packs are on back order and the company estimates a release date of early-April 2019 for the 1 mg tablets, late-February to early-March 2019 for the 2 mg and 5 mg tablets, and mid-January 2019 for the 10 mg tablets.
•Upsher-Smith has trifluoperazine 1 mg, 2 mg, 5 mg, and 10 mg tablets in 100 count bottles on long-term back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=457

Betamethasone Acetate/Betamethasone Sodium Phosphate Suspension for Injection

January 3, 2019

Reason for the Shortage
•American Regent has betamethasone acetate/betamethasone sodium phosphate on shortage due to minor shipping delays.
•Merck did not provide a reason for the shortage.

Estimated Resupply Dates
•American Regent has betamethasone acetate/betamethasone sodium phosphate 6 mg/mL 5 mL vials available in limited supply.
•Merck has betamethasone acetate/betamethasone sodium phosphate (Celestone Soluspan) 6 mg/mL 5 mL vials on back order with an estimated release date of early-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=485

Atropine Sulfate Injection

January 3, 2019

Reason for the Shortage
•American Regent had atropine injection on shortage due to market demand.
•Amphastar has atropine injection available.
•Pfizer has atropine injection on shortage due to manufacturing delays.
•Hikma has atropine injection available.

Estimated Resupply Dates
•Pfizer has atropine 0.1 mg/mL 10 mL LifeShield syringes on back order and the company estimates release dates of 1st quarter 2019. The 0.1 mg/mL 10 mL Ansyr syringes are on back order and the company estimates a release date of January 2019. The 0.1 mg/mL 5 mL LifeShield syringes are on back

order and the company estimates release dates of 1st quarter 2019. The 0.05 mg/mL 5 mL Ansyr syringes are available with an expiration date of 1st quarter 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=46

Abciximab Injection
January 3, 2019

Reason for the Shortage
•Janssen has Reopro on shortage due to a production interruption at their third party manufacturing site. The contract manufacturer cannot guarantee supply continuity in 2018 and beyond.
•There are no other suppliers of abciximab

Estimated Resupply Dates
•Janssen has Reopro on long-term back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=413

50% Dextrose Injection
January 3, 2019

Reason for the Shortage
•Amphastar has 50% dextrose injection on allocation due to increased demand.
•Pfizer has 50% dextrose injection on shortage due to manufacturing delays.

Estimated Resupply Dates
•Pfizer has 50% dextrose 50 mL LifeShield syringes on back order and the company estimates a release date of 2nd quarter 2019. The 50% dextrose 50 mL Ansyr syringes are on back order and the company estimates a release date of January 2019. The 50% dextrose 50 mL vials are on back order and the company estimates a release date of February 2019.
•Amphastar has 50% dextrose 50 mL Luer-Jet syringes on allocation with regular releases.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=306

Heparin Injection
January 4, 2019

Reason for the Shortage
•Fresenius Kabi has heparin on shortage due to increased demand.
•Hikma did not provide a reason for the shortage.
•Mylan has heparin presentations available.
•Pfizer did not provide a reason for the shortage.
•Sagent did not provide a reason for the shortage.

Estimated Resupply Dates
•Fresenius Kabi has heparin 10,000 unit/mL 0.5 mL preservative-free vials on back order and the company estimates a release date of early-January 2019. The 10,000 unit/mL 4 mL vials are available as short-dated product (<2 months expiration date). The 1,000 unit/mL 2 mL vials are on back order and the company estimates a release date of late-January 2019. The 5,000 unit/mL 10 mL vials are on back order and the company estimates a release date of early-January 2019.

•Hikma has 1,000 unit/mL 30 mL vials and 5,000 unit/mL 10 mL vials on back order and the company cannot estimate a release date. The 5,000 unit/mL 2 mL vials are on back order and the company estimates a release date of December 2018.
•Pfizer has 5,000 unit/mL 1 mL Carpuject syringes on back order and the company estimates a release date of 4th quarter 2019. The 1,000 unit/mL 10 mL and 30 mL vials, 5,000 unit/mL 10 mL multidose vials, and 10,000 unit/mL 1 mL vials are on back order and the company cannot estimate a release date. The 5,000 unit/mL 1 mL glass vials and the 10,000 unit/mL 1 mL glass vials are on back order and the company estimates a release date of 2nd quarter 2019. The 10,000 unit/mL 0.5 mL carpuject syringes are available in limited supply.
•Sagent has 1,000 unit/mL 2 mL vials on back order and the company estimates a release date in January 2019. The 5,000 unit/mL 10 mL vials and 10,000 unit/mL 1 mL vials are on back order and the company estimates a release date of May 2019. The 1,000 unit/mL 1 mL vials and the 5,000 unit/mL 1 mL vials are on allocation.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=353

Guanfacine Hydrochloride Tablets

January 4, 2019

Reason for the Shortage
•Amneal did not provide a reason for the shortage.
•Mylan did not provide a reason for the shortage.
•Teva did not provide a reason for the shortage.

Estimated Resupply Dates
•Amneal has guanfacine 1 mg and 2 mg tablets in 100 count bottles on back order and the company estimates a release date of late-January 2019.
•Mylan has guanfacine 1 mg and 2 mg tablets in 100 count bottles on back order and the company estimates a release date of late-January 2019.
•Teva has guanfacine 1 mg and 2 mg tablets in 100 count bottles on back order and the company estimates a release date of late-February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=508

Fluorouracil Injection

January 4, 2018

Reason for the Shortage
•Accord did not provide a reason for the shortage.
•Fresenius Kabi did not provide a reason for the shortage.
•Sagent had fluorouracil injection on shortage due to manufacturing delays.
•Teva had fluorouracil injection on allocation due to increased demand.

Estimated Resupply Dates
•Accord has fluorouracil 50 mg/mL 100 mL vials on back order and the company cannot estimate a release date.
•Fresenius Kabi has fluorouracil 50 mg/mL 100 mL vials on back order and the company estimates a release date of early-January 2019.
•Sagent has fluorouracil 50 mg/mL 100 mL vials on allocation.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=401

Fluconazole Injection

January 4, 2019

Reason for the Shortage
•Baxter did not provide a reason for the fluconazole injection shortage.
•Hikma discontinued fluconazole injection in August 2018.
•Pfizer has fluconazole injection on shortage due to manufacturing delays. The 200 mg/100 mL fluconazole in dextrose bags were discontinued in August 2018.
•Renaissance Lakewood Pharmaceuticals bought fluconazole in sodium chloride premixed bags from Claris Lifescience.
•Sagent has fluconazole injection on shortage due to increased demand and manufacturing delays.

Estimated Resupply Dates
•Pfizer has fluconazole 200 mg/100 mL and 400 mg/200 mL in 0.9% sodium chloride on back order and the company estimates a release date of February 2019 for the 200 mg/100 mL bags and 1st quarter 2019 for the 400 mg/200 mL bags.
•Renaissance Lakewood has all fluconazole injection presentations on back order except the 6-count 100 mL bags and the company cannot estimate a release date.
•Sagent has fluconazole injection 200 mg/100 mL in 0.9% sodium chloride on back order and the company has an estimated release date of January 2019. The 400 mg/200 mL in 0.9% sodium chloride bags are on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=318

Dexmedetomidine Hydrochloride 100 mcg/mL Vials for Injection

January 4, 2019

Reason for the Shortage
•Akorn has dexmedetomidine vials available.
•Athenex has dexmedetomidine vials available.
•Fresenius Kabi has dexmedetomidine vials available.
•Mylan has dexmedetomidine vials available.
•Par has dexmedetomidine vials available.
•Pfizer did not provide a reason for the shortage.
•Sandoz has dexmedetomidine vials available.
•Teva has dexmedetomidine vials available.
•Hikma did not provide a reason for the shortage.
•Sun Pharma did not provide a reason for the shortage.
•AuroMedics has dexmedetomidine vials available.
•WG Critical Care has dexmedetomidine vials available.
•Accord did not provide a reason for the shortage.

Estimated Resupply Dates
•Hikma has dexmedetomidine 100 mcg/mL 2 mL vials on allocation.
•Mylan has dexmedetomidine 100 mcg/mL 2 mL vials on back order and the company cannot estimate a release date.
•Sandoz has short dated dexmedetomidine 100 mcg/mL 2 mL vials available with an expiration date of July 2019.https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=491

Dexamethasone Sodium Phosphate Injection

January 4, 2019

Reason for the Shortage
•American Regent is not marketing dexamethasone sodium phosphate injection at this time.
•AuroMedics has dexamethasone sodium phosphate on intermittent back order.
•Fresenius Kabi has dexamethasone sodium phosphate presentations available.
•Mylan Institutional has dexamethasone sodium phosphate available.
•Hikma did not provide a reason for the shortage.

Estimated Resupply Dates
•AuroMedics has dexamethasone sodium phosphate 4 mg/mL 1 mL, 5mL, and 30 mL vials on intermittent back order and the company is releasing product as it becomes available. The company estimates more release dates of March 2019.
•Fresenius Kabi has dexamethasone sodium phosphate 4 mg/mL 1 mL prefilled syringes on back order and the company estimates a release date of 1st quarter 2019. The 10 mg/mL 1 mL preservative-free vials are on back order and the company estimates a release date of early-January 2019. The 10 mg/mL 10 mL vials are on back order and the company estimates a release date of mid-January 2019. The 4 mg/mL 1 mL, 5mL, and 30 mL vials are on back order and the company estimates a release date of early-January 2019 for the 1 mL and 5 mL vials and late-January 2019 for the 30 mL vials.
•Hikma has dexamethasone sodium phosphate 4 mg/mL 1 mL and 5 mL vials on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=140

C1-Esterase Inhibitor (Human) Injection

January 4, 2019

Reason for the Shortage
•CSL Behring has Berinert available.
•Shire has resumed manufacturing and Cinryze is available.
•The subcutaneous dosage form of C1-esterase inhibitor (human) is unaffected by this shortage.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=340

Argatroban Injection

January 4, 2019

Reason for the Shortage
•Chiesi did not provide a reason for the shortage.
•Fresenius Kabi has argatroban injection available.
•Hikma did not provide a reason for the shortage.
•Mylan Institutional did not provide a reason for the shortage.
•Par did not provide a reason for the shortage.
•Pfizer states the reason for the shortage is manufacturing delay.
•Sandoz did not provide a reason for the shortage.
•Teva has argatroban temporarily unavailable.

Estimated Resupply Dates
•Chiesi has argatroban 1 mg/mL 50 mL vials on back order and the company cannot estimate a release date.
•Hikma has argatroban 1 mg/mL 50 mL vials and 100 mg/mL 2.5 mL vials on back order and the company estimates a release date of early- to mid-January 2019.
•Par has argatroban 100 mg/mL 2.5 mL vials on back order and the company estimates a release date in late-January 2019.
•Pfizer has argatroban 100 mg/mL 2.5 mL vials on back order and the company estimates a release date in February 2019.
•Novartis has argatroban 100 mg/mL 2.5 mL vials available with short expiration dating (November 2019).
•Sandoz has argatroban 1 mg/mL 50 mL vials on back order and the company estimates a release date of mid-February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=494

Sterile Water for Injection - Small Volume Vials

January 7, 2019

Reason for the Shortage
•American Regent has sterile water for injection available.
•Fresenius Kabi has sterile water on shortage due to increased demand.
•Hikma has sterile water for injection available.
•Pfizer has sterile water for injection in vials on shortage due to increased demand.

Estimated Resupply Dates
•Fresenius Kabi has sterile water for injection 50 mL vials on back order and the company estimates a release date of mid-February 2019. The 100 mL vials are on back order and the company cannot estimate a release date. Check wholesalers for inventory.
•Pfizer has sterile water for injection 50 mL vials on back order and the company estimates a release date of January 2019. The 20 mL and 100 mL vials are available in limited supply.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=375

Sodium Acetate Injection

January 7, 2019
Reason for the Shortage
•American Regent is not currently marketing sodium acetate injection.
•Fresenius Kabi has sodium acetate injection available.
•Pfizer has sodium acetate injection available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=317

Rosuvastatin Calcium Tablets

January 7, 2019

Reason for the Shortage
•Accord, Biocon, Glenmark, Mylan, Sandoz, and Rising did not provide a reason for the shortage.
•Sun Pharma will be discontinuing production of all rosuvastatin presentations.

Estimated Resupply Dates
•Accord has rosuvastatin 10 mg tablets in 1,000 count bottles and 40 mg tablets in 30 count bottles on back order and the company estimates a release date of late-October to early-November 2019. The 20 mg tablets in 90 count and 1,000 count bottles are on back order and the company estimates a release date of late-October 2019. The 40 mg tablets in 90 count and 1,000 count bottles are on back order and the company estimates release dates of mid-October 2019 for the 90 count bottles and early- to mid-October 2019 for the 1,000 count bottles.
•Biocon has rosuvastatin 40 mg tablets in limited supply.
•Mylan has rosuvastatin 5 mg tablets in 100 count unit-dose packaging available with short expiration dating of May 2019. The 10 mg tablets in 100 count unit-dose packaging have been discontinued.
•Rising has rosuvastatin 10 mg tablets in 90 count bottles on allocation. The 5 mg tablets in 500 count bottles, 20 mg tablets in 90 count bottles, and 40 mg tablets in 90 and 500 count bottles are on back order and the company cannot estimate a release date.
•Sun Pharma will be discontinuing production of rosuvastatin 5 mg, 10 mg, 20 mg, and 40 mg tablets in 90 count bottles.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=473

Mycophenolate Mofetil Capsules and Tablets

January 7, 2019

Reason for the Shortage
•Accord did not provide a reason for the shortage.
•Ascend did not provide a reason for the shortage.
•Hikma did not provide a reason for the shortage.
•Mylan did not provide a reason for the shortage.
•Genentech has Cellcept available.
•Sandoz did not provide a reason for the shortage.

Estimated Resupply Dates
•Accord has all mycophenolate mofetil presentations on allocation.
•Ascend has all mycophenolate mofetil presentations on intermittent back order and the company is releasing product as it becomes available.
•Hikma has all mycophenolate mofetil presentations on allocation.
•Mylan has mycophenolate mofetil 250 mg tablets in 500 count on back order and the company estimates a release date of late-March 2019. The 500 mg capsules in 100 count unit-dose presentations are on back order and the company estimates a release date of late-January to early-February 2019.
•Sandoz has mycophenolate mofetil 500 mg tablets in 500 count on back order and the company estimates a release date of mid-January 2019. The 250 mg capsules in 1440 count are on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=448

Mannitol Injection

January 7, 2019

Reason for the Shortage
•American Regent is not currently marketing mannitol.
•Baxter did not provide a reason for the mannitol shortage.
•BBraun has mannitol 500 mL premixed bags available. The 250 mL premixed bags were discontinued.

•Fresenius Kabi had mannitol on shortage due to increased demand.
•Pfizer has mannitol on shortage due to manufacturing delays.

Estimated Resupply Dates
•Fresenius Kabi has mannitol 250 mg/mL 50 mL vials on back order and the company estimates a release date of late-January 2019.
•Pfizer has mannitol 250 mg/mL 50 mL vials on back order and the company estimates a release date of January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=341

Magnesium Sulfate Injection

January 7, 2019

Reason for the Shortage
•American Regent is not currently marketing magnesium sulfate which has been unavailable since late 2012.
•Fresenius Kabi has magnesium sulfate injection on shortage due to increased demand for the product.
•Pfizer has magnesium sulfate injection on shortage due to manufacturing delays.
•X-Gen discontinued magnesium sulfate in April 2018.
•Exela launched magnesium sulfate vials in May 2018.
•WG Critical Care had magnesium sulfate injection on shortage due to increased demand for the product.

Estimated Resupply Dates
•Fresenius Kabi has magnesium sulfate 500 mg/mL 50 mL vials on back order and the company estimates a release date of late-January 2019. Check wholesalers for inventory.
•Pfizer has magnesium sulfate 500 mg/mL 20 mL vials on back order and the company estimates a release date of 2019. The 500 mg/mL 10 mL syringes are on back order and the company estimates a release date in first quarter 2019. The magnesium sulfate 40 mg/mL 1000 mL bags are on back order and the company estimates a release date of January 2019. The 40 mg/mL 50 mL and 100 mL bags and 80 mg/mL 50 mL bags are available in limited supply.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=21

Latanoprost Ophthalmic Solution

January 7, 2019

Reason for the Shortage
•Akorn has latanoprost ophthalmic solution on back order and the company cannot estimate a release date.
•Bausch Health has latanoprost ophthalmic solution available.
•Greenstone has latanoprost ophthalmic solution on back order and the company cannot estimate a release date.
•Rising has latanoprost ophthalmic solution available.
•Sandoz (Falcon) has latanoprost ophthalmic solution available.

Estimated Resupply Dates
•Akorn has latanoprost ophthalmic solution on back order and the company cannot estimate a release date.

•Greenstone has latanoprost ophthalmic solution on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=507

Ketorolac Injection

January 7, 2019

Reason for the Shortage
•Alvogen did not provide a reason for the shortage.
•Amphastar did not provide a reason for the shortage.
•Athenex has ketorolac available.
•BD RX is now part of Fresenius Kabi.
•Fresenius Kabi has most ketorolac presentations available.
•Pfizer has ketorolac injection on back order due to manufacturing delays.
•Sagent states the reason for the shortage is manufacturing delay.
•Hikma did not provide a reason for the shortage.
•Ben Venue closed its plant in Bedford, Ohio in July 2014.
•Virtus has ketorolac injection available.
•FDA imposed an import ban in mid-2013 on several Wockhardt products including ketorolac.
•Sprix Nasal Spray is not affected by this shortage.

Estimated Resupply Dates
•Alvogen has 15 mg/mL 1 mL vials and 30 mg/mL 2 mL vials on back order and the company cannot estimate a release date.
•Amphastar has ketorolac 30 mg/mL 1 mL vials on back order and the company cannot estimate a release date.
•Fresenius Kabi has ketorolac 15 mg/mL 1 mL and 30 mg/mL 1 mL prefilled syringes on back order with an estimated release date of the first quarter of 2019. There are limited quantities of ketorolac 15 mg/mL 1 mL prefilled syringes available with short expiration dating of < 5 months. The 30 mg/mL 1 mL prefilled syringes are also available in limited quantities with short expiration dating of < 3 months. The 30 mg/mL 2 mL syringes for intramuscular use are available with an expiration date of < 7 months. The 15 mg/mL and 30 mg/mL 1 mL vials are on back order and the company estimates a release date of early- to mid-January 2019.The 30 mg/mL 2 mL vials for intramuscular use are on back order and the company estimates a release date in early- to mid-January 2019.
•Pfizer has ketorolac 30 mg/mL 1 mL Carpuject syringes, 30 mg/mL 2 mL Carpuject syringes for intramuscular injection, and 30 mg/mL 1 mL iSecure syringes on back order and the company estimates a release date of 1st quarter 2020.
•Sagent has ketorolac 15 mg/mL 1 mL, 30 mg/mL 1 mL, and 30 mg/mL 2 mL vials for intramuscular injection are on back order and the company estimates a release date of January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=113

Fentanyl Citrate Injection

January 8, 2019

Reason for the Shortage
•Akorn has fentanyl injection on shortage due to increased demand. The 25 count ampules are temporarily unavailable.

•Hikma has fentanyl injection on shortage due to supply and demand issues. They are not currently marketing fentanyl ampules, just vials.
•Pfizer has fentanyl injection on shortage due to manufacturing delays. The 20 mL ampules were discontinued in September 2017.

Estimated Resupply Dates
•Akorn has Sublimaze 50 mcg/mL 2 mL and 5 mL ampules in 25 count temporarily unavailable and the company cannot estimate a release date.
•Pfizer has fentanyl 50 mcg/mL 2 mL vials on back order and the company estimates a release date of January 2019. The 2 mL Carpuject syringes are on back order and the company estimates a release date of 4th quarter 2019. The 2 mL ampules are on back order and the company estimates a release date of 2nd quarter 2019. The 50 mL vials are on back order and the company estimates a release date of March 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=315

Cefuroxime Sodium Injection

January 8, 2019

Reason for the Shortage
•Sagent has cefuroxime injection on shortage due to manufacturing delays.
•Teligent discontinued all Zinacef presentations in February 2018.
•Hikma did not provide a reason for the cefuroxime injection shortage. They are not currently marketing the 7.5 gram vials.

Estimated Resupply Dates
•Sagent has cefuroxime 750 mg vials on back order and the company cannot estimate a release date. The 1.5 gram vials are on allocation.
•Hikma has cefuroxime 750 mg and 1.5 gram vials on back order and the company estimates a release date of February or March 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=13

Octreotide Injection

January 8, 2019

Reason for the Shortage
•Mylan reports that product is on back order due to manufacturing delays.
•Unichem Pharmaceuticals reports that product is available in limited supply due to market demand.

Estimated Resupply Dates
•Mylan has bisoprolol 5 mg tablets in 30- and 100-count bottles on back order and the company estimates a release date of late-January 2019. The 10 mg tablets in 30- and 100-count bottles are on back order and the company estimates a release date of mid-March 2019.
•Unichem Pharmaceuticals has bisoprolol 5 and 10 mg tablets in 30- and 100-count bottles available in limited supply. The company estimates that it will be able to meet demand in mid-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=512

Vancomycin Hydrochloride Injection

January 9, 2019

Reason for the Shortage
•Alvogen has vancomycin injection available.
•Athenex has vancomycin injection available.
•AuroMedics has vancomycin injection available.
•Pfizer has vancomycin vials on back order due to manufacturing delays.
•Fresenius Kabi has vancomycin injection on shortage due to increased demand.
•Mylan Institutional has vancomycin injection available.
•Baxter has vancomycin injection available.
•Samson Medical Technologies has vancomycin injection available.
•Sagent has vancomycin injection on shortage due to manufacturing delays and increased demand.
•Xellia has vancomycin injection available.

Estimated Resupply Dates
•Fresenius Kabi has vancomycin 5 gram and 10 gram vials on back order and the company estimates a release date of early-January 2019.
•Pfizer has 500 mg ADD-Vantage vials, 750 mg vials, 750 mg ADD-Vantage vials, 1 gram vials, and 5 gram vials available in limited supply. The 1 gram ADD-Vantage vials are on back order and the company estimates a release date of February 2018. The 10 gram vials are on back order and the company cannot estimate a release date.
•Sagent has vancomycin 5 gram vials on allocation. The 10 gram vials are on back order and the company estimates a release date of January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=25

Spironolactone Tablets

January 9, 2019

Reason for the Shortage
•Accord, Amneal, Cadista, Mylan, and Sun Pharma did not provide a reason for the shortage.
•Par discontinued spironolactone tablets in August 2018.
•Pfizer states Aldactone is on shortage due to manufacturing delays.

Estimated Resupply Dates
•Accord has spironolactone 25 mg tablets in 500 and 1,000 count bottles on intermittent back order and the company is releasing supplies as they become available. The 100 mg tablets in 100 count bottles are on back order and the company estimates a release date of early- to mid-January 2019.
•Amneal has all spironolactone presentations on back order and the company cannot estimate a release date.
•Cadista has spironolactone presentations on allocation.
•Mylan has spironolactone 50 mg tablets in 100 count unit-dose blister packs on back order and the company estimates a release date in mid-January 2019. The 50 mg tablets in 100 and 500 count bottles and 100 mg tablets in 100 count bottles are on back order and the company estimates release dates of mid-February 2019 for the 50 mg tablets in 100 count and 500 count bottles and late-January 2019 for the 100 mg tablets in 100 count bottles.
•Par has most presentations on back order and the company cannot estimate a release date.

•Pfizer has Aldactone 25 mg tablets in 100 count bottles on back order and the company cannot estimate a release date. The 50 mg tablets in 100 count bottles are on back order and the company estimates a release date in mid-February 2019.
•Sun Pharma has spironolactone 50 mg tablets in 100 count bottles on back order and the company cannot estimate a release date. The 100 mg tablets in 100-count bottles are on back order and the company estimates a release date of January 2019. The 25 mg tablets in 100 and 1,000 count bottles are on back order and the company cannot estimate release dates.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=447

Promethazine Injection

January 9, 2019

Reason for the Shortage
•Hikma did not provide a reason for the shortage.
•X-Gen has promethazine injection available.

Estimated Resupply Dates
•Hikma has promethazine 25 mg/mL 1 mL ampules on back order and the company estimates a release date of February to March 2019. The 50 mg/mL 1 mL ampules are on back order and the company estimates a release date of January to February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=460

Piperacillin and Tazobactam Injection

January 9, 2019

Reason for the Shortage
•Apotex temporarily discontinued piperacillin/tazobactam in April 2018.
•AuroMedics could not provide a reason for the shortage.
•Fresenius Kabi had piperacillin/tazobactam on shortage due to increased demand.
•Mylan Institutional launched piperacillin/tazobactam 3.375 gram and 4.5 gram vials in early-June 2016.
•Pfizer has Zosyn single dose vials and piperacillin/tazobactam on shortage due to manufacturing delays.
•Sagent had piperacillin/tazobactam on shortage due to increased demand.
•WG Critical Care states the reason for the shortage is increased demand.
•FDA in conjunction with SteriMax was allowing temporary importation of piperacillin/tazobactam 3.375 gram, 4.5 gram, and 40.5 gram vials from Canada. This was being distributed through X-Gen Pharmaceuticals. These are no longer being imported with the launch of the products from X-Gen. The product codes on these items will not be recognized by U.S. systems so institutions will need to implement alternative plans to assure the dose is being given correctly. More information can be found on the FDA site at: https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM543149.pdf.
•Wockhardt has piperacillin/tazobactam injection available.
•X-Gen has piperacillin/tazobactam injection available.

Estimated Resupply Dates
•Apotex has temporarily discontinued all piperacillin/tazobactam presentations.
•Baxter has Zosyn 2.25 gram/50 mL and 3.375 gram/50 mL frozen premixed bags on allocation with intermittent delivery of product.

•Mylan has piperacillin/tazobactam 3.375 gram vials on back order and the company estimates a release date of mid-January 2019. The 4.5 gram vials are on back order and the company cannot estimate a release date.
•Pfizer has Zosyn 2.25 gram vials, 3.375 gram vials, 4.5 gram vials, and 40.5 gram vials on back order and the company estimates a release date of 2019.
•WG Critical Care has 2.25 gram vials on back order and the company estimates a release date of February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=158

Orphenadrine Citrate Injection

January 9, 2019

Reason for the Shortage
•Akorn did not provide a reason for the shortage.
•Hikma did not provide a reason for the shortage.
•Teva discontinued orphenadrine in November 2018.

Estimated Resupply Dates
•Akorn has orphenadrine 30 mg/mL 2 mL vials on back order and the company estimates a release date of mid-January 2019.
•Hikma has orphenadrine 30 mg/mL 2 mL vials on back order and the company estimates a release date of mid-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=471

Ondansetron Hydrochloride Injection

January 9, 2019

Reason for the Shortage
•Apotex did not provide a reason for the shortage.
•Athenex had ondansetron injection on shortage due to increased demand.
•AuroMedics did not provide a reason for the shortage.
•Fresenius Kabi has ondansetron injection available.
•Heritage had ondansetron on shortage due to increased demand. Heritage discontinued ondansetron 2 mg/mL 2 mL vials in 10 count in late-2018.
•Hikma did not provide a reason for the shortage.
•Mylan Institutional did not provide a reason for the shortage.
•Pfizer has ondansetron injection on shortage due to manufacturing delays.
•Sagent has ondansetron injection on shortage due to increased demand and manufacturing delays.
•Novartis discontinued Zofran 20 mL vials in May 2018.

Estimated Resupply Dates
•Apotex has ondansetron 2 mg/mL 2 mL vials on back order and the company cannot estimate a release date.
•AuroMedics has ondansetron 2 mg/mL 2 mL vials and 20 mL vials on intermittent back order and the company is releasing supplies as they become available.
•Fresenius Kabi has ondansetron 2 mg/mL 20 mL vials with a short-expiration date (< 4 months). The 2 mg/mL 2 mL prefilled syringes are on back order and the company estimates a release date of 1st quarter 2019.

•Hikma has ondansetron 2 mg/mL 2 mL vials in 25 count on allocation.
•Mylan Institutional has ondansetron 2 mg/mL 2 mL and 20 mL vials on back order and the company estimates a release date in early- to mid-January 2019.
•Pfizer has ondansetron 2 mg/mL 20 mL vials available in limited supply. The 2 mg/mL 2 mL iSecure syringes are on back order and the company estimates a release date of 4th quarter 2019.
•Sagent has ondansetron 2 mg/mL 2 mL vials and 20 mL vials on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=405

Nystatin Oral Suspension

January 9, 2019

Reason for the Shortage
•Akorn did not provide a reason for the shortage.
•Pharmaceutical Associates, Inc. did not provide a reason for the shortage.
•Precision Dose has nystatin suspension on allocation due to increased demand.
•Vista Pharma did not provide a reason for the shortage.
•Wockhardt USA did not provide a reason for the shortage.

Estimated Resupply Dates
•Akorn has nystatin 100,000 unit/mL suspension 60 mL and 473 mL bottles on back order and the company cannot estimate a release date.
•Pharmaceutical Associates, Inc. has all nystatin suspension presentations on back order and the company estimates release dates of late-January 2019.
•Precision Dose has all nystatin suspension presentations on allocation.
•Vista Pharma has nystatin 100,000 units/mL suspension 60 mL bottles, 480 mL bottles, and 5 mL unit-dose cups in 100 count on back order and the company cannot estimate release dates.
•Wockhardt USA has nystatin 100,000 units/mL suspension 60 mL and 473 mL bottles on back order and the company estimates a release data of mid-February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=500

Lorazepam Tablets

January 9, 2019

Reason for the Shortage
•Aurobindo did not provide a reason for the shortage.
•Leading has lorazepam tablets on shortage due to increased demand.
•Major did not provide a reason for the shortage.
•Mylan has discontinued all bottled presentations.
•Mylan Institutional did not provide a reason for the shortage for the unit-dose blister packs.
•Sandoz discontinued all lorazepam presentations.
•Teva did not provide a reason for the shortage.

Estimated Resupply Dates
•Leading has all lorazepam tablets on allocation.
•Major has lorazepam 0.5 mg tablets in 100-count unit-dose packs, 1 mg tablets in 100-count bottles and 100-count unit-dose packs, and 2 mg tablets in 100-count bottles and 100-count unit-dose packs on back

order and the company cannot estimate a release date. Lorazepam 0.5 mg tablets in 100-count bottles are available in limited supply.
•Mylan Institutional has lorazepam 0.5 mg, 1 mg, and 2 mg tablets in 100-count unit-dose packs on back order and the company estimates release dates of mid-February 2019.
•Teva has all lorazepam 0.5 mg tablet presentations on back order and the company estimates a release date of late-January 2019. All lorazepam 1 mg tablet presentations are on back order and the company estimates a release date in late-January 2019. All lorazepam 2 mg tablet presentations are also on back order and the company estimates a release date of late-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=480

Ketamine Injection

January 9, 2019

Reason for the Shortage
•Hikma did not provide a reason for the shortage.
•Mylan Institutional did not provide a reason for the shortage.
•Par has Ketalar on shortage due to increased demand.
•Pfizer has ketamine on shortage due to manufacturing delays.

Estimated Resupply Dates
•Hikma has ketamine 50 mg/mL 10 mL and 100 mg/mL 5 mL vials on back order and the company estimates a release date of February to March 2019.
•Mylan Institutional has ketamine 10 mg/mL 20 mL on back order and the company estimates a release date of mid-February 2019. The 50 mg/mL 10 mL vials are on back order and the company estimates a release date of mid-February 2019. The 100 mg/mL 10 mL vials are on back order and the company estimates a release date of mid-January 2019.
•Pfizer has ketamine 50 mg/mL 10 mL vials on back order and the company estimates a release date of 1st quarter 2020. The 100 mg/mL 5 mL vials are on back order and the company estimates a release date of 4th quarter 2019.
•Par has Ketalar 10 mg/mL 20 mL vials, 50 mg/mL 10 mL vials, and 100 mg/mL 5 mL vials on intermittent back order with monthly releases.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=391

Cefazolin Injection

January 9, 2019

Reason for the Shortage
Apotex has discontinued all presentations except cefazolin 1 gram vials.
Baxter did not provide a reason for the shortage.
BBraun has cefazolin on shortage due to manufacturing delays.
•Fresenius Kabi has cefazolin on shortage due to increased demand. They are not manufacturing the 20 gram vials at this time to focus on the other sizes.
•Pfizer states the reason for the shortage is manufacturing delay.
•Sagent states the reason for the shortage is manufacturing delays and increased demand.
•Samson Medical Technologies has cefazolin injection available.
•Sandoz has cefazolin injection available.
•Hikma did not provide a reason for the shortage.
•WG Critical Care did not provide a reason for the shortage.

Estimated Resupply Dates
•Baxter has cefazolin 2 gram/100 mL premixed bags on allocation.
•BBraun has 1 gram/50 mL and 2 gram/50 mL premixed bags on allocation.
•Fresenius Kabi has cefazolin 500 mg vials on back order and the company estimates a release date of early-January 2019. The 1 gram vials are on back order and the company estimates a release date of mid-February 2019. The 10 gram vials are on back order and the company estimates a release date of mid-January 2019.
•Pfizer has 1 gram and 10 gram vials on back order and the company cannot estimate a release date. The 1 gram ADD-Vantage vials are on back order and the company estimates a release date of 2nd quarter 2019.
•Sagent has cefazolin 500 mg, 1 gram, and 10 gram vials on back order and the company estimates a release date of March 2019 for the 500 mg vials and January 2019 for the 1 gram and 10 gram vials.
•Sandoz has cefazolin 500 mg, 1 gram, and 10 gram vials on back order and the company estimates a release date of mid-January 2019.
•Hikma has cefazolin 500 mg vials on back order and the company estimates a release date of February or March 2019. The 1 gram and 10 gram vials are on allocation.
•WG Critical Care has cefazolin 1 gram vials on intermittent back order and the company is releasing product weekly to wholesalers. There are 1 gram vials reserved for allocation to current contract customers. The 500 mg vials are on back order and the company estimates a release date of mid-late January 2019. The 10 gram vials are on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=432

Bumetanide Injection

January 9, 2019

Reason for the Shortage
•Pfizer has bumetanide injection on shortage due to manufacturing delays.
•Hikma did not provide a reason for the shortage.

Estimated Resupply Dates
•Hikma has bumetanide 0.25 mg/mL 10 mL vials on back order and the company estimates a release date of mid-January 2019.
•Pfizer has bumetanide 0.25 mg/mL 4 mL and 10 mL vials on back order and the company estimates a release date of 2nd quarter 2019 for the 4 mL vials and 2019 for the 10 mL vials.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=307

Benztropine Mesylate Injection

January 9, 2019

Reason for the Shortage
•Akorn did not provide a reason for the shortage.
•Fresenius Kabi did not provide a reason for the shortage.
•Hikma did not provide a reason for the shortage.

Estimated Resupply Dates
•Akorn has benztropine 1 mg/mL 2 mL ampules and Cogentin 1 mg/mL 2 mL ampules on back order and the company cannot estimate a release date.
•Fresenius Kabi has benztropine 1 mg/mL 2 mL vials on back order and the company estimates a release date of mid-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=497

Belatacept Injection

January 9, 2019

Reason for the Shortage

•Bristol-Myers Squibb has Nulojix in short supply due to manufacturing delays.

Estimated Resupply Dates

•Bristol-Myers Squibb has Nulojix 250 mg vials available. Nulojix is distributed by McKesson Plasma Biologics through the Nulojix Distribution Program.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=299

Atropine Ophthalmic Solution

January 9, 2019

Reason for the Shortage

•Akorn did not provide a reason for the atropine ophthalmic solution shortage.
•Altaire has homatropine ophthalmic solution available.

Estimated Resupply Dates

•Akorn has atropine ophthalmic solution in 5 mL, 10 mL, and 15 mL bottles on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=514

Ampicillin Sodium and Sulbactam Sodium Injection

January 9, 2019

Reason for the Shortage

•Pfizer has discontinued generic ampicillin sulbactam except for the 1.5 gram and 3 gram ADD-Vantage vials. These are on shortage due to manufacturing delays.
•Sagent had ampicillin sulbactam vials on back order due to manufacturing delays.
•Sandoz cannot provide a reason for the shortage.
•WG Critical Care states the shortage was due to increased demand.

Estimated Resupply Dates

•AuroMedics has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on long-term back order and the company cannot estimate a release date.
•Fresenius Kabi has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on long-term back order and the company cannot estimate a release date.
•Hikma has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on back order and the company estimates a release date of late-January 2019 to early-February 2019 for the 1.5 gram vials and mid- to late-January 2019 for the 3 gram vials. The company cannot estimate a release date for the 15 gram vials.
•Mylan Institutional has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on back order and the company estimates a release date of early-April 2019 for the 1.5 gram vials, late-January to early-February 2019 for the 3 gram vials, and late-January 2019 for the 15 gram vials.
•Pfizer has Unasyn 1.5 gram vials and 3 gram vials on back order and the company estimates a release date of 2nd quarter 2019 for the 1.5 gram vials and February 2019 for the 3 gram vials. Unasyn 15 gram bulk vials are on back order and the company cannot estimate a release date.

•Sandoz has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on long-term back order and the company cannot estimate a release date.
•Sagent has ampicillin sulbactam 1.5 gram and 3 gram vials on back order and the company estimates a release date of February 2019.
•WG Critical Care has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on back order and the company estimates a release date of March 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=159

Lidocaine Injection

January 9, 2019

Reason for the Shortage
•Amphastar had lidocaine 2% emergency syringes on shortage due to increase demand for the product.
•AuroMedics introduced lidocaine injection in February 2014.
•Fresenius Kabi had generic lidocaine presentations on shortage due to a supply interruption of raw ingredients.
•Pfizer has lidocaine presentations on shortage due to manufacturing delays.

Estimated Resupply Dates
•Amphastar has 2% lidocaine 5 mL syringes on intermittent back order and the company is releasing product as it becomes available.
•AuroMedics has 1% lidocaine 5 mL ampules and 5 mL vials on intermittent back order and the company is releasing product as it becomes available. AuroMedics has 2% lidocaine 5 mL vials on intermittent back order and the company is releasing product as it becomes available.
•Fresenius Kabi has 0.5% Xylocaine 50 mL vials on back order and the company cannot estimate a release date. The 1% lidocaine 10 mL vials are on back order and the company estimates a release date of early- to mid-January 2019. The 1% Xylocaine 20 mL and 50 mL vials are on back order and the company estimates a release date of mid-January 2019. The 1% Xylocaine-MPF 2 mL and 30 mL vials are on back order and the company estimates a release date of early- to mid-January 2019 for the 2 mL vials, and late-February 2019 for the 30 mL vials. The 1% Xylocaine-MPF 10 mL ampule sterile packs are on back order and the company estimates a release date of mid-January 2019. The 1% Xylocaine-MPF 30 mL vial sterile packs are on back order and the company cannot estimate a release date. The 1.5% Xylocaine-MPF 20 mL ampules are on back order and the company estimates a release date of late-January 2019. The 2% Xylocaine 10 mL, 20 mL, and 50 mL vials are on back order and the company estimates a release date of mid-January 2019 for the 10 mL and 20 mL vials and late-January 2019 for the 50 mL vials. The 2% Xylocaine-MPF 5 mL vials are on back order and the company estimates a release date of mid-January 2019. Check wholesalers for inventory.
•Pfizer has 0.5% lidocaine 50 mL flip top vials on back order and the company estimates a release date of February 2019. The 1% lidocaine 2 mL preservative-free ampules are available in limited supply. The 1% lidocaine 5 mL preservative-free ampules are on back order and the company estimates a release date of 1st quarter 2020. The 1% lidocaine 20 mL vials and 30 mL preservative-free vials are on back order and the company estimates a release date of January 2019 for the 20 mL vials and February 2019 for the 30 mL vials. The 1% lidocaine 50 mL vials are on back order and the company estimates a release date of January 2019. The 1% lidocaine 5 mL Lifeshield syringes are on back order and the company estimates a release date of January 2019. The 1% lidocaine 5 mL Ansyr syringes are on back order and the company estimates a release date of January 2019. The 1.5% lidocaine 20 mL preservative-free ampules are on back order and the company estimates a release date of 4th quarter 2019. The 2% lidocaine 2 mL preservative-free ampules are on back order and the company estimates a release date of January 2019. The 2% lidocaine 10 mL ampules are on back order and the company cannot estimate a release date. The 2% lidocaine 5 mL vials are on back order and the company estimates a release date of 4th quarter 2019. The 2% lidocaine 20 mL and 50 mL vials

are on back order and the company estimates a release date of February 2019 for the 20 mL vials and January 2019 for the 50 mL vials. The 2% lidocaine 5 mL Lifeshield syringes are on back order and the company estimates a release date of 1st quarter 2019. The 2% lidocaine 5 mL Ansyr syringes are available in limited supply. The 4% lidocaine 5 mL ampules are on back order and the company estimates a release date of February 2019.
•Hikma has 2% lidocaine 5 mL vials on allocation. The 1% lidocaine 50 mL vials are on back order and the company estimates a release date of mid-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=88

Leucovorin Calcium Injection

January 9, 2019

Reason for the Shortage
•Fresenius Kabi has leucovorin on shortage due to manufacturing delays and increased demand.
•Hikma did not provide a reason for the current shortage.
•Sagent had leucovorin on shortage due to increased demand.
•Teva has leucovorin available.

Estimated Resupply Dates
•Fresenius Kabi has leucovorin 200 mg and 500 mg vials on back order and the company estimates a release date of early- to mid-January 2019.
•Hikma has leucovorin 100 mg vials on back order and the company estimates a release date of February to March 2019. The 350 mg vials are on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=35

Labetalol Injection

January 10, 2019

Reason for the Shortage
•Akorn did not provide a reason for the shortage.
•Alvogen did not provide a reason for the shortage.
•Pfizer has labetalol injection on shortage due to manufacturing delays.
•Hikma has labetalol injection on shortage due to increase demand.

Estimated Resupply Dates
•Akorn has labetalol 5 mg/mL 20 mL and 40 mL vials on back order and the company cannot estimate a release date.
•Alvogen has labetalol 5 mg/mL 20 mL and 40 mL vials on back order and the company cannot estimate a release date.
•Hikma has labetalol 5 mg/mL 40 mL vials on back order and the company estimates a release date of February to March 2019. The 20 mL vials are on allocation.
•Pfizer has labetalol 5 mg/mL 20 mL and 40 mL vials on back order and the company estimates a release date of 3rd quarter 2019 for the 20 mL vials and January 2019 for the 40 mL vials. The 5 mg/mL 4 mL Carpuject syringes are on back order and the company estimates a release date of 1st quarter 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=286

Iopamidol Injection

January 10, 2019

Reason for the Shortage

•Bracco Diagnostics is the sole supplier of iopamidol and did not provide a reason for the shortage.

Estimated Resupply Dates

•Isovue-200 (iopamidol 41%) 50 mL vials are on back order and the company cannot estimate a release date.
•All Isovue-300 (iopamidol 61%) presentations are on back order and the company cannot estimate a release date for the 30 mL vials, 50 mL vials, and 75 mL bottles. The 100 mL bottles and 150 mL bottles are on back order and the company estimates a release date of mid-February 2019 for the 100 mL bottles and early-February 2019 for the 150 mL bottles.
•Isovue Multipack-300 (iopamidol 61%) in 500 mL bottles are on back order and the company cannot estimate a release date.
•Isovue-370 (iopamidol 76%) in 50 mL vials and 75 mL and 125 mL bottles are on back order and the company cannot estimate a release date. Isovue-370 150 mL bottles are on back order and the company estimates a release date of early-February 2019.
•Isovue Multipack-370 (iopamidol 76%) in 200 mL bottles is on back order and the company estimates a release date of mid-January 2019.
•Isovue-370 (iopamidol 76%) Imaging Bulk Packages in 500 mL bottles are on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=495

Indomethacin Capsules

January 10, 2019

Reason for the Shortage

•Camber did not provide a reason for the shortage.
•Glenmark has indomethacin on shortage due to manufacturing delays.
•Heritage discontinued all indomethacin presentations in early-2018.
•Mylan did not provide a reason for the shortage. Mylan is in the process of discontinuing all presentations.
•Sandoz discontinued indomethacin in mid-2016.
•Teva discontinued all indomethacin presentations in mid-2018.

Estimated Resupply Dates

•Camber has indomethacin 25 mg and 50 mg capsules on back order and the company estimates a release date of mid-January 2019.
•Glenmark has indomethacin 25 mg capsules in 100 count on back order and the company estimates a release date of early-February 2019. Indomethacin 50 mg capsules in 100 count and 500 count are on back order and the company estimates a release date of mid-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=235

Hydromorphone Hydrochloride Injection

January 10, 2019

Reason for the Shortage

•Akorn has hydromorphone injection on shortage due to increased demand.
•Fresenius Kabi has Dilaudid syringes on shortage due to increased demand. They are focusing their product on the 0.5 mg strength. They launched hydromorphone vials in late-June 2018.
•Pfizer did not provide a reason for the shortage.
•Purdue discontinued Dilaudid and Dilaudid HP in May 2017 for marketing reasons.
•Teva did not provide a reason for the shortage.
•Hikma did not provide a reason for the shortage.

Estimated Resupply Dates

•Akorn has hydromorphone 10 mg/mL 50 mL vials on allocation.
•Fresenius Kabi has Dilaudid 1 mg/mL 0.5 mL and 1 mL syringes on back order and the company estimates a release date of early- to mid-January 2019. The 2 mg/mL 1 mL syringes are on back order and the company estimates a release date of 1st quarter 2019. The hydromorphone 1 mg/mL 1 mL vials are on back order and the company estimates a release date of late-January to early-February 2019. The hydromorphone 4 mg/mL 1 mL vials and 10 mg/mL 1 mL vials and 5 mL vials are on back order and the company cannot estimate a release date. Check wholesalers for inventory.
•Hikma has hydromorphone 2 mg/mL 1 mL vials (NDC 00641-0121-25) on back order and the company estimates a release date of late-January to early-February 2019.
•Pfizer has 1 mg/mL 1 mL Carpuject syringes on back order and the company cannot estimate a release date.
•The 10 mg/mL 50 mL vials are on back order and the company estimates a release date of 2nd quarter 2019.
•The 10 mg/mL 5 mL vials are on back order and the company estimates a release date of March 2019. The 0.5 mg/0.5 mL 0.5 mL iSecure syringes and 2 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 1st quarter 2019. The 1 mg/mL 1 mL ampules, 2 mg/mL 1 mL ampules, and 4 mg/mL 1 mL ampules are on back order and the company estimates a release date of 2nd quarter 2019. The 1 mg/mL 1 mL iSecure syringes, 2 mg/mL 1 mL iSecure syringes, and 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 4th quarter 2019. The 2 mg/mL 1 mL vials are available in limited supply.
•Teva has 10 mg/mL 1 mL, 5 mL, and 50 mL vials on intermittent back order and the company is allocating upon release.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=329

Hepatitis A Virus Vaccine Inactivated

January 10, 2019

Reason for the Shortage

•Merck did not provide a reason for the Vaqta shortage.
•GlaxoSmithKline did not provide a reason for the Havrix shortage.
•GlaxoSmithKline discontinued the Havrix pediatric vials in late-2018. The Havrix adult vials were discontinued in November 2017.

Estimated Resupply Dates

•GlaxoSmithKline has Havrix adult prefilled syringes on back order and the company cannot estimate a release date.
•Merck has Vaqta adult formulation 50 U/1 mL vials in 1 count on back order and the company does not expect it will be available in 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=280

Busulfan Injection

January 10, 2019

Reason for the Shortage
•American Regent did not provide a reason for the shortage.
•Amneal did not provide a reason for the shortage.
•Sagent did not provide a reason for the shortage.

Estimated Resupply Dates
•Amneal has busulfan 6 mg/mL 10 mL vials on back order and the company cannot estimate a release date.
•Sagent has busulfan 6 mg/mL 10 mL vials on allocation and the company estimates a release date of late-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=509

Valganciclovir HCl Oral Powder for Solution

January 11, 2019

Reason for the Shortage
•Teva did not provide a reason for the shortage.

Estimated Resupply Dates
•Teva has valganciclovir 50 mg/mL 100 mL bottles on back order and the company estimates a release date of early-February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=511

Quinidine Gluconate Injection

January 11, 2019

Reason for the Shortage
•Lilly USA is the sole supplier of quinidine gluconate injection and is discontinuing the manufacture of the product.

Estimated Resupply Dates
•Lilly USA has quinidine gluconate 80 mg/mL 10 mL vials available with short expiry dating of March 2019. They will not be manufacturing more product once currently available product is gone.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=516

Secobarbital Capsules

January 14, 2019

Reason for the Shortage
•Bausch Health is the sole supplier of secobarbital capsules. The company states that Seconal capsules are on back order due to a short-term stock out.

Estimated Resupply Dates

•Bausch Health has Seconal (secobarbital) 100 mg capsules on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=517

Enoxaparin Sodium Injection
January 14, 2019

Reason for the Shortage
•Amphastar has enoxaparin on intermittent back order due to increased demand.
•Fresenius Kabi did not provide a reason for the shortage.
•Sandoz discontinued enoxaparin presentations in mid-2018 due to a supplier issue.
•Sanofi-Aventis did not provide a reason for the shortage.
•Teva did not provide a reason for the shortage.
•Winthrop did not provide a reason for the shortage.

Estimated Resupply Dates
•Amphastar has enoxaparin 150 mg/1 mL, 120 mg/0.8 mL, and 80 mg/0.8 mL prefilled syringes on intermittent back order and is shipping the product when available.
•Sandoz has discontinued enoxaparin prefilled syringes. They continue to supply product to customers according to forecast until their supply is depleted.
•Sanofi-Aventis has all Lovenox prefilled syringes on allocation.
•Teva has enoxaparin 150 mg/1 mL, 120 mg/0.8 mL, 100 mg/1 mL, 80 mg/0.8 mL, and 60 mg/0.6 mL prefilled syringes on allocation.
•Winthrop has all enoxaparin prefilled syringes on allocation.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=466

Folic Acid Injection
January 14, 2019

Reason for the Shortage
•Fresenius Kabi did not provide a reason for the shortage.

Estimated Resupply Dates
•Fresenius Kabi has folic acid on allocation as short-dated product (<4 months and <9 months expiration dating).
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=518

Thiamine Injection
January 15, 2019

Reason for the Shortage
•Fresenius Kabi has thiamine injection on shortage due to short manufacturing delay.
•Mylan Institutional has thiamine injection available.

Estimated Resupply Dates
•Fresenius Kabi has thiamine 100 mg/mL 2 mL vials on back order and the company estimates a release date of late-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=502

Sodium Phosphate Injection

January 15, 2019

Reason for the Shortage

•American Regent is not currently marketing sodium phosphate injection.
•Fresenius Kabi states the reason for the shortage is increased demand.
•Pfizer has sodium phosphate injection on shortage due to manufacturing delay.

Estimated Resupply Dates

•Fresenius Kabi has sodium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of late-January to early-February 2019.
•Pfizer has sodium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of 3rd quarter 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=227

Sodium Bicarbonate Injection

January 15, 2019

Reason for the Shortage

•Amphastar has sodium bicarbonate injection available.
•Pfizer has sodium bicarbonate injection on shortage due to manufacturing delays.
•Fresenius Kabi had sodium bicarbonate injection temporarily available, but have run out of stock, there is more in production at this time.

Estimated Resupply Dates

•Fresenius Kabi has 8.4% sodium bicarbonate 50 mL vials on back order and the company estimates a release date of late-January 2019.
•Pfizer has sodium bicarbonate 4.2% 10 mL LifeShield syringes and 7.5% 50 mL syringes available in limited supply. The 8.4% 10 mL syringes and 50 mL vials are on back order and the company estimates a release date of January 2019. The 8.4% 50 mL syringes are on back order and the company estimates a release date of 2nd quarter 2019.
•Pfizer has Neut 4% 5 mL vials on back order and the company estimates a release date of February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=293

Procainamide Hydrochloride Injection

January 15, 2019

Reason for the Shortage

•Amphastar has procainamide injection available.
•Nexus has procainamide injection available.
•Pfizer has procainamide injection on shortage due to manufacturing delays.

Estimated Resupply Dates

•All marketed presentations are available.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=469

Potassium Phosphate Injection

January 15, 2019

Reason for the Shortage

•American Regent has not had potassium phosphate injection available since 2012. It is unclear if and when product will return to market.
•Fresenius Kabi had potassium phosphate injection on shortage due to increased demand.
•Pfizer had potassium phosphate injection on shortage due to manufacturing delays.

Estimated Resupply Dates

•Fresenius Kabi has potassium phosphate 3 mmol/mL 15 mL and 50 mL vials on back order and the company estimates a release date of mid-January 2019 for the 15 mL vials and early-February 2019 for the 50 mL vials.
•Pfizer has potassium phosphate 3 mmol/mL 15 mL vials available in limited supply.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=305

Calcium Chloride Injection

January 15, 2019

Reason for the Shortage

•American Regent has calcium chloride injection available.
•Amphastar has calcium chloride injection available.
•Pfizer has calcium chloride on shortage due to manufacturing delays.
•Mylan Institutional has withdrawn calcium chloride syringes from the market. The company recalled the syringes in April 2015 due to incompatibility of the syringes and some needless adaptors.

Estimated Resupply Dates

•American Regent has calcium chloride 100 mg/mL 10 mL vials available in limited supply.
•Pfizer has calcium chloride 100 mg/mL 10 mL LifeShield syringes available in limited supply.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=48

Thrombin Topical Solution (Bovine)

January 16, 2019

Reason for the Shortage

•Pfizer has Thrombin-JMI on shortage due to manufacturing delays.
•Recombinant thrombin is not affected by this shortage.

Estimated Resupply Dates

•Pfizer has Thrombin-JMI 20,000 unit syringe spray kits on back order and the company cannot estimate a release date. The 5,000 unit vials, 5,000 unit epistaxis kits, 5,000 unit syringe spray kits, and 20,000 unit pump spray kits are available in limited supply.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=479

Theophylline 12-Hour Extended-Release Tablets

January 16, 2019

Reason for the Shortage

•Major has discontinued theophylline extended-release tablets.

•Teva has had theophylline extended-release tablets temporarily unavailable for several years. Relaunch is estimated in June 2019.
•Theophylline 24-hour extended-release presentations are available from Mylan, Rhodes, and Endo Pharmaceuticals.

Estimated Resupply Dates
•Teva has theophylline extended-release tablets temporarily unavailable. Relaunch is estimated to occur in June 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=205

Sterile Talc

January 16, 2019

Reason for the Shortage
•Lymol has Sclerosol and talc powder on shortage due to manufacturing delays.
•Novatech SA has Steritalc powder available.

Estimated Resupply Dates
•Lymol has Sclerosol and talc powder on long-term back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=260

Sodium Polystyrene Sulfonate Oral or Rectal Suspension

January 16, 2019

Reason for the Shortage
•Sodium polystyrene sulfonate powder is not affected by this shortage.
•CMP Pharma reports that increased demand has led to a shortage of raw material required to manufacture the products.
•Perrigo has temporarily discontinued their Kionex suspension and sodium polystyrene sulfonate (sorbitol-free) suspension. They cannot estimate when these products will be manufactured again.
•Hikma is not currently marketing sodium polystyrene sulfonate suspension.

Estimated Resupply Dates
•CMP Pharma has SPS Suspension on back order and the company estimates a release date of late-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=430

Pentamidine Isethionate

January 16, 2019

Reason for the Shortage
•Fresenius Kabi is the only supplier of pentamidine isethionate and did not provide a reason for the shortage.

Estimated Resupply Dates
•Fresenius Kabi has NebuPent 300 mg vials on back order and the company estimates a release date of late-January 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=513

Nitrofurantoin Oral Suspension

January 16, 2019

Reason for the Shortage
•Amneal did not provide a reason for the shortage.
•Casper Pharma did not provide a reason for the Furadantin shortage.
•Lupin is no longer manufacturing this product.
•Nostrum did not provide a reason for the shortage.
•Teva did not provide a reason for the shortage.

Estimated Resupply Dates
•Casper has Furadantin oral suspension available with short expiration dating (May 2019).
•Teva has nitrofurantoin oral suspension on back order and the company cannot estimate a release date.
•Nostrum has nitrofurantoin oral suspension on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=433

Mineral Oil and Petrolatum Ophthalmic Ointment

January 16, 2019

Reason for the Shortage
•Allergan states the shortage is due to production delays.
•Bausch Health has Soothe Night Time ointment available.
•Major did not provide a reason for the shortage.
•Alcon states the shortage is due to manufacturing issues.
•Perrigo did not provide a reason for the shortage. Perrigo discontinued the Puralube 1 gram 20 count tubes in January 2019.
•Rugby did not provide a reason for the shortage.

Estimated Resupply Dates
•Allergan has Refresh PM and Lacri-Lube SOP ointment 3.5 gram tubes on back order and the company cannot estimate a release date. Lacri-Lube SOP 7 gram tubes are also on back order and the company cannot estimate a release date.
•Rugby has Artificial Tears 3.5 gram tubes available in limited supply.
•Alcon has Systane Lubricating Night ointment on back order and the company estimates a release date in February 2019.
•Perrigo has Puralube ointment in 3.5 gram tubes on back order and the company estimates a release date in late-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=435

Levothyroxine Sodium Injection

January 16, 2019

Reason for the Shortage
•Athenex started marketing levothyroxine sodium in January 2019
•Fresenius Kabi has levothyroxine sodium available.
•Par has levothyroxine sodium on shortage due to increased demand.

•Piramal Critical Care has levothyroxine sodium available.

Estimated Resupply Dates
•Par has levothyroxine 100 mcg vials on allocation with an estimated recovery date of February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=506

Heparin Sodium Premixed Bags

January 16, 2019

Reason for the Shortage
•Baxter has heparin on shortage due to manufacturing delays.
•BBraun has heparin premixes available.
•Fresenius Kabi has heparin premixes on shortage due to increased demand.
•Pfizer has heparin on shortage due to manufacturing delays.

Estimated Resupply Dates
•Baxter has heparin 2000 units/1000 mL premixed bags on back order and the company estimates a release date of 1st quarter 2019.
•Fresenius Kabi has heparin 25,000 units/500 mL 5% dextrose premixed bags on back order and the company estimates a release date of mid- to late-January 2019. The 25,000 units/250 mL in 5% dextrose are on back order and the company estimates a release date in early-March 2019.
•Pfizer has heparin 2000 units/1000 mL 0.9% sodium chloride premixed bags on back order and the company estimates a release date of February 2019. Heparin 1000 units/500 mL 0.9% sodium chloride premixed bags and 25,000 units/250 mL 0.45% sodium chloride premixed bags are available in limited supply. Heparin 25,000 units/250 mL 5% dextrose premixed bags are on back order and the company estimates a release date of January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=468

Eflornithine Hydrochloride Cream

January 16, 2019

Reason for the Shortage
•Allergan has Vaniqa available.

Estimated Resupply Dates
•Allergan has Vaniqa topical cream available.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=438

Dicyclomine Injection

January 16, 2019

Reason for the Shortage
•Allergan has Bentyl injection available.
•American Regent did not provide a reason for the shortage.
•Hikma did not provide a reason for the shortage.

Estimated Resupply Dates
•American Regent has dicyclomine 10 mg/mL 2 mL vials on back order and the company estimates a release date of early-February 2019.

•Hikma has short-dated dicyclomine 10 mg/mL 2 mL vials available with an expiration date of May 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=520

Cefoxitin Sodium Injection

January 16, 2019

Reason for the Shortage
•Apotex did not provide a reason for the shortage.
•BBraun has cefoxitin on allocation due to increased demand.
•Fresenius Kabi did not provide a reason for the shortage.
•Hikma did not provide a reason for the shortage. Hikma is not currently marketing cefoxitin.
•Sagent has cefoxitin on shortage due to increased demand and manufacturing delay.
•WG Critical Care did not provide a reason for the shortage.

Estimated Resupply Dates
•Apotex has temporarily discontinued cefoxitin 1 gram, 2 gram, and 10 gram vials and the company cannot estimate when product will be available again.
•BBraun has cefoxitin 1 gram and 2 gram vials on allocation.
•Fresenius Kabi has cefoxitin 1 gram and 2 gram vials on back order and the company estimates a release date of mid-April 2019 for the 1 gram vials and late-February 2019 for the 2 gram vials.
•Sagent has cefoxitin 1 gram and 2 gram vials on back order and the company estimates a release date of January 2019. The 10 gram vials are on allocation.
•WG Critical Care has cefoxitin 2 gram vials on back order and the company estimates a release date of March 2019. The 10 gram vials are on back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=271

Cefepime Injection

January 16, 2019

Reason for the Shortage
•Apotex did not provide a reason for the shortage.
•Baxter has cefepime on allocation due to increased demand.
•BBraun has cefepime on shortage due to manufacturing delays.
•Fresenius Kabi did not provide a reason for the shortage.
•Pfizer has Maxipime on shortage due to manufacturing delays.
•Sagent has cefepime injection on shortage due to increased demand.
•Sandoz discontinued cefepime injection in early-2016.
•WG Critical Care had cefepime injection on shortage due to increased demand.

Estimated Resupply Dates
•Baxter has cefepime 2 gram premixed bags on allocation.
•BBraun has cefepime 1 gram and 2 gram premixed bags on allocation.
•Fresenius Kabi has cefepime 2 gram vials on back order and the company estimates a release date of mid-February 2019.
•Pfizer has Maxipime 1 gram vials, 2 gram vials, 1 gram ADD-Vantage vials, and 2 gram ADD-Vantage vials on back order and the company estimates a release date of 2019.
•Sagent has cefepime 2 gram vials on allocation.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=59

BCG Live Intravesical

January 16, 2019

Reason for the Shortage

•Because of increased global demand, and as the only source of BCG Live (Intravesical) in the United States and many other countries, Merck anticipates supply constraints for Tice BCG in 2019. To minimize disruption to patient care and address the current imbalance between supply and increased global demand Tice BCG will be under allocation when demand exceeds production plans and available inventory.

Estimated Resupply Dates

•Merck has Tice BCG available on allocation. Beginning January 2, 2019, Merck will cease to accept drop shipment orders for TICE BCG and will move to a direct purchaser allocation model. Wholesalers and distributors will manage the distribution of TICE BCG based on available supply and customers' historical purchasing patterns.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=519

Tobramycin Sulfate Injection

January 17, 2019

Reason for the Shortage

•Akorn discontinued tobramycin injection in late-2018.
•Pfizer had tobramycin injection on shortage due to manufacturing delays.
•Teva discontinued tobramycin 40 mg/mL 30 mL vials in June 2018.

Estimated Resupply Dates

•Baxter (formerly Claris) has tobramycin 40 mg/mL 2 mL and 30 mL vials on back order and the company cannot estimate a release date.
•Mylan Institutional has tobramycin 40 mg/mL 2 mL vials on back order and the company cannot estimate a release date.
•Teva has temporarily discontinued tobramycin 40 mg/mL 2 mL vials.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=164

Ropivacaine Injection

January 17, 2019

Reason for the Shortage

•Akorn has ropivacaine on shortage due to increased demand.
•AuroMedics did not provide a reason for the shortage.
•Fresenius Kabi has Naropin on shortage due to increased demand and manufacturing delays.
•Pfizer had ropivacaine on shortage due to manufacturing delays.

Estimated Resupply Dates

•AuroMedics has ropivacaine 10 mg/mL 10 mL vials on intermittent back order and the company is releasing product as it becomes available.
•Fresenius Kabi has Naropin 5 mg/mL 30 mL Steripak ampules on back order and the company cannot estimate a release date. The 5 mg/mL 30 mL vials are on back order and the company estimates a release date of mid-January 2019. Check wholesalers for inventory.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=384

Proparacaine Hydrochloride Ophthalmic Solution

January 17, 2019

Reason for the Shortage
•Akorn, Bausch Health, and Sandoz did not provide a reason for the shortage.

Estimated Resupply Dates
•Akorn has proparacaine 0.5% ophthalmic drops on allocation.
•Bausch Health has proparacaine 0.5% ophthalmic drops on back order and the company estimates a release date of late-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=489

Potassium Chloride Injection

January 17, 2019

Reason for the Shortage
•Baxter had their highly concentrated potassium chloride in sterile water on shortage because a manufacturing facility was affected by Hurricane Maria. Baxter did not provide a reason for the shortage of their other potassium chloride products.
•Fresenius Kabi did not provide a reason for the shortage.
•Pfizer has potassium chloride injection on shortage due to increase demand. Pfizer discontinued 2 mEq/mL 250 mL bottles in mid-2018.
•ICU Medical has potassium chloride injection on shortage due to increased demand.
•ICU Medical discontinued potassium chloride 10 mEq/500 mL in 5% dextrose and 0.225% sodium chloride in 2018.

Estimated Resupply Dates
•Fresenius Kabi has potassium chloride 10 mEq/5 mL vials on back order and the company cannot estimate a release date.
•ICU Medical has all potassium chloride injection presentations available to current customers.
•Pfizer has potassium chloride 40 mEq/20 mL vials available in limited supply.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=12

Pentostatin Injection

January 17, 2019

Reason for the Shortage
•Pfizer has Nipent on shortage due to manufacturing delays.

Estimated Resupply Dates
•Pfizer has Nipent 10 mg vials available.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=474

Penicillin G Procaine Injection

January 17, 2019

Reason for the Shortage
•Pfizer had penicilliin G procaine on shortage due to manufacturing delays.
•Pfizer is the sole supplier of penicillin G procaine.

Estimated Resupply Dates
•Pfizer has penicillin G procaine 600,000 unit/mL 1 mL and 2 mL syringes available.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=240

Morphine Injection

January 17, 2019

Reason for the Shortage
•Fresenius Kabi procured morphine syringes from BD in 2016. They discontinued the 8 mg/mL and 10 mg/mL 1 mL syringes in early-2018.
•Astramorph injection has been unavailable since 2012. Fresenius Kabi changed manufacturing sites and cannot estimate if Astramorph will return.
•Pfizer has a shortage of several prefilled syringe products, including morphine, starting in late-July 2017 due to issues at a manufacturing facility. To minimize the impact of the shortage, Pfizer is prioritizing production of certain morphine Carpuject syringes.
•Hikma did not provide a reason for the shortage.

Estimated Resupply Dates
•Fresenius Kabi has morphine 2 mg/mL 1 mL syringes on back order and the company estimates a release date of early-February 2019. The morphine 4 mg/mL 1 mL syringes are on back order and the company estimates a release date of 2nd quarter 2019. The morphine 5 mg/mL 1 mL syringes are on back order and the company estimates a release date of 2nd quarter 2019. The 2 mg/mL 1 mL vials are on back order and the company estimates a release date of late-January 2019. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of late-January 2019. The 5 mg/mL 1 mL vials are on back order and the company estimates a release date of mid-January 2019. The 8 mg/mL 1 mL vials are on back order and the company cannot estimate a release date. Check wholesalers for inventory.
•Pfizer has morphine 2 mg/mL 1 mL Carpuject syringes are on back order and the company cannot estimate a release date. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of February 2019. The 1 mg/mL 10 mL preservative-free vials are on back order and the company estimates a release date of 1st quarter 2019. The 2 mg/mL 1 mL iSecure syringes, 4 mg/mL 1 mL iSecure syringes, 8 mg/mL 1 mL iSecure syringes, and 10 mg/mL 1 mL iSecure syringes are on back order and the company estimates a release date of 4th quarter 2019. The 8 mg/mL 1 mL Carpuject syringes and 10 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date in 2nd quarter 2019. The 25 mg/mL 1 mL preservative-free vials are on back order and the company estimates a release date of 2nd quarter 2019. The 50 mg/mL 20 mL vials are on back order and the company estimates a release date of 2nd quarter 2019. The 50 mg/mL 50 mL vials are on back order and the company estimates a release date of 1st quarter 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=41

Metoprolol Injection

January 17, 2019

Reason for the Shortage
•Alvogen has metoprolol injection available.
•American Regent is not currently marketing metoprolol injection.
•Athenex has metoprolol injection available.
•Baxter did not provide a reason for the shortage.
•Fresenius Kabi has metoprolol injection on shortage due to increased demand.

•Mylan Institutional acquired metoprolol injection from Sagent. They discontinued metoprolol injection in
•March 2018.
•Pfizer has metoprolol injection on shortage due to manufacturing delays.
•Hikma did not provide a reason for the shortage.

Estimated Resupply Dates
•Alvogen has metoprolol 1 mg/mL 5 mL vials on back order and the company estimates a release date of February 2019.
•Baxter (formerly Claris) has metoprolol 1 mg/mL 5 mL vials on back order and the company estimates a release date of April 2019.
•Fresenius Kabi has metoprolol 1 mg/mL 5 mL vials on back order and the company estimates a release date of early-March 2019.
•Hikma has metoprolol 1 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of February to March 2019.
•Pfizer has metoprolol 1 mg/mL 5 mL Carpuject syringes on back order and the company estimates a release date of 1st quarter 2020. The 1 mg/mL 5 mL ampules are on back order and the company estimates a release date of 2019. The 1 mg/mL 5 mL vials are on back order and the company estimates a release date of 1st quarter 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=363

Lidocaine with Epinephrine Injection

January 17, 2019

Reason for the Shortage
•Fresenius Kabi has Xylocaine with epinephrine presentations on shortage due to increased demand for the product and manufacturing delays.
•Pfizer has lidocaine with epinephrine presentations on shortage due to manufacturing delays.

Estimated Resupply Dates
•Fresenius Kabi has 0.5% Xylocaine with epinephrine (1:200,000) 50 mL vials on back order and the company estimates a release date of late-January 2019. The 1% Xylocaine with epinephrine (1:200,000) 10 mL vials are on back order and the company estimates a release date of mid-January 2019. The 1% Xylocaine with epinephrine (1:200,000) 20 mL vials are on back order and the company estimates release dates of mid-January 2019. The 1% Xylocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates release dates of late-January 2019. The 1% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials are on back order and the company estimates a release date of late-January 2019. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company cannot estimate a release date. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company cannot estimate a release date. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 10 mL regular vials are on back order and the company estimates a release date of late-January 2019. The 2% Xylocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates a release date of late-January 2019. The 2% Xylocaine-MPF with epinephrine (1:200,000) 20 mL vials in sterile packs are on back order and the company cannot estimate a release date. Check wholesalers for inventory.
•Pfizer has 1% lidocaine with epinephrine (1:100,000) 20 mL vials on back order and the company estimates a release date of January 2019. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are on back order and the company estimates a release date of January 2019. The 1% lidocaine with epinephrine (1:100,000) 50 mL vials are on back order and the company estimates a release date of January 2019. The 1.5% lidocaine with epinephrine (1:200,000) 30 mL vials are on back order and the company estimates a release date of 1st

quarter 2019. The 1.5% lidocaine with epinephrine (1:200,000) 5 mL ampules are on back order and the company estimates a release date of February 2019. The 2% lidocaine with epinephrine (1:100,000) 20 mL vials are on back order and the company estimates a release date of March 2019. The 2% lidocaine with epinephrine (1:100,000) 30 mL and 50 mL vials are on back order and the company estimates a release date of 1st quarter 2019 for the 30 mL vials and 2nd quarter 2019 for the 50 mL vials. The 2% lidocaine with epinephrine (1:200,000) 20 mL vials are available in limited supply.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=98

Immune Globulin, Subcutaneous (Human)

January 17, 2019

Reason for the Shortage
•Baxalta has HyQvia and Cuvitru on shortage due to increased demand.
•CSL Behring has Hizentra available.

Estimated Resupply Dates
•Baxalta has Cuvitru on allocation and the company is reviewing all orders.
•Baxalta has HyQvia on allocation and the company is reviewing all orders.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=515

Dexmedetomidine Hydrochloride 4 mcg/mL Premix for Injection

January 17, 2019

Reason for the Shortage
•Pfizer did not provide a reason for the shortage.
•WG Critical Care began marketing premixed bags in November 2018.
•Baxter has dexmedetomidine premixed bags available

Estimated Resupply Dates
•Pfizer has Precedex 4 mcg/mL 20 mL glass vials on back order and the company estimates a release date of January 2019. The 4 mcg/mL 50 mL and 100 mL premixed bottles are available in limited supply.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=398

Bupivacaine with Epinephrine Injection

January 17, 2019

Reason for the Shortage
•Fresenius Kabi has bupivacaine and epinephrine on shortage due to increased demand and manufacturing delays.
•Pfizer has bupivacaine with epinephrine on shortage due to manufacturing delays.

Estimated Resupply Dates
•Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 10 mL vials on back order and the company estimates a release date of late-January 2019. The 0.25% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of late-January 2019. The 0.25% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of mid-January 2019. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of mid-January 2019. The 0.5% Sensorcaine-MPF with epinephrine 30 mL sterile packs are on

back order and the company cannot estimate a release date. The 0.5% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of late-January 2019.
•Pfizer has 0.25% bupivacaine with epinephrine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of 3rd quarter 2019. The 0.25% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 3rd quarter 2019. The 0.5% bupivacaine with epinephrine 10 mL preservative-free vials are on back order and the company estimates a release date of 3rd quarter 2019. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 3rd quarter 2019.
•Pfizer has 0.25% Marcaine with epinephrine 30 mL preservative-free vials on back order and the company estimates a release date of 3rd quarter 2019. The 0.25% Marcaine with epinephrine 10 mL preservative-free vials are on back order and the company estimates a release date of 1st quarter 2020. The 0.25% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 3rd quarter 2019. The 0.5% Marcaine with epinephrine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of 1st quarter 2020. The 0.5% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 3rd quarter 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=261

Bupivacaine Injection

January 17, 2019

Reason for the Shortage
•AuroMedics has not provided a reason for the shortage.
•Fresenius Kabi had Sensorcaine on shortage due to increased demand for the product.
•Pfizer has bupivacaine on shortage due to manufacturing delays. Pfizer discontinued 0.5% bupivacaine 30 mL glass ampules in December 2017.

Estimated Resupply Dates
•AuroMedics has 0.25% bupivacaine 10 mL and 30 mL preservative-free vials on intermittent back order and the company is releasing product as it becomes available. The 0.5% bupivacaine 10 mL and 30 mL preservative-free vials are on intermittent back order and the company is releasing product as it becomes available. The 0.75% bupivacaine 10 mL and 30 mL preservative-free vials are on intermittent back order and the company is releasing product as it becomes available.
•Fresenius Kabi has 0.25% Sensorcaine 10 mL preservative-free vials on back order and the company estimates a release date of early-February 2019. The 0.25% 30 mL preservative-free vials are on back order and the company estimates a release date of late-January. The 0.25% 50 mL vials are on back order and the company estimates a release date of late-January 2019. The 0.5% Sensorcaine 10 mL preservative-free vials are on back order and the company estimates release dates of mid- to late-February 2019. The 0.5% Sensorcaine 30 mL preservative-free vials are on back order and the company estimates release dates of late-January 2019. The 0.5% Sensorcaine 50 mL vials are on back order and the company estimates a release date of mid-January 2019. The 0.75% 30 mL preservative-free vials are on back order and the company estimates a release date of mid-January 2019. The 0.25% and 0.5% Sensorcaine 30 mL preservative-free vials in sterile packs are on back order and the company cannot estimate release dates.
•Pfizer has 0.25% bupivacaine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of March 2019 for the 10 mL vials and February 2019 for the 30 mL vials. The 0.25% bupivacaine 50 mL vials are on back order and the company estimates release dates of February 2019. The 0.5% bupivacaine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of March 2019 for the 10 mL vials and February 2019 for the 30 mL vials. The 0.5% bupivacaine 50 mL vials are on back order and the company estimates a release date of January 2019. The 0.75% bupivacaine 10 mL preservative-free vials are on back order and the company estimates a release date of March 2019.

•Pfizer has all Marcaine vials on back order and the company estimates a release date of 1st quarter 2020. The 0.75% Marcaine Spinal in 8.25% dextrose 2 mL ampules are available.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=172

Bacteriostatic 0.9% Sodium Chloride Vials

January 17, 2019

Reason for the Shortage
•Fresenius Kabi did not provide a reason for the shortage.
•Pfizer has bacteriostatic sodium chloride vials on shortage due to manufacturing delays.

Estimated Resupply Dates
•Pfizer has bacteriostatic 0.9% sodium chloride 10 mL vials on back order and the company estimates a release date of January 2019. The 30 mL vials are available in limited supply.
•Fresenius Kabi has bacteriostatic 0.9% sodium chloride 10 mL vials on back order and the company estimates a release date of mid-February 2019. The 30 mL vials are on back order and the company estimates a release date of late-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=441

Calcium Gluconate Injection

January 18, 2019

Reason for the Shortage
•American Regent is not currently marketing calcium gluconate.
•Fresenius Kabi has calcium gluconate available.
•WG Critical Care launched calcium gluconate premixed bags in January 2019.

Estimated Resupply Dates
•All marketed presentations are available.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=150

Bumetanide Injection

January 18, 2019

Reason for the Shortage
•Pfizer has bumetanide injection on shortage due to manufacturing delays.
•Hikma did not provide a reason for the shortage.

Estimated Resupply Dates
•Pfizer has bumetanide 0.25 mg/mL 4 mL and 10 mL vials on back order and the company estimates a release date of 2nd quarter 2019 for the 4 mL vials and 2019 for the 10 mL vials.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=307

Amiodarone Injection

January 18, 2019

Reason for the Shortage
• Baxter has Nexterone premixed bags on shortage due to manufacturing delays.
• Mylan Institutional did not provide a reason for the shortage.

• Hikma did not provide a reason for the shortage; however, the 50 mg/mL, 3 mL 10 count presentation was discontinued in December 2018.

Estimated Resupply Dates
•Auromedics has amiodarone 50 mg/mL 9 mL and 18 mL vials on back order and the company estimates a release date of late-January 2019.
•Hikma has amiodarone 50 mg/mL 3 mL vials on back order and the company estimates a release date of February 2019.
•Mylan Institutional has amiodarone 50 mg/mL 3 mL vials on back order and the company estimates a release date of mid-February 2019.
• Sagent has amiodarone 50 mg/mL 3 mL vials available with short expiration dating of February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=374

Alpha-1 Proteinase Inhibitor

January 18, 2019

Reason for the Shortage
• CSL Behring did not provide a reason for the Zemaira shortage.
•The other alpha-1 proteinase inhibitors such as Aralast and Prolastin-C are not affected by this shortage.

Estimated Resupply Dates
•CLS Behring has Zemaira 1 mg vials on intermittent back order with regular releases.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=374

Acetylcysteine Oral and Inhalation Solution

January 18, 2019

Reason for the Shortage
• American Regent has acetylcysteine oral and inhalation solution on shortage due to manufacturing delays. They are not currently marketing the 10 mL and 30 mL vial presentations.
•Fresenius Kabi has acetylcysteine oral and inhalation solution available.
•Pfizer had acetylcysteine oral and inhalation solution on shortage due to manufacturing delays.
•Roxane Labs discontinued acetylcysteine oral and inhalation solution in April 2014.
•Arbor has Cetylev effervescent tablets available. These are for oral use only.

Estimated Resupply Dates
•American Regent has acetylcysteine solution 100 mg/mL 4 mL vials and 200 mg/mL 4 mL vials available in limited supply.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=43

25% Dextrose Injection

January 18, 2019

Reason for the Shortage
• Pfizer has 25% dextrose on shortage due to manufacturing delays.

Estimated Resupply Dates
•Pfizer has 25% dextrose 10 mL Ansyr syringes on back order and the company estimates a release date of 1st quarter 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=483

14.6% Sodium Chloride Concentrated Solution for Injection

January 18, 2019

Reason for the Shortage

• Pfizer has 14.6% sodium chloride concentrated solution for injection on shortage due to manufacturing delays.

Estimated Resupply Dates

•Pfizer has 14.6% sodium chloride concentrated solution for injection 20 mL and 40 mL vials on back order and the company cannot estimate a release date for the 20 mL vials and estimates a release date of January 2019 for the 40 mL vials.

•Fresenius Kabi has 14.6% sodium chloride concentrated solution for injection 40 mL vials on back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=416

Sodium Polystyrene Sulfonate Powder

January 22, 2019

Reason for the Shortage

• CMP Pharma has sodium polystyrene sulfonate on back order due to a raw material shortage.
• ECI Pharmaceuticals did not provide a reason for the shortage.
• KVK-Tech did not provide a reason for the shortage.
• Sunrise Pharmaceuticals has sodium polystyrene sulfonate on back order due to a raw material shortage.
• Trigen did not provide a reason for the shortage.

Estimated Resupply Dates

•CMP Pharma has sodium polystyrene sulfonate in 454 gram bottles on back order and the company estimates a release date of late-January 2019.

•ECI Pharmaceuticals has sodium polystyrene sulfonate in 454 gram bottles on back order and the company estimates a release date of mid-February 2019.

•KVK-Tech has sodium polystyrene sulfonate in 15 gram and 454 gram bottles on back order and the company estimates a release date of late-February 2019.

•Sunrise Pharmaceuticals has sodium polystyrene sulfonate in 15 gram and 454 gram bottles on back order and the company estimates a release date of late-January 2019.

•Trigen has sodium polystyrene sulfonate in 454 gram bottles on back order and the company estimates a release date of mid-February 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=523

Sodium Polystyrene Sulfonate Oral or Rectal Suspension

January 22, 2019

Reason for the Shortage

• CMP Pharma reports that increased demand has led to a shortage of raw material required to manufacture the products.

•Perrigo has temporarily discontinued their Kionex suspension and sodium polystyrene sulfonate (sorbitol-free) suspension. They cannot estimate when these products will be manufactured again.

•Hikma is not currently marketing sodium polystyrene sulfonate suspension.

Estimated Resupply Dates
•CMP Pharma has SPS Suspension on back order and the company estimates a release date of late-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=430

Penicillamine

January 22, 2019

Reason for the Shortage
• Mylan did not provide a reason for the shortage.
•Bausch Health did not provide a reason for the shortage.

Estimated Resupply Dates
•Mylan has Depen 250 mg tablets on back order and the company estimates a release date of mid-March 2019.
•Bausch Health has Cuprimine 250 mg capsules on back order and the company estimates a release date of late-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=379

Ondansetron Hydrochloride Injection

January 22, 2019

Reason for the Shortage
• Apotex did not provide a reason for the shortage.
•Athenex had ondansetron injection on shortage due to increased demand.
•AuroMedics did not provide a reason for the shortage.
•Fresenius Kabi has ondansetron injection available.
•Heritage had ondansetron on shortage due to increased demand. Heritage discontinued ondansetron 2 mg/mL 2 mL vials in 10 count in late-2018.
•Hikma did not provide a reason for the shortage.
•Mylan Institutional has ondansetron injection available.
•Pfizer has ondansetron injection on shortage due to manufacturing delays.
•Sagent has ondansetron injection on shortage due to increased demand and manufacturing delays.
•Novartis discontinued Zofran 20 mL vials in May 2018.

Estimated Resupply Dates
•Apotex has ondansetron 2 mg/mL 2 mL vials on back order and the company cannot estimate a release date.
•AuroMedics has ondansetron 2 mg/mL 2 mL vials and 20 mL vials on intermittent back order and the company is releasing supplies as they become available.
•Fresenius Kabi has ondansetron 2 mg/mL 20 mL vials with a short-expiration date (< 4 months). The 2 mg/mL 2 mL prefilled syringes are on back order and the company estimates a release date of 1st quarter 2019.
•Hikma has ondansetron 2 mg/mL 2 mL vials in 25 count on allocation.
•Pfizer has ondansetron 2 mg/mL 20 mL vials available in limited supply. The 2 mg/mL 2 mL iSecure syringes are on back order and the company estimates a release date of 4th quarter 2019.
•Sagent has ondansetron 2 mg/mL 2 mL vials and 20 mL vials on back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=405

Hydralazine injection

January 22, 2019

Reason for the Shortage
•Akorn has product on back order due to increased demand.
•American Regent is not currently marketing hydralazine injection.
•Fresenius Kabi did not provide a reason for the shortage.
•X-Gen did not provide a reason for the shortage.

Estimated Resupply Dates
•Akorn has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of late-January 2019.
Fresenius Kabi has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of late-January 2019. Check wholesalers for inventory.
X-Gen has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of mid-February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=431

Dicyclomine Oral Presentations

January 22, 2019

Reason for the Shortage
• Hikma did not provide a reason for the shortage.
•Lannett did not provide a reason for the shortage.
•Mylan did not provide a reason for the shortage.
•Par Pharmaceuticals has dicyclomine oral solution available.
•Teva did not provide a reason for the shortage.

Estimated Resupply Dates
•Hikma has 10 mg capsules in 100 and 1,000 count bottles and 20 mg tablets in 100 and 1,000 count bottles on available on allocation.
•Lannett has 10 mg capsules in 100 and 1,000 count bottles and 20 mg tablets in 100 and 1,000 count bottles on back order and the company estimates a release date of late-January 2019.
•Mylan has 10 mg capsules in 100 and 500 count bottles on back order and the company estimates a release date of mid-February 2019. The 20 mg tables in 100 and 500 count bottles are on back order and the company estimates a release date of mid- to late-March 2019.
•Mylan Institutional has 10 mg capsules and 20 mg tablets on back order and the company estimates a release date of mid-May 2019 for the 10 mg capsules and early-March for the 20 mg tablets.
•Teva has 10 mg capsules in 100 and 1,000 count bottles and 20 mg tablets in 100 and 1,000 count bottles on back order and the company estimates a release date of early- to mid-February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=521

Cosyntropin Injection
January 22, 2019

Reason for the Shortage
• Amphastar has Cortrosyn on shortage due to increased demand.
•Mylan Institutional did not provide a reason for the shortage.
•Sandoz did not provide a reason for the shortage.

Estimated Resupply Dates
•Mylan Institutional has cosyntropin 0.25 mg vials on back order and the company estimates a release date of late-August 2019.
•Sandoz has cosyntropin 0.25 mg vials temporarily unavailable and the company cannot estimate a release date.
•Amphastar has Cortrosyn 0.25 mg vials on intermittent back order with regular releases.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=522

Busulfan Injection
January 22, 2019

Reason for the Shortage
• American Regent did not provide a reason for the shortage.
•Amneal did not provide a reason for the shortage.
•Sagent has busulfan on shortage due to increased demand.

Estimated Resupply Dates
•Amneal has busulfan 6 mg/mL 10 mL vials on back order and the company cannot estimate a release date.
•Sagent has busulfan 6 mg/mL 10 mL vials on back order and the company estimates a release date of February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=509

Betamethasone Acetate/Betamethasone Sodium Phosphate Suspension for Injection
January 22, 2019

Reason for the Shortage
• American Regent has betamethasone acetate/betamethasone sodium phosphate on shortage due to minor shipping delays.
• Merck did not provide a reason for the shortage.

Estimated Resupply Dates
•American Regent has betamethasone acetate/betamethasone sodium phosphate 6 mg/mL 5 mL vials available in limited supply.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=485

Benztropine Mesylate Injection
January 22, 2019

Reason for the Shortage
• Akorn did not provide a reason for the shortage.
•Fresenius Kabi did not provide a reason for the shortage.

•Hikma did not provide a reason for the shortage.

Estimated Resupply Dates
•Akorn has benztropine 1 mg/mL 2 mL ampules and Cogentin 1 mg/mL 2 mL ampules on back order and the company cannot estimate a release date.
•Fresenius Kabi has benztropine 1 mg/mL 2 mL vials on back order and the company estimates a release date of mid-February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=497

Belladonna and Opium Suppositories

January 22, 2019

Reason for the Shortage
• Perrigo had belladonna and opium suppositories on shortage because they were waiting to get more raw ingredient.

Estimated Resupply Dates
•Perrigo has belladonna and opium 16.3 mg/30 mg suppositories on intermittent back order and the company is releasing product as it becomes available.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=425

5% Lidocaine and 7.5% Dextrose Injection

January 22, 2019

Reason for the Shortage
• Pfizer has 5% lidocaine and 7.5% dextrose 2 mL ampules on shortage due to manufacturing delays. Pfizer is the sole supplier of this combination.

Estimated Resupply Dates
•Pfizer has 5% lidocaine and 7.5% dextrose 2 mL ampules on long-term back order and the company estimates a release date of 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=253

23.4% Sodium Chloride Injection

January 22, 2019

Reason for the Shortage
• Fresenius Kabi has 23.4% sodium chloride injection on shortage due to increased demand. Pfizer has 23.4% sodium chloride injection on shortage due to increased demand.

Estimated Resupply Dates
•Fresenius Kabi has 23.4% sodium chloride 30 mL, 100, and 200 mL vials on back order and the company estimates a release date of early-February 2019 for the 30 mL vials, mid-February 2019 for the 100 mL vials, and late-January 2019 for the 200 mL vials. Check wholesalers for inventory.
Pfizer has 23.4% sodium chloride 200 mL vials on back order and the company estimates a release date of 3rd quarter 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=336

Vancomycin Hydrochloride Injection

January 23, 2019

Reason for the Shortage
•Alvogen has vancomycin injection available.
•Athenex has vancomycin injection available.
•AuroMedics has vancomycin injection available.
•Pfizer has vancomycin vials on back order due to manufacturing delays.
•Fresenius Kabi has vancomycin injection on shortage due to increased demand.
•Mylan Institutional has vancomycin injection available.
•Baxter has vancomycin injection available.
•Samson Medical Technologies has vancomycin injection available.
•Sagent has vancomycin injection on shortage due to manufacturing delays and increased demand.
•Xellia Pharmaceuticals has vancomycin injection available.

Estimated Resupply Dates
•Fresenius Kabi has vancomycin 5 gram and 10 gram vials on intermittent back order with regular releases.
•Pfizer has 500 mg ADD-Vantage vials, 750 mg vials, 750 mg ADD-Vantage vials, 1 gram vials, 5 gram, and 10 gram vials available in limited supply. The 1 gram ADD-Vantage vials are on back order and the company estimates a release date of March 2018.
•Sagent has vancomycin 5 gram and 10 gram vials on allocation.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=25

Trifluoperazine Tablets

January 23, 2019

Reason for the Shortage
•Mylan did not provide a reason for the shortage.
•Upsher-Smith did not provide a reason for the shortage.

Estimated Resupply Dates
•Mylan has trifluoperazine 1 mg, 2 mg, 5 mg, and 10 mg tablets in 100 count bottles on back order and the company estimates a release date of early-April 2019. The 1 mg, 2 mg, 5 mg, and 10 mg tablets in 100 count unit-dose packs are on back order and the company estimates a release date of late-April 2019 for the 1 mg tablets, mid-March 2019 for the 2 mg and 5 mg tablets, and late-February to early-March 2019 for the 10 mg tablets.
•Upsher-Smith has trifluoperazine 1 mg, 2 mg, 5 mg, and 10 mg tablets in 100 count bottles on long-term back order and the company cannot estimate a release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=457

Testosterone Enanthate Intramuscular Injection

January 23, 2019

Reason for the Shortage
•Hikma did not provide a reason for the shortage.
•Teva did not provide a reason for the shortage.

Estimated Resupply Dates

•Hikma has testosterone enanthate 200 mg/mL 5 mL vials on back order and the company estimates a release date of late-January 2019.
•Teva has testosterone enanthate 200 mg/mL 5 mL vials temporarily unavailable with no estimated release date.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=498

Progesterone Injection

January 23, 2019

Reason for the Shortage
• American Regent is not currently marketing progesterone injection.
• Fresenius Kabi has progesterone on shortage due to increased demand and manufacturing delays.

Estimated Resupply Dates
•Fresenius Kabi has progesterone in oil 50 mg/mL 10 mL vials for intramuscular injection on back order and the company estimates a release date of late-January 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=381

Orphenadrine Citrate Injection

January 23, 2019

Reason for the Shortage
•Akorn did not provide a reason for the shortage.
•Hikma did not provide a reason for the shortage.
•Teva discontinued orphenadrine in November 2018.

Estimated Resupply Dates
•Akorn has orphenadrine 30 mg/mL 2 mL vials on allocation.
•Hikma has orphenadrine 30 mg/mL 2 mL vials on back order and the company estimates a release date of February 2019.https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=471

Lidocaine with Epinephrine Injection

January 23, 2019

Reason for the Shortage
• Fresenius Kabi has Xylocaine with epinephrine presentations on shortage due to increased demand for the product and manufacturing delays.
• Pfizer has lidocaine with epinephrine presentations on shortage due to manufacturing delays.

Estimated Resupply Dates
•Fresenius Kabi has 0.5% Xylocaine with epinephrine (1:200,000) 50 mL vials on back order and the company estimates a release date of late-January 2019. The 1% Xylocaine with epinephrine (1:200,000) 10 mL vials are on back order and the company estimates a release date of mid-February 2019. The 1% Xylocaine with epinephrine (1:200,000) 20 mL vials are on back order and the company estimates release dates of late-January 2019. The 1% Xylocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates release dates of mid-February 2019. The 1% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials are on back order and the company estimates a release date of mid-February 2019. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company cannot

estimate a release date. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company cannot estimate a release date. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 10 mL regular vials are on back order and the company estimates a release date of late-January 2019. The 2% Xylocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates a release date of late-January 2019. The 2% Xylocaine-MPF with epinephrine (1:200,000) 20 mL vials in sterile packs are on back order and the company cannot estimate a release date. Check wholesalers for inventory.
•Pfizer has 1% lidocaine with epinephrine (1:100,000) 20 mL vials on back order and the company estimates a release date of January 2019. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are on back order and the company estimates a release date of January 2019. The 1% lidocaine with epinephrine (1:100,000) 50 mL vials are on back order and the company estimates a release date of January 2019. The 1.5% lidocaine with epinephrine (1:200,000) 30 mL vials are on back order and the company estimates a release date of 1st quarter 2019. The 1.5% lidocaine with epinephrine (1:200,000) 5 mL ampules are on back order and the company estimates a release date of February 2019. The 2% lidocaine with epinephrine (1:100,000) 20 mL vials are on back order and the company estimates a release date of March 2019. The 2% lidocaine with epinephrine (1:100,000) 30 mL and 50 mL vials are on back order and the company estimates a release date of 1st quarter 2019 for the 30 mL vials and 2nd quarter 2019 for the 50 mL vials.https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=98

Ketamine Injection

January 23, 2019

Reason for the Shortage
• Hikma did not provide a reason for the shortage.
•Mylan Institutional did not provide a reason for the shortage.
•Par has Ketalar on shortage due to increased demand.
•Pfizer has ketamine on shortage due to manufacturing delays.

Estimated Resupply Dates
•Hikma has ketamine 50 mg/mL 10 mL and 100 mg/mL 5 mL vials on back order and the company estimates a release date of February to March 2019.
•Mylan Institutional has ketamine 10 mg/mL 20 mL on back order and the company estimates a release date of late-January 2019. The 50 mg/mL 10 mL vials are on back order and the company estimates a release date of late-January 2019. The 100 mg/mL 10 mL vials are on back order and the company estimates a release date of mid-March 2019.
•Pfizer has ketamine 50 mg/mL 10 mL vials on back order and the company estimates a release date of 1st quarter 2020. The 100 mg/mL 5 mL vials are on back order and the company estimates a release date of 4th quarter 2019.
•Par has Ketalar 10 mg/mL 20 mL vials, 50 mg/mL 10 mL vials, and 100 mg/mL 5 mL vials on intermittent back order with monthly releases.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=391

Hydromorphone Hydrochloride Injection

January 23, 2019

Reason for the Shortage
• Akorn has hydromorphone injection on shortage due to increased demand.
•Fresenius Kabi has Dilaudid syringes on shortage due to increased demand. They are focusing their product on the 0.5 mg strength. They launched hydromorphone vials in late-June 2018.

•Pfizer did not provide a reason for the shortage.
•Purdue discontinued Dilaudid and Dilaudid HP in May 2017 for marketing reasons.
•Teva did not provide a reason for the shortage.
•Hikma did not provide a reason for the shortage.

Estimated Resupply Dates
•Akorn has hydromorphone 10 mg/mL 50 mL vials on allocation.
•Fresenius Kabi has Dilaudid 2 mg/mL 1 mL syringes on back order and the company cannot estimate a release date. The hydromorphone 4 mg/mL 1 mL vials and 10 mg/mL 5 mL vials are on back order and the company estimates a release date of late-February to early-March 2019. The hydromorphone 10 mg/mL 1 mL vials are on back order and the company cannot estimate a release date. Check wholesalers for inventory.
•Hikma has hydromorphone 2 mg/mL 1 mL vials (NDC 00641-0121-25) on back order and the company estimates a release date of February 2019.
•Pfizer has 1 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of late-February 2019. The 10 mg/mL 50 mL vials are on back order and the company estimates a release date of 2nd quarter 2019. The 10 mg/mL 5 mL vials are on back order and the company estimates a release date of March 2019. The 0.5 mg/0.5 mL 0.5 mL iSecure syringes and 2 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 2nd quarter 2019. The 1 mg/mL 1 mL ampules, 2 mg/mL 1 mL ampules, and 4 mg/mL 1 mL ampules are on back order and the company estimates a release date of 2nd quarter 2019. The 1 mg/mL 1 mL iSecure syringes, 2 mg/mL 1 mL iSecure syringes, and 4 mg/mL 1 mL
•Carpuject syringes are on back order and the company estimates a release date of 4th quarter 2019. The 2 mg/mL 1 mL vials are available in limited supply.
•Teva has 10 mg/mL 1 mL, 5 mL, and 50 mL vials on intermittent back order and the company is allocating upon release.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=329

Dorzolamide 2% and Timolol 0.5% Ophthalmic Solution

January 23, 2019

Reason for the Shortage
• Akorn has dorzolamide and timolol ophthalmic solution on shortage due to manufacturing delays.
Sandoz did not provide a reason for the shortage.
• Teva discontinued dorzolamide and timolol ophthalmic solution in April 2018.
• Bausch Health has dorzolamide and timolol ophthalmic solution on shortage due to manufacturing delays.

Estimated Resupply Dates
•Akorn has Cosopt 2%/0.5% ophthalmic solution in 10 mL bottles on back order and the company cannot estimate a release date.
•Bausch Health has dorzolamide 2% and timolol 0.5% ophthalmic solution in 10 mL bottles on back order and the company estimates a release date of early-February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=360

Diphenhydramine Injection

January 23, 2019

Reason for the Shortage
• Fresenius Kabi has diphenhydramine injection on shortage due to increased demand.
•Hikma did not provide a reason for the shortage.
•Mylan did not provide a reason for the shortage.

•Pfizer has diphenhydramine injection on shortage due to manufacturing delays.

Estimated Resupply Dates
•Fresenius Kabi has diphenhydramine 50 mg/mL 1 mL vials on back order and the company estimates a release date of late-January 2019. The 50 mg/mL 1 mL syringes are on back order and the company estimates a release date of mid-March 2019. Check wholesalers for inventory.
•Hikma has diphenhydramine 50 mg/mL 1 mL vials on allocation.
•Mylan Institutional has diphenhydramine 50 mg/mL 10 mL vials on back order and the company estimates a release date of mid-February 2019.
•Pfizer has diphenhydramine 50 mg/mL 1 mL vials on back order and the company estimates a release date of 1st quarter 2020.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=456

Sterile Water for Injection Large Volume Bags

January 23, 2019

Reason for the Shortage
• Baxter had sterile water for injection on shortage due to manufacturing delays.
• BBraun has sterile water for injection available.
• ICU Medical has sterile water for injection available.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=368

Ropivacaine Injection

January 24, 2019

Reason for the Shortage
• Akorn has ropivacaine on shortage due to increased demand.
•AuroMedics did not provide a reason for the shortage.
•Fresenius Kabi has Naropin on shortage due to increased demand and manufacturing delays.
•Pfizer had ropivacaine on shortage due to manufacturing delays.

Estimated Resupply Dates
•Akorn has ropivacaine 5 mg/mL 30 mL vials on back order and the company cannot estimate a release date.
•AuroMedics has ropivacaine 10 mg/mL 10 mL vials on intermittent back order and the company is releasing product as it becomes available.
•Fresenius Kabi has Naropin 5 mg/mL 30 mL Steripak ampules on back order and the company cannot estimate a release date. The 5 mg/mL 30 mL vials are on back order and the company estimates a release date of late-January 2019. Check wholesalers for inventory.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=384

Potassium Phosphate Injection

January 24, 2019

Reason for the Shortage
• American Regent has not had potassium phosphate injection available since 2012. It is unclear if and when product will return to market.
•Fresenius Kabi had potassium phosphate injection on shortage due to increased demand.
•Pfizer had potassium phosphate injection on shortage due to manufacturing delays.

Estimated Resupply Dates
•Fresenius Kabi has potassium phosphate 3 mmol/mL 15 mL and 50 mL vials on back order and the company estimates a release date of late-January 2019 for the 15 mL vials and early-February 2019 for the 50 mL vials.
•Pfizer has potassium phosphate 3 mmol/mL 15 mL vials available in limited supply.https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=305

Multiple Electrolytes Large Volume Solutions for Injection

January 24, 2019

Reason for the Shortage
•Baxter has Plasma-Lyte 148 and Plasma-Lyte A presentations available.
•ICU Medical had Normosol-R presentations on back order due to manufacturing delays.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=389

Leucovorin Calcium Injection

January 24, 2019

Reason for the Shortage
• Fresenius Kabi has leucovorin on shortage due to manufacturing delays and increased demand.
• Hikma did not provide a reason for the current shortage.
• Sagent has leucovorin on shortage due to manufacturing delays.
• Teva has leucovorin available.

Estimated Resupply Dates
•Fresenius Kabi has leucovorin 200 mg and 500 mg vials on back order and the company estimates a release date of late-January 2019 for the 200 mg vials and early-February 2019 for the 500 mg vials.
•Hikma has leucovorin 100 mg and 350 mg vials on back order and the company estimates a release date of February to March 2019.
•Sagent has leucovorin 200 mg vials on allocation.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=35

Lactated Ringer's Injection

January 24, 2019

Reason for the Shortage
• Baxter has lactated ringer's injection available.
•BBraun had lactated ringer's injection on shortage due to increased demand.
•ICU Medical had lactated ringer's on shortage due to increased demand.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=361

Hydroxyprogesterone Caproate Injection

January 24, 2019

Reason for the Shortage
•AMAG has Makena vials on shortage due to manufacturing delay.
•American Regent has hydroxyprogesterone injection available.
•Mylan has hydroxyprogesterone injection available.
•Prasco has hydroxyprogesterone injection available.

•Slayback Pharma launched hydroxyprogesterone injection in January 2019.

Estimated Resupply Dates
•AMAG has Makena 250 mg/mL 1 mL and 5 mL vials on back order and the company estimates a release date in early-2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=501

Diltiazem Hydrochloride Injection

January 24, 2019

Reason for the Shortage
•Akorn states the reason for the shortage was increased demand due to market conditions. They are not currently producing the 25 mL vials in 10 count.
•Pfizer states the reasons for the shortage is manufacturing delays and increases in demand.
•Hikma has diltiazem injection on shortage due to manufacturing delays caused by increased demand due to current market conditions.

Estimated Resupply Dates
•Akorn has diltiazem 5 mg/mL 5 mL, 10 mL, and 25 mL vials on allocation.
•Hikma has diltiazem 5 mg/mL 25 mL vials on back order and the company estimates a release date of February 2019.
•Pfizer has 100 mg ADD-Vantage vials on back order and the company estimates a release date of March 2019. The 5 mg/mL 5 mL and 10 mL vials are also on back order and the company estimates a release date of 2020.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=26

Cefepime Injection

January 24, 2019

Reason for the Shortage
• Apotex has cefepime injection available.
•Baxter has cefepime on allocation due to increased demand.
•BBraun has cefepime on shortage due to manufacturing delays.
•Fresenius Kabi did not provide a reason for the shortage.
•Pfizer has Maxipime on shortage due to manufacturing delays.
•Sagent has cefepime injection on shortage due to increased demand.
•Sandoz discontinued cefepime injection in early-2016.
•WG Critical Care has cefepime injection available.

Estimated Resupply Dates
•Baxter has cefepime 2 gram premixed bags on allocation.
•BBraun has cefepime 1 gram and 2 gram premixed bags on allocation.
•Fresenius Kabi has cefepime 2 gram vials on back order and the company estimates a release date of mid-February 2019.
•Pfizer has Maxipime 1 gram vials, 2 gram vials, 1 gram ADD-Vantage vials, and 2 gram ADD-Vantage vials on back order and the company estimates a release date of 2019.
•Sagent has cefepime 2 gram vials on allocation.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=59

Bupivacaine with Epinephrine Injection

January 24, 2019

Reason for the Shortage

• Fresenius Kabi has bupivacaine and epinephrine on shortage due to increased demand and manufacturing delays.
• Pfizer has bupivacaine with epinephrine on shortage due to manufacturing delays.

Estimated Resupply Dates

•Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 10 mL vials on back order and the company estimates a release date of late-January 2019. The 0.25% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of late-January 2019. The 0.25% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of late-January 2019.
•The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of ;ate-January 2019. The 0.5% Sensorcaine-MPF with epinephrine 30 mL sterile packs are on back order and the company cannot estimate a release date.
•Pfizer has 0.25% bupivacaine with epinephrine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of 3rd quarter 2019. The 0.25% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 3rd quarter 2019. The 0.5% bupivacaine with epinephrine 10 mL preservative-free vials are on back order and the company estimates a release date of 3rd quarter 2019. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 3rd quarter 2019.
•Pfizer has 0.25% Marcaine with epinephrine 30 mL preservative-free vials on back order and the company estimates a release date of 3rd quarter 2019. The 0.25% Marcaine with epinephrine 10 mL preservative-free vials are on back order and the company estimates a release date of 1st quarter 2020. The 0.25% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 3rd quarter 2019. The 0.5% Marcaine with epinephrine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of 1st quarter 2020. The 0.5% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 3rd quarter 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=261

Bupivacaine Injection

January 24, 2019

Reason for the Shortage

• AuroMedics has not provided a reason for the shortage.
•Fresenius Kabi had Sensorcaine on shortage due to increased demand for the product.
•Pfizer has bupivacaine on shortage due to manufacturing delays. Pfizer discontinued 0.5% bupivacaine 30 mL glass ampules in December 2017.

Estimated Resupply Dates

•AuroMedics has 0.25% bupivacaine 10 mL and 30 mL preservative-free vials on intermittent back order and the company is releasing product as it becomes available. The 0.5% bupivacaine 10 mL and 30 mL preservative-free vials are on intermittent back order and the company is releasing product as it becomes available. The 0.75% bupivacaine 10 mL and 30 mL preservative-free vials are on intermittent back order and the company is releasing product as it becomes available.
•Fresenius Kabi has 0.25% Sensorcaine 10 mL preservative-free vials on back order and the company estimates a release date of early-February 2019. The 0.25% 30 mL preservative-free vials are on back order and the company estimates a release date of late-January. The 0.25% 50 mL vials are on back order and the

company estimates a release date of early-February 2019. The 0.5% Sensorcaine 10 mL preservative-free vials are on back order and the company estimates release dates of mid- to late-February 2019. The 0.5% Sensorcaine 30 mL preservative-free vials are on back order and the company estimates release dates of late-January 2019. The 0.5% Sensorcaine 50 mL vials are on back order and the company estimates a release date of early-March 2019. The 0.75% 30 mL preservative-free vials are on back order and the company estimates a release date of late-January 2019. The 0.25% and 0.5% Sensorcaine 30 mL preservative-free vials in sterile packs are on back order and the company cannot estimate release dates.
•Pfizer has 0.25% bupivacaine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of March 2019 for the 10 mL vials and February 2019 for the 30 mL vials. The 0.25% bupivacaine 50 mL vials are on back order and the company estimates release dates of February 2019. The 0.5% bupivacaine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of March 2019 for the 10 mL vials and February 2019 for the 30 mL vials. The 0.5% bupivacaine 50 mL vials are on back order and the company estimates a release date of January 2019. The 0.75% bupivacaine 10 mL preservative-free vials are on back order and the company estimates a release date of March 2019.
•Pfizer has all Marcaine vials on back order and the company estimates a release date of 1st quarter 2020. The 0.75% Marcaine Spinal in 8.25% dextrose 2 mL ampules are available.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=172

BCG Live Intravesical

January 24, 2019

Reason for the Shortage
• Because of increased global demand, and as the only source of BCG Live (Intravesical) in the United States and many other countries, Merck anticipates supply constraints for Tice BCG in 2019. To minimize disruption to patient care and address the current imbalance between supply and increased global demand, Tice BCG will be under allocation when demand exceeds production plans and available inventory.

Estimated Resupply Dates
•Merck has Tice BCG available on allocation. Beginning January 2, 2019, Merck will cease to accept drop shipment orders for TICE BCG and will move to a direct purchaser allocation model. Wholesalers and distributors will manage the distribution of TICE BCG based on available supply and customers' historical purchasing patterns.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=519

Amphotericin B Injection

January 24, 2019

Reason for the Shortage
• X-Gen did not provide a reason for the shortage. They are the sole suppliers of amphotericin B lyophilized powder for injection.

Estimated Resupply Dates
• X-Gen has amphotericin B 50 mg vials on back order and the company estimates a release date of mid- to late-February 2019.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=524

5% Dextrose Injection (PVC-free and DEHP-free)

January 24, 2019

Reason for the Shortage

- ICU Medical had 5% dextrose PVC/DEHP-free bags due to increased demand.
- Baxter is not currently marketing 5% dextrose PVC/DEHP-free bags.
- BBraun had 5% dextrose PVC/DEHP-free bags on shortage due to manufacturing delays.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=314

5% Dextrose Injection

January 24, 2019

Reason for the Shortage

- Baxter has 5% dextrose injection available.
- ICU Medical states the shortage was due to increased demand.
- Pfizer states that the shortage was due to increased demand.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=303