PERFORMRx℠

Drug Information Update

September 2018

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NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
IMIQUIMOD	3.75 % CREAM	OCEANSIDE PHARM	ZYCLARA
ADAPALENE	0.1% SOLUTION	ALLEGIS PHARMAC	DIFFERIN
PLIXDA (ADAPALENE)	0.1 %	MARNEL PHARM.	DIFFERIN
THERAPEVO (HYALURONATE SODIUM/HE-CELL/PEG)	2.5 % GEL	GENTEX PHARMA	HYLASE
DALFAMPRIDINE	10 MG TABLET	ACCORD, ASCEND, AUROBINDO, MYLAN	AMPYRA

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	LENVIMA	LENVATINIB MESYLATE	4 MG CAPSULE	NEW STRENGTH
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	LENVIMA	LENVATINIB MESYLATE	12 MG (4 MG X 3) CAPSULE	NEW STRENGTH
THROMBOPOIETIN RECEPTOR AGONISTS	MULPLETA	LUSUTROMBOPAG	3 MG TABLET	NEW ENTITY
ANTINEOPLASTICS ANTIBODY/ANTIBODY-DRUG COMPLEXES	POTELIGEO	MOGAMULIZUMAB-KPKC	20 MG/5 ML IV SOLUTION, VIAL	NEW ENTITY
ANTIPSORIATIC AGENTS,SYSTEMIC	ILUMYA	TILDRAKIZUMAB-ASMN	100 MG/ML SQ SOLUTION, SYRINGE	NEW ENTITY
PLASMA KALLIKREIN INHIBITORS	TAKHZYRO	LANADELUMAB-FLYO	300 MG/ 2 ML SQ SOLUTION, VIAL	NEW ENTITY
SOMATOSTATIC AGENTS	SIGNIFOR LAR	PASIREOTIDE PAMOATE	10 MG IM SUSPENSION, VIAL	NEW STRENGTH
SOMATOSTATIC AGENTS	SIGNIFOR LAR	PASIREOTIDE PAMOATE	30 MG IM SUSPENSION, VIAL	NEW STRENGTH
TOPICAL ANTI-INFLAMMATORY NSAID-LOCAL ANESTHETIC	TRIXYLITRAL	DICLOFENAC/LIDOCAINE /TAPE	1.5% CREAM-3.88% SOLUTION KIT	RX + OTC + DEVICE
TOPICAL ANTICHOLINERGIC HYPERHIDROSIS TX AGENTS	QBREXZA	GLYCOPYRRONIUM TOSYLATE	2.40% TOWELETTE	NEW ENTITY
ANTIHEMOPHILIC FACTORS	JIVI	FVIII REC,B-DOM DELET PEG-AUCL	500 (+/-) IV SOLUTION, VIAL	NEW ENTITY
ANTIHEMOPHILIC FACTORS	JIVI	FVIII REC,B-DOM DELET PEG-AUCL	1000 (+/-)IV SOLUTION, VIAL	NEW ENTITY
ANTIHEMOPHILIC FACTORS	JIVI	FVIII REC,B-DOM DELET PEG-AUCL	2000 (+/-)IV SOLUTION, VIAL	NEW ENTITY
ANTIHEMOPHILIC FACTORS	JIVI	FVIII REC,B-DOM DELET PEG-AUCL	3000 (+/-) IV SOLUTION, VIAL	NEW ENTITY

LEUKOCYTE (WBC) STIMULANTS	NIVESTYM	FILGRASTIM-AAFI	300MCG/0.5 ML SQ SOLUTION, SYRINGE	NEW ENTITY
LEUKOCYTE (WBC) STIMULANTS	NIVESTYM	FILGRASTIM-AAFI	480MCG/0.8 ML SQ SOLUTION, SYRINGE	NEW ENTITY
PROTECTIVES	SCARCARE	GEL PAD/DMC/ DIME/DEC/OCT/VIT E	2" X 5.5" TOPICAL KIT	MEDICAL DEVICE
PROTECTIVES	SCARCIN ROLL-ON	PROTECTIVES COMBINATION NO.5	LIQD ROLON	MEDICAL DEVICE

NEW INDICATIONS (EXISTING DRUGS)

IMBRUVICA®

August 27, 2018

Janssen Pharmaceutical Companies of Johnson & Johnson today announced the U.S. Food and Drug Administration (FDA) approval of IMBRUVICA® (ibrutinib) in combination with rituximab for the treatment of Waldenström's macroglobulinemia (WM), a rare blood cancer.1 The approval expands the label for IMBRUVICA in WM beyond its current approved use as a monotherapy to include combination use with rituximab. This approval represents the first approved non-chemotherapy combination option for the treatment of WM. IMBRUVICA first received FDA approval in WM as a monotherapy in January 2015 via the Breakthrough Therapy Designation pathway, making it the first FDA-approved therapy for the disease. The expanded label marks the ninth FDA approval for IMBRUVICA since 2013. IMBRUVICA is a first-in-class Bruton's tyrosine kinase (BTK) inhibitor jointly developed and commercialized by Janssen Biotech, Inc. and Pharmacyclics LLC, an AbbVie company.

Source: Janssen Pharmaceutical Companies of Johnson & Johnson

ACTEMRA®

September 13, 2018

Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), announced today that the U.S. Food and Drug Administration (FDA) has approved the subcutaneous (SC) formulation of Actemra® (tocilizumab) for the treatment of active systemic juvenile idiopathic arthritis (SJIA) in patients two years of age and older. Actemra can be given alone or in combination with methotrexate (MTX) in patients with SJIA. In 2011, FDA approved the intravenous (IV) formulation of Actemra for patients two years of age and older with active SJIA.

Source: Genentech

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

FDA alerts consumers not to use products distributed by Years to Your Health

[Posted 09/14/2018]

The U.S. Food and Drug Administration is alerting consumers not to use any products made by Years to Your Health of Irving, Texas. FDA is concerned these products could put consumers at risk for serious infection because they are made in a facility with poor manufacturing practices.
Years to Your Health markets hundreds of products online and in its retail store.

FDA recently conducted an inspection at Years to Your Health following a warning letter the agency issued in August 2017. FDA investigators observed several repeat violations of federal law that could lead to consumer harm. For example, the company does not perform any testing of incoming ingredients used to manufacture the drug products or test finished drug products. This could result in high-risk products, such as eyewash, being contaminated and unsafe for use.

FDA recently approached Years to Your Health following this inspection to recommend the company recall its products to protect consumers from potential harm. But the company has not acted to recall its products.

To date, FDA is not aware of any adverse event reports associated with the use of Years to Your Health's products. FDA encourages health care professionals and consumers to report adverse events to FDA's MedWatch Adverse Event Reporting program by:

- Completing and submitting the report online at MedWatch Online Voluntary Reporting Form
- Downloading and completing the form, then submitting it via fax at 1-800-FDA-0178.

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

BioLyte Laboratories Issues Voluntary Nationwide Recall Due to the Voluntary Nationwide Recall initiated by King Bio Inc. (a Raw Material Supplier) for NeoRelief for Muscle Cramping and Restlessness Topical Gel Due to Possible Microbial Contamination

[Posted 09/12/2018]

BioLyte Laboratories is voluntarily recalling lot numbers 1138, 1139, 1146, and 1160 of NeoRelief for Muscle Cramping and Restlessness Topical Gel to the retail and consumer level. King Bio Inc., a manufacturer of some of the active ingredients in this product, has been found to have some water contamination issues that potentially could have affected this product. King Bio has issued a recall of these active ingredients in BioLyte's lot specific product. To date, there have been no reports of illness or injury due to the use of this product.

The administration or use of drug products with microbial contamination could potentially result in increased infections that may require medical intervention and could result in infections that could be life threatening to certain individuals.

Lot Number	Expiry	UPC	Size	Package type
1138	1/31/2020	358368002021	2 oz	white airless pump bottle
1139	1/31/2020	358368002021	2 oz	white airless pump bottle
1146	3/29/2020	358368002045	4 ml	4” x 2” mylar foil pack
1160	10/10/2019	358368002021	2 oz	white airless pump bottle

NeoRelief for Muscle Cramping and Restlessness (package examples are attached)
BioLyte Laboratories is notifying its retail partners, distributors and customers by letter and is arranging for return and replacement of the recalled product.

Consumers/distributors/retailers that have this product which is being recalled should discontinue use/distribution and contact BioLyte Laboratories at support@biolytelabs.com to make arrangements to return the product. These products were distributed Nationwide to retailers (doctor offices, pharmacies, health food stores) and consumers (expo’s, direct sales, website) between February 7, 2017 through August 30, 2018.

Consumers with questions regarding this recall can contact BioLyte Laboratories, LLC at 800- 538-1455 Ext. 1 or e-mail support@biolytelabs.com, Monday C Friday 7:30 am C 3:30 pm EST. Consumers should contact their physician or healthcare provider if they believe 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.

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

Pharm D Solutions, LLC Issues Voluntary Nationwide Recall of all Sterile Compounded Drugs Due to A Potential Lack of Sterility Assurance

[Posted 09/10/2018]

Pharm D Solutions, LLC is voluntarily recalling all sterile compounded drug products within expiry to the clinic, physician or consumer level. These drug products are being voluntarily recalled due to concerns that practices at the pharmacy have the potential to pose a risk of contamination to products that are intended to be sterile. These concerns arose following a routine inspection of the pharmacy by FDA.

Administration of a non-sterile product that is intended to be sterile by subcutaneous, intramuscular, intravenous or ocular routes of administration may result in serious injury or death. The pharmacy has not received any reports of patient complaints or adverse events related to this recall. To date, Pharm D

Solutions, LLC is not aware of any adverse events related to this recall. Nor is there any indication that the compounded sterile drug products being recalled are actually contaminated. No medications or any component thereof have been shown to be non-sterile. This voluntary recall is being conducted out of an abundance of caution and to promote patient safety, which is the pharmacy's highest priority.

The recall encompasses all compounded sterile drug products, within expiry, that were dispensed within the last twelve months. The sterile drug products subject to this recall were distributed nationwide and directly to customers and/or medical facilities. The recall does not affect the pharmacy's non-sterile compounded products or retail pharmacy operations.

The pharmacy has notified potentially affected customers of the voluntary recall via U.S. Mail and direct outreach. Customers who have received sterile compounded products subject to the voluntary recall should stop using and return the product to the pharmacy for a full refund.

Consumers with questions regarding this recall can contact Pharm D Solutions, LLC by calling Luis R DeLeon or Carlos DeLeon at 713-790-1693, Monday through Friday between 9:00 a.m. and 5:00 p.m., CST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products.
Adverse reactions or quality problems experienced with the use of these products 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: http://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)

FDA announces voluntary recall of Montelukast tablets by Camber Pharmaceuticals due to incorrect drug in bottles

[Posted 08/31/2018]

The U.S. Food and Drug Administration is warning consumers and health care professionals about a voluntary recall of one lot of Montelukast Sodium Tablets – lot number MON17384, expiration 12/31/2019 – by Camber Pharmaceuticals, Inc., Piscataway, N.J. Sealed bottles labeled as montelukast sodium tablets, 10 milligram, 30-count bottle from Camber were found to instead contain 90 tablets of Losartan Potassium Tablets, 50 mg.

This tablet mix-up may pose a safety risk as taking losartan tablets when not prescribed has the potential to cause renal dysfunction, elevated potassium levels and low blood pressure. This risk is especially high for pregnant women taking the allergy and asthma medication montelukast because losartan, which is indicated to treat high blood pressure, could harm or kill the fetus. The FDA recommends that consumers who have this recalled product should contact their health care provider or pharmacist immediately.

This recall is not related to the recent valsartan recalls that were due to an impurity, N-nitrosodimethylamine (NDMA).

“We want to ensure that patients who take montelukast are aware of this recall due to the serious risks associated with taking losartan in its place,” said Donald D. Ashley J.D., director of the office of compliance in the FDA’s center for drug evaluation and research. “Patients who take prescription drugs expect and deserve to have the medication their doctor prescribed.”

Montelukast is used to prevent wheezing, difficulty breathing, chest tightness and coughing caused by asthma. It is also used to prevent bronchospasm (breathing difficulties) during exercise and to treat the symptoms of seasonal and perennial allergic rhinitis. Montelukast is in a class of medications called leukotriene receptor antagonists (LTRAs) which work by blocking the action of substances in the body that cause the symptoms of asthma and allergic rhinitis.

Losartan is often used alone or in combination with other medications to treat high blood pressure. Losartan is also used to decrease the risk of stroke in people who have high blood pressure and a heart condition called left ventricular hypertrophy (enlargement of the walls of the left side of the heart).

Patients should contact their health care provider or pharmacist to determine if their medicine has been recalled. Patients should also look at the drug name and company name on the label of their prescription bottle. If the information is not on the bottle, patients should contact the pharmacy that dispensed the medicine.

Montelukast sodium tablets are beige, rounded square-shaped, film coated tablets that are imprinted with “I” on one side and “114” on the reverse. Losartan tablets are white and oval-shaped with the letter “I” imprinted on one side and the number “5” imprinted on the reverse.
Recalled lots of montelukast sodium tablets, USP 10mg have the following information:

- Label: Montelukast Sodium Tablets 10 mg 30 ct
- Lot number: MON17384
- Expiration date: 12/31/2019
- NDC: 31722-726-30

To date, Camber has not received adverse event reports associated with this recall. The FDA encourages health care professionals and consumers to report adverse events to the FDA’s MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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

SGLT2 (sodium-glucose cotransporter-2) Inhibitors for Diabetes: Drug Safety Communication - Regarding Rare Occurrences of a Serious Infection of the Genital Area

[Posted 08/29/2018]

ISSUE: FDA is warning that cases of a rare but serious infection of the genitals and area around the genitals have been reported with the class of type 2 diabetes medicines called sodium-glucose cotransporter-2 (SGLT2) inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. We are requiring a new warning about this risk to be added to the prescribing information of all SGLT2 inhibitors and to the patient Medication Guide.

BACKGROUND: SGLT2 inhibitors are FDA-approved for use with diet and exercise to lower blood sugar in adults with type 2 diabetes. SGLT2 inhibitors lower blood sugar by causing the kidneys to remove sugar from the body through the urine. First approved in 2013, medicines in the SGLT2 inhibitor class include canagliflozin, dapagliflozin, empagliflozin, and ertugliflozin (see FDA-Approved SGLT2 Inhibitors). In addition, empagliflozin is approved to lower the risk of death from heart attack and stroke in adults with type 2 diabetes and heart disease. Untreated, type 2 diabetes can lead to serious problems, including blindness, nerve and kidney damage, and heart disease.

RECOMMENDATION: To read all of the recommendations see the Drug Safety Communication.

Patients should:

- Seek medical attention immediately if you experience any symptoms of tenderness, redness, or swelling of the genitals or the area from the genitals back to the rectum, and have a fever above 100.4 F or a general feeling of being unwell. These symptoms can worsen quickly, so it is important to seek treatment right away.
- Read the patient Medication Guide every time you receive a prescription for an SGLT2 inhibitor because there may be new or important additional information about your drug. The Medication Guide explains the benefits and risks associated with the medicine Health care professionals should:
- Assess patients for Fournier's gangrene if they present with the symptoms described above. If suspected, start treatment immediately with broad-spectrum antibiotics and surgical debridement if necessary.
- Discontinue the SGLT2 inhibitor, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control.

Health care 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)

Accord Healthcare Inc. Issues Voluntary Nationwide Recall of Hydrochlorothiazide Tablets USP 12.5 Mg Due to Labeling Mix-up

[Posted 08/28/2018]

Accord Healthcare Inc. is voluntarily recalling One lot (Lot PW05264 – 46632 Bottles, NDC 16729-182-01) of Hydrochlorothiazide Tablets USP, 12.5 mg, to the consumer level.

A 100 count bottle of Hydrochlorothiazide Tablets USP 12.5 mg has been found to contain 100 Spironolactone Tablets USP 25 mg. Since the individual lot, PW05264, of the product is involved in a potential mix-up of labeling, Accord is recalling this individual lot from the market. Based on findings of both preliminary and interim investigations carried out at the manufacturing site, Accord believes that no other lots of Hydrochlorothiazide Tablets are involved in this mix-up. Accord became aware of this finding through a product complaint reported from a pharmacy.

Spironolactone tablets are indicated in the management of primary hyperaldosteronism, edematous conditions for patients with congestive heart failure, cirrhosis of the liver accompanied by edema and/or ascites, nephrotic syndrome, essential hypertension, hypokalemia, severe heart failure. Use of spironolactone tablets instead of hydrochlorothiazide tablets, poses the risk of contracting hyperkalemia (increase potassium levels) in certain individuals resulting in adverse events that range from limited health consequences to life-threatening situations in certain individuals. To date, Accord has not received any reports of adverse events related to this recall.

Hydrochlorothiazide tablets are indicated in the management of hypertension either as the sole therapeutic agent or to enhance the effectiveness of other antihypertensive drugs in the more severe forms of hypertension.

Accord's Hydrochlorothiazide Tablets USP 12.5 mg are light orange to peach colored, round, biconvex tablets debossed with H on one side and 1 on another side. An image of this product is below, if you are unable to view the image, please click this link:

If you are in possession of Accord Hydrochlorothiazide that does not match this image or if you are unsure, please return to your pharmacy or healthcare provider for confirmation.

Accord is notifying its Wholesalers, Distributors and Retailers by letter and is arranging for return of all recalled products. Wholesalers, Distributors, and Retailers that have product which is being recalled should discontinue distribution of the product and notify consumers. Consumers that have the product should return the product to the pharmacy.

Consumers/Pharmacies with questions regarding this recall can contact Accord Healthcare, Inc. by phone at 1-855-869-1081, fax: 1-817-868-5362 or e-mail at rxrecalls@inmar.com Monday to

Friday during business hours 8 am to 5 pm EST. 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)

Pfizer, Inc. Issues A Voluntary Nationwide Recall Of One Lot Of Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle

[Posted 08/27/2018]

Pfizer Consumer Healthcare, a division of Pfizer Inc., is voluntarily recalling one lot of Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle because of customer complaints that the dosage cup provided is marked in teaspoons and the instructions on the label are described in milliliters (mL).

Pfizer concluded that the use of the product with an unmatched dosage cup marked in teaspoons rather than milliliters has a chance of being associated with potential overdose. The most common symptoms associated with ibuprofen overdose include nausea, vomiting, headache, drowsiness, blurred vision and dizziness.

Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle temporarily reduces fever, relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches.

Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle, NDC 0573-0207-30, lot R51129 was distributed nationwide to wholesalers, distributors and retailers in the United States from May 2018 through June 2018.

Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle Lot and Packaging Information

- NDC: 0573-0207-30
- Lot Number: R51129
- Expiration Date: 11/20
- SKU: F005730207300
- UPC: 3-0573-0207-30-0
- Configuration/Count: 4 FL OZ (120 mL) Bottle, 36 bottles/case

Pfizer, Inc. places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process.

Pfizer, Inc. has notified wholesalers, distributors and retailers to arrange for return of any recalled product. Wholesalers, distributors and retailers with an existing inventory of the lot being recalled, should stop use and distribution and quarantine the product immediately. Wholesalers, distributors and retailers that have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product from them. For instructions on returning product or additional assistance, call Stericycle at 1-800-805-3093 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

If consumers have questions regarding this recall or to report an adverse event, please contact the Pfizer Consumer Healthcare Information Line at 1-800-88-Advil (1-800-882-3845). Their hours of operation are Mon-Fri, 9am-5pm EST.

Consumers should contact their 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 executed with the knowledge of the U.S. Food and Drug Administration.

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

STUDIES AND RECENT TOPICS

Esbriet Enables Stable Lung Function Over 2 Years in IPF Patients, Real-World Study Confirms

September 19, 2018

Treatment of idiopathic pulmonary fibrosis (IPF) with Esbriet (pirfenidone) leads to stable lung function over two years, according to a real-world study. The data matches previous results from Phase 3 trials.

The research, “Functional decline over time in patients with IPF treated with pirfenidone: the PROOF registry,” was presented at the European Respiratory Society (ERS) International Congress 2018, held in Paris, France, Sept. 15-19.

Source: pulmonaryfibrosisnews.com

Why Eczema Is Tougher to Treat for Black Patients

September 19, 2018

Eczema, or atopic dermatitis, can be very difficult to control in some people.

But the skin condition, which leads to dry, itchy and inflamed skin, is particularly problematic for black people, according to new research.

Source: healthday.com

A Simplified Dose Schedule of Cetuximab as a Maintenance Therapy in Head and Neck Cancer May Reduce Drug Toxicities

September 14, 2018

Researchers found that a reduction from weekly to biweekly administration in the maintenance dose schedule for cetuximab reduced the number of toxicities patients experienced during the study period. As a result, they said, this type of reduction could increase patient compliance to the medication and patient quality of life (QoL).

Source: cancertherapyadvisor.com

FDA finds another impurity in recalled heart drug

September 14, 2018

The US Food and Drug Administration said it found an additional "unexpected impurity" in three lots of Torrent Pharmaceuticals' recalled valsartan drug.

Several pills that contain valsartan, a generic ingredient that helps people with high blood pressure and heart failure, have been under a voluntary recall since July. The drugs were tainted with N-nitrosodimethylamine, or NDMA, an impurity that is considered a possible carcinogen by the US Environmental Protection Agency. It's an organic chemical used to make liquid rocket fuel and a byproduct from manufacturing some pesticides and processing fish. NDMA can be unintentionally introduced into manufacturing through certain chemical reactions.

Source: cnn.com

Montelukast Plus Budesonide Effective for Cough Variant Asthma
September 12, 2018

The combination of montelukast and budesonide was found more effective than budesonide alone in children with chronic cough variant asthma (CCVA), in a recent retrospective study conducted in China. The condition is a very common subtype of bronchial asthma in children, according to Jin-fang Zhou, MB, Department of Pediatrics, Yan'an People's Hospital, Yan'an, China, and colleagues. As a possible precursor of asthma, early intervention with anti-inflammatory agents has been utilized.

Source: mdmag.com

Rituximab Maintenance Improved Long-Term Survival in Elderly With Follicular Lymphoma
September 11, 2018

Rituximab maintenance therapy is feasible and leads to good survival rates among elderly patients with follicular lymphoma (FL), according to a study published in Leukemia Research.

Although FL is an incurable disease, patients achieve good rates of progression-free survival (PFS) and overall survival (OS) after standard-care rituximab-based chemotherapy (R-CHEMO), and particularly when maintained with rituximab maintenance (RM). The effect of RM particularly among the elderly — older than 65 years — however, has not been adequately investigated.

Source: oncologynurseadvisor.com

Bayer adds label warning after death linked to stomach relief drops
September 12, 2018

German drug maker will add a warning of rare cases of liver damage to the label of prescription-free stomach relief drops Iberogast after Germany's drugs regulator said a death was linked to the product.

Drug safety watchdog BfArM said Bayer had dropped a legal challenge against a stricter warning after fresh reports of liver damage in users of the drops, including one patient who died after receiving a liver transplant.

Source: reuters.com

FDA takes new steps to address epidemic of youth e-cigarette use, including a historic action against more than 1,300 retailers and 5 major manufacturers for their roles perpetuating youth access
September 12, 2018

The U.S. Food and Drug Administration today announced a series of critical and historic enforcement actions related to the sale and marketing of e-cigarettes to kids. In the largest coordinated enforcement effort in the FDA's history, the agency issued more than 1,300 warning letters and civil money penalty complaints (fines) to retailers who illegally sold JUUL and other e-cigarette products to minors during a nationwide, undercover blitz of brick-and-mortar and online stores this summer. As a result of these violations of the law C and other indications that e-cigarette use among youth has hit epidemic

proportions C FDA Commissioner Scott Gottlieb, M.D., signaled that the agency intends to take new and significant steps to address this challenge in a speech at the agency's headquarters.

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

FDA panel to discuss Celltrion biosimilar

September 11, 2018

FDA's Oncologic Drugs Advisory Committee will meet on Oct. 10 to review a resubmitted BLA for CT-P10 from Celltrion Inc. (KRX:068270), the company's biosimilar of Rituxan/MabThera rituximab.
Celltrion resubmitted the BLA in May, two months after it received complete response letters for CT-P10 and CT-P6, its biosimilar of Herceptin trastuzumab. Celltrion said at the time the letters were "directly related" to FDA's January warning letter describing GMP violations observed during a visit to Celltrion's manufacturing facility (see "FDA Issues CRLs for Celltrion Biosimilars").

Source: biocentury.com

Telavancin: Promising Treatment Option for MRSA in Cystic Fibrosis Patients?

September 10, 2018

Methicillin-resistant Staphylococcus aureus continues to plague patients in the health care and community setting, as well as the providers who treat them. When acquired in patients with cystic fibrosis, clinical outcomes are known to be even worse, resulting in an increased rate of declined respiratory function as well as infections that can have severe, and sometimes deadly, consequences.

Source: raredr.com

Rituximab-Based Immunotherapy May Be As Effective as Chemotherapy in Follicular Lymphoma

September 10, 2018

Rituximab plus lenalidomide may be as effective as rituximab plus chemotherapy among patients with previously untreated advanced follicular lymphoma (FL), according to a study published in The New England Journal of Medicine.

Source: cancertherapyadvisor.com

Fluoxetine And Antibiotic Resistance: Key Ingredient In Antidepressants Linked To Rise Of Superbugs

September 10, 2018

An ingredient in many commonly used antidepressants could be helping bacteria to develop resistance to antibiotics, according to a study published in the journal Environment International.
Antibiotic resistance is one of the biggest threats to global health, food security and development in the world today. Most significantly, it has led to the rise of "superbugs," or strains of bacteria which are resistant to several treatments.

Source: newsweek.com

Tiotropium Associated With Increased Cardiovascular Risk in COPD
September 10, 2018

The combination of tiotropium and inhaled long-acting β2 agonists/inhaled corticosteroids in chronic obstructive pulmonary disease (COPD) is correlated with a 2-fold increase of cardiovascular risk, according to a study published in Mayo Clinic Proceedings. This risk was greatest in the period between 1 and 2 months after the start of inhalation therapy.

Source: pulmonologyadvisor.com

Antidepressant Use During Pregnancy Doubles Risk of Persistent PH in Newborns, Study Suggests
September 10, 2018

Use of antidepressants during pregnancy doubles the risk for persistent pulmonary hypertension in the newborn (PPHN), a systematic review of several studies suggests.
Out of the antidepressants analyzed, researchers proposed sertraline (brand name Zoloft, marketed by Pfizer) as the best choice for use during pregnancy as it was seen to carry the lowest risk of pulmonary hypertension to infants.

Source: pulmonaryhypertensionnews.com

1 in 4 Seniors Who Take Xanax, Valium Use Them Long Term
September 10, 2018

When older people use drugs like Valium or Xanax to calm anxiety or help them sleep, they run a high risk of becoming drug-dependent, new research suggests.
In the study of almost 600 adults averaging 78 years of age, about one in four who were prescribed these types of benzodiazepine sedatives ended up using them for at least a year.

Source: healthday.com

Mepolizumab Use in Patients with Severe Eosinophilic Asthma: Real-World Experience
August 30,2018

In one practitioner's experience, adding mepolizumab (Nucala, GlaxoSmithKline) to the treatment regimens of patients with severe eosinophilic asthma in his practice resulted in improved symptoms and quality of life, similar to those reported in controlled clinical trials with screened participants.
Source: mdmag.com

FDA Announces New Approach To Pain Drugs
August 29, 2018

FDA announced Wednesday new approaches to developing analgesic drugs, including encouraging the development of drugs that reduce the use of opioids and long-acting local analgesics that could replace oral opioids.
The agency is withdrawing a 2014 guidance on developing drugs for analgesic indications, and will replace it with at least four new guidance documents, FDA Commissioner Scott Gottlieb said in a statement.

Source: biocentury.com

MMJ International Asks FDA to Approve Studies of Cannabis-based Therapies
August 28, 2018

MMJ International has filed two applications with the U.S. Food and Drug Administration (FDA) requesting permission to begin clinical studies testing its pharmaceutical grade cannabis-based therapies in easing symptoms associated with multiple sclerosis and Huntington's disease.
Source: multiplesclerosisnewstoday.com

Death Rates From Heart Disease And Stroke Could Be Significantly Less With These Drugs, Study Says
August 27, 2018

Findings of a long-term study of more than 8,500 people in the U.K. has found evidence that blood pressure and cholesterol-lowering drugs work to improve survival rates of their users after a decade of treatment.
Source: forbes.com

FDA proposes restricting compounding of three drug substances
August 27, 2018

The U.S. Food and Drug Administration on Monday proposed excluding three substances from a list of ingredients that could be used to manufacture compounded medications in bulk for use by hospitals and doctors' offices.
Source: reuters.com

FDA Plan to Combat Fraud by Compounders Would Boost Patient Safety
August 24, 2018

The Food and Drug Administration says it will take a multipronged approach to combating drug compounding fraud.
The Food and Drug Administration this summer announced steps the agency will take to curb fraud and other abuses by drug compounders, makers of specialized medicines that have not been approved by FDA. For example, the agency will now look for evidence of inappropriate practices when inspecting facilities and provide information on drugs that are part of some fraud schemes. Progress in these efforts would not only rein in costs but also boost patient safety.

Source: pewtrusts.org

RECALLS

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drug	Compulsin, Homeopathic (OTC Medicine), 2 fl oz (59 mL) per bottle, Mftd for: HelloLife, Inc. 4635 40th St SE, Grand Rapids, MI 49512. NDC: 49726-034-02	Class I	Lot: CO/030717B, exp 7/2019	Microbial Contamination of Non Sterile Products; Products contaminated with microorganisms, including but not limited to Staphylococcus saprophyticus and Burkholderia cepacia	Hellolife
Drug	Neuroveen, Homeopathic (OTC Medicine), 2 fl oz (59 mL) per bottle, Mftd for: HelloLife, Inc. 4635 40th St SE, Grand Rapids, MI 49512. NDC: 49726-015-02	Class I	Lot: NV/030717D, exp 7/2019	Microbial Contamination of Non Sterile Products; Products contaminated with microorganisms, including but not limited to Staphylococcus saprophyticus and Burkholderia cepacia	Hellolife
Drug	Thyroveev, Homeopathic (OTC Medicine), 2 fl oz (59 mL) per bottle, Mftd for: HelloLife, Inc. 4635 40th St SE, Grand Rapids, MI 49512. NDC: 49726-025-02	Class I	Lot: TV/030717F, exp 7/2019	Microbial Contamination of Non Sterile Products; Products contaminated with microorganisms, including but not limited to Staphylococcus saprophyticus and Burkholderia cepacia	Hellolife
Drug	Respitrol, Homeopathic (OTC Medicine), 2 fl oz (59 mL) per bottle, Mftd for: HelloLife, Inc. 4635 40th St SE, Grand Rapids, MI 49512. NDC: 49726-003-02	Class I	Lot: RE/030717E, exp 7/2019	Microbial Contamination of Non Sterile Products; Products contaminated with microorganisms, including but not limited to Staphylococcus saprophyticus and Burkholderia cepacia	Hellolife

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drug	Furosemide 100 mg added to 0.9% Sodium Chloride 100 mL Injection, 100 mL Single Dose Container bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct., Little Rock, AR 72205, 877.550.5059, barcode 70004063032.	Class I	Lots: 20180711@18, BUD: 10/3/2018; 20180712@19, 20180712@21, 20180712@24 BUD: 10/4/2018; 20180713@19, BUD: 10/5/2018; 20180727@21, BUD: 10/19/2018; 20180803@20, BUD: 10/26/2018	Presence of Precipitate: Customer complaint for visible precipitate in product believed to be the active ingredient furosemide	SCA Pharmaceuticals
Drugs	Human Chorionic Gonadotropin 5000 IU Vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009	Class II	Lots: HCG50319 Exp. 4/30/2019; HCG50316 Exp. 3/31/2019; HCG50317 Exp. 4/30/2019; HCG50315 Exp. 3/31/2019; HCG50318 Exp. 4/30/2019; HCG50320 Exp. 4/30/2019; HCG50321 Exp. 4/30/2019; HCG50311 Exp. 3/31/2019;	Lack of assurance of sterility.	Pharmcore Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			HCG50310 Exp. 3/31/2019; HCG50309 Exp. 3/31/2019; HCG50313 Exp. 3/31/2019; HCG50314 Exp. 3/31/2019		
Drugs	Human Chorionic Gonadotropin 11000 IU Vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009	Class II	Lots: HCG1116 Exp. 3/31/2019; HCG1117 Exp. 4/30/2019	Lack of assurance of sterility.	Pharmcore Inc.
Drugs	Human Chorionic Gonadotropin 20000 IU Vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009	Class II	Lots: HCG22038 Exp. 3/31/2019; HCG22039 Exp. 4/30/2019	Lack of assurance of sterility.	Pharmcore Inc.
Drugs	Human Chorionic Gonadotropin 2500 IU Vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009	Class II	Lots: HCG25112 Exp. 2/28/2019; HCG25110 Exp. 1/31/2019; HCG25115 Exp. 4/30/2019; HCG25114 Exp. 4/30/2019; HCG25111 Exp. 2/28/2019	Lack of assurance of sterility.	Pharmcore Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Human Chorionic Gonadotropin 4000 IU Vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009	Class II	Lots: HCG40160 Exp. 2/28/2019; HCG40161 Exp. 4/30/2019; HCG40159 Exp. 2/28/2019; HCG40162 Exp. 4/30/2019; HCG50308 Exp. 2/28/2019	Lack of assurance of sterility.	Pharmcore Inc.
Drugs	Human Chorionic Gonadotropin 6000 IU Vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009	Class II	Lots: HCG60122 Exp. 4/30/2019; HCG60124 Exp. 6/30/2019; HCG60121 Exp. 4/30/2019; HCG60123 Exp. 5/31/2019; HCG60120 Exp. 4/30/2019; HCG60118 Exp. 2/28/2019; HCG1115 Exp. 1/31/2019	Lack of assurance of sterility.	Pharmcore Inc.
Drugs	Ipamorelin 3 mg Lyophilized 1 vial 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009	Class II	Lot: IPA3-17 Exp. 07/2018	Lack of assurance of sterility.	Pharmcore Inc

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Methylcobalamin 10 mg vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009	Class II	Lots: MTLY-19 Exp. 10/31/2018; MTLY-18 Exp. 8/31/2018	Lack of assurance of sterility.	Pharmcore Inc.
Drugs	Doxycycline Hyclate USP Tablets, 100 mg packaged in a) 2-count bottles, NDC 55289-866-02; b) 6-count bottles, NDC 55289-866-06; c) 7-count bottles, NDC 55289-866-07; d) 10-count bottles, NDC 55289-866-10; e) 14-count bottles, NDC 55289-866-14; f) 20-count bottles, NDC 55289-866-20; g) 28-count bottles, NDC 55289-866-28; h) 30-count bottles, NDC 55289-866-30; i) 120-count bottles, NDC 55289-866-98; j) 300-count bottles, NDC 55289-866-87; k) 400-count bottles, NDC 55289-866-74; Rx only, Packaged By PD-Rx Pharmaceuticals, Oklahoma City, OK 73127	Class II	Lot #: a) D17D29, L17C73, F18E73, Exp. 1/31/19; b) H17D70, K17F66, G18F26, Exp. 1/31/19; c) C18G26, F18E36, Exp. 1/31/19; d) F18A85, Exp. 1/31/19; e) K17B44, K17E29, L17D93, Exp. 1/31/19; E17B88, Exp. 5/31/19; H17A52, H17D67, Exp. 7/31/19; f) E17B01, E17E83, Exp. 5/31/19; F17C99, Exp. 6/30/19; G17C08, G17E18, H17B01,	Failed Dissolution Specifications: manufacturer West-Ward Pharm Corp. recalled these repackaged lots due to failed dissolution results.	PD-Rx Pharmaceuticals, Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			H17B66, H17F67, I17A56, Exp. 7/31/19; g) E17E27, Exp. 1/31/19, I17A33, G17D62, Exp. 7/31/19; h) E17B35, E17D90, Exp. 5/31/19, F17C13, Exp. 6/30/19, G17B25, H17C58, Exp. 7/31/19; i) G17D59, Exp. 7/31/19; j) I17A69, G17D58, Exp. 7/31/19; k) G17D56, Exp. 7/31/19		
Drugs	Ipamorelin 9 mg vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009	Class II	Lots: IPA9-15 Exp. 3/31/2019; IPA9-14 Exp. 1/31/2019	Lack of assurance of sterility.	Pharmcore Inc
Drugs	Valsartan Tablets, USP 40 mg Rx Only NDC 50268-783-15 50 Tablets (5x10) Unit Dose Manufactured for: AvKARE, Inc.	Class II	Lots: 18491 Exp. 10/2018; 19531 Exp. 04/2019; 20168 Exp. 05/2019;	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	AVKARE Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Pulaski, TN 38478		20671 Exp. 08/2019; 21049 Exp. 10/2019; 21635 Exp. 10/2019		
Drugs	Valsartan Tablets, USP 80 mg Rx Only 50 Tablets (5x10) Unit Dose NDC 50268-784-15 Manufactured for: AvKARE, Inc. Pulaski, TN 38478	Class II	Lots: 18492 Exp. 11/2018; 20169 Exp. 05/2019	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product	AVKARE Inc.
Drugs	Valsartan Tablets, USP 160 mg Rx Only 50 Tablets (5x10) Unit Dose NDC 50268-785-15 Manufactured for: AvKARE, Inc. Pulaski, TN 38478	Class II	Lots: 17717 Exp. 07/2018; 18493 Exp. 01/2019; 19761 Exp. 04/2019	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product	AVKARE Inc.
Drugs	Valsartan Tablets, USP 320 mg Rx Only 30 Tablets (6x5) Unit Dose NDC 50268-786-13 Manufactured for: AvKARE, Inc. Pulaski, TN 38478	Class II	Lots: 17718 Exp. 07/2018; 18700 Exp. 01/2019; 19133 Exp. 02/2019; 19532 Exp. 04/2019	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	AVKARE Inc.
Drugs	Valsartan Tablets USP, 80mg, 90 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-068-90	Class II	Batch: BV46C007, BV46C008, BV46C009, BV46C010, BV46C011, BV46C012, BV46C003, BV46C006	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Torrent Pharma Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Valsartan Tablets USP, 160mg, 90 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-069-90	Class II	Batch: BV47C005, BV47C006, BV47D001, BV47C003, BV47C004	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Torrent Pharma Inc.
Drugs	Valsartan Tablets USP, 320mg, 90 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-070-90	Class II	Batch: BV48D001, BV48D002	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Torrent Pharma Inc.
Drugs	Amlodipine and Valsartan Tablets, USP, 10 mg/320 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-204-30	Class II	Batch: BV77D013, BV77C011, BV77D001, BV77D002, BV77D003, BV77D004, BV77D005, BV77D006, BV77D007, BV77D008, BV77D009 , BV77D010, BV77D011, BV77D012, BV77C009, BV77C010	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Torrent Pharma Inc.
Drugs	Children s Advil Suspension Ibuprofen Oral Suspension, 100 mg per 5mL, 4 FL OZ (120 ml) bottle, Pfizer, Madison, NJ	Class II	Lot #: R51129, Exp. 11/20	Labeling Error: Not elsewhere classified. product has a dosage cup marked in teaspoons and the instructions on the label are described in milliliters.	Pfizer Global Supply

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	07940 USA, NDC 0573-0207-30, UPC 3-0573-0207-30-0				
Drugs	0.9% Sodium Chloride Injection USP 100 mL bags, Rx only, Baxter Healthcare Corporation Deerfield, IL 60015 USA, NDC 0338-0049-18	Class II	Lot #: P380287, Exp. date 12/2019	CGMP Deviations	Baxter Healthcare Corporation
Drugs	CoEnzyme-Q10 injectable, 20 mg/mL, 10 mL Multiple Dose vial, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631	Class II	Lot #: 180626/3, Exp 25-Aug-18	Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.	Auro Pharmacies, Inc
Drugs	Amlodipine/Valsartan/HCTZ 10mg/320mg/25 mg Tablet, Rx Only (HDPE 90cc Bottles in cardboard trays) MFG Torrent Pharma LTD, Indrad, India 38272, NDC #70518-1220-0	Class II	70518-1220-0; Lot #: B0476653-080218; Exp. Date: 08/2019	CGMP Deviations: Detection of trace amounts of NDMA, a possible impurity or contaminant in an active pharmaceutical ingredient.	RemedyRepack Inc.
Drugs	Amlodipine and Valsartan Tablets, USP, 5 mg/320 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC:	Class II	Batch: BV84D010, BV84E001, BV84C011, BV84D001, BV84D002, BV84D005, BV84D006, BV84D007, BV84D008,	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Torrent Pharma Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	13668-205-30		BV84D009, BV84C006, BV84C007, BV84C008, BV84C009		
Drugs	Amlodipine and Valsartan Tablets, USP, 10 mg/160mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-206-30	Class II	Batch: BV65D002, BV65C002, BV65C003, BV65C004, BV65D001	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Torrent Pharma Inc.
Drugs	Amlodipine and Valsartan Tablets, USP, 5 mg/160 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-207-30	Class II	Batch: BV53D004, BV53C006, BV53D001, BV53D002, BV53D003, BV53C004, BV53C005	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Torrent Pharma Inc.
Drugs	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP, 10 mg/320 mg/25 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-325-30	Class II	Batch: BBX2D025, BBX2D026, BBX2E001, BBX2E002, BBX2E003, BBX2E004, BBX2E005, BBX2D003, BBX2D004, BBX2D005, BBX2D006, BBX2D007, BBX2D008, BBX2D015, BBX2D016, BBX2D017,	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Torrent Pharma Inc

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			BBX2D018, BBX2D019, BBX2D020, BBX2D021, BBX2D022, BBX2D023, BBX2D024, BBX2D001, BBX2D002, BBX2D009, BBX2D010, BBX2D011, BBX2D012, BBX2D013, BBX2D014, BBX2C007		
Drugs	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP, 5 mg/160 mg/12.5 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-326-30	Class II	Batch: BBY1E001, BBY1E003, BBY1C002, BBY1E002, BBY1D001	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Torrent Pharma Inc
Drugs	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP, 10 mg/160 mg/25 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-328-30	Class II	Batch: BBX9D004, BBX9E001, BBX9D001, BBX9D002, BBX9D003	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Torrent Pharma Inc

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP, 5 mg/160 mg/25 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-329-30	Class II	Batch: BBY4D004, BBY4E001, BBY4D001, BBY4D002, BBY4D003	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Torrent Pharma Inc
Drugs	Calcium Gluconate injectable, 10%, 50 ml Single Dose vial, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631	Class II	Lot #: 180626/10, Exp 24-Sep-18	Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.	Auro Pharmacies, Inc
Drugs	Dexpanthenol injectable, 250 mg/mL, 10 mL Single Dose vial, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631	Class II	Lot #: 180529/2, Exp 27-Aug-18 and 180620/11, Exp 18-Sep-18	Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.	Auro Pharmacies, Inc
Drugs	Glutathione injectable, 200 mg/mL, 30 mL Multiple Dose vial, Rx only, Central Drugs Compounding	Class II	Lot #: 180716/21, Exp 14-Oct-18	Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.	Auro Pharmacies, Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631				
Drugs	Methyl-Cobalamin injectable, 1 mg/mL, packaged in a) 5 mL and b) 30 mL Multiple Dose vials, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631	Class II	Lot #: a) 180618/2, Exp 16-Sep-18; b) 180618/2, Exp 16-Sep-18	Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.	Auro Pharmacies, Inc.
Drugs	Methyl-Cobalamin injectable, 5 mg/mL, 30 mL Multiple Dose vial, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631	Class II	Lot #: 180618/3, Exp 16-Sep-18	Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.	Auro Pharmacies, Inc.
Drugs	Methyl-Cobalamin injectable, 10 mg/mL, 30 mL Multiple Dose vial, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631	Class II	Lot #: 180702/1, Exp 30-Sep-18	Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.	Auro Pharmacies, Inc.
Drugs	Testosterone Cypionate/Enanthate injectable, 126/54 mg/mL, packaged in a) 3 mL and b) 5 mL Multiple Dose vials, Rx only,	Class II	Lot #: 180709/21, Exp 07-Sep-18	Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile	Auro Pharmacies, Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631				
Drugs	Testosterone Cypionate/Enanthate injectable, 200/50 mg/mL, packaged in a) 5 mL and 8 mL Multiple Dose vials, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631	Class II	Lot #: 180606/18, Exp 30-Nov-18	Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.	Auro Pharmacies, Inc.
Drugs	Testosterone Enanthate/Cypionate injectable, 126/54 mg/mL, packaged in a) 3 mL and b) 5 mL Multiple Dose vials, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631	Class II	Lot #: 180709/24, Exp 07-Sep-18	Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.	Auro Pharmacies, Inc.
Drugs	Folic Acid injectable, 10 mg/ml, 30 ml Multiple Dose vial, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631	Class II	Lot #: 180611/1, Exp 09-Sep-18	Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.	Auro Pharmacies, Inc.
Drugs	Methyl-Cobalamin injectable, 2 mg/mL, 30 ml Multiple Dose vial,	Class II	Lot #: 180620/2, Exp 18-Sep-18	Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to	Auro Pharmacies, Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631			be sterile.	
Drug	Megestrol Acetate Oral Suspension, USP 400 mg/mL, 10 mL (10 mL UD cups in boxes of 20 cups), Rx Only, Mfg. By: Par Pharmaceutical One Ram Ridge Rd Chestnut Ridge, NY 10977 Dist. By: McKesson Packaging Services a business unit of McKesson Corporation 7101 Weddington Rd. Concord, NC 28027, NDC63739-549-51	Class II	Lot #: 0116158 Exp. 4/30/19; 0113903, 0113902, 0113901, Exp. 8/31/18	Superpotent Drug	McKesson Corporation
Drug	Ethosuximide Capsules, USP, 250 mg, 100 capsules per bottle, Rx only, Mfg For VersaPharm Incorporated, Maroerre, GA 30062. Mfg By: Swiss Caps AG, Kirchberg, Switzerland. NDC: 61748-025-01	Class II	Lots: 1165280100, 1165280101, EXP 3/2019	Failed Impurities/Degradation Specifications: Out of specification (OOS) results for unspecified impurity.	Akorn, Inc.
Drug	AvKARE Valsartan and Hydrochlorothiazide 80 mg/12.5 mg tablets, 90-count	Class II	Lots: 17349 Exp. 08/2018; 18395 Exp. 08/2018;	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Avkare Incorporated

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	bottle, Rx Only, Manufactured for: AvKARE, Inc. Pulaski, TN 38478, NDC 42291-884-90		19221 Exp. 06/2019; 20029 Exp. 06/2019; 20158 Exp. 07/2019; 20843 Exp. 07/2019; 21411 Exp. 09/2019.		
Drug	AvKARE Valsartan and Hydrochlorothiazide 160 mg/12.5 mg tablets, 90-count bottle, Rx Only, Manufactured for: AvKARE, Inc. Pulaski, TN 38478, NDC 42291-885-90	Class II	Lots: 17325 Exp. 09/2018; 17856 Exp. 09/2018; 18396 Exp. 09/2018; 18702 Exp. 02/2019; 19020 Exp. 02/2019; 19222 Exp. 02/2019; 20030 Exp. 04/2019; 20381 Exp. 04/2019	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Avkare Incorporated
Drug	AvKARE Valsartan and Hydrochlorothiazide 160 mg/25 mg tablets, 90-count bottle, Rx Only, Manufactured for: AvKARE, Inc. Pulaski, TN 38478, NDC 42291-887-90	Class II	Lots: 17325 Exp. 09/2018; 17856 Exp. 09/2018; 18396 Exp. 09/2018; 18702 Exp. 02/2019; 19020 Exp. 02/2019; 19222 Exp. 02/2019; 20030 Exp. 04/2019; 20381 Exp. 04/2019	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Avkare Incorporated

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drug	AvKARE Valsartan and Hydrochlorothiazide 320 mg/12.5 mg tablets, 90-count bottle, Rx Only, Manufactured for: AvKARE, Inc. Pulaski, TN 38478, NDC 42291-886-90	Class II	Lots: 17780 Exp. 09/2018; 18029 Exp. 09/2018; 18398 Exp. 09/2018; 18723 Exp. 09/2018; 19017 Exp. 02/2019; 19224 Exp. 02/2019; 20032 Exp. 08/2019; 20289 Exp. 08/2019; 21076 Exp. 08/2019; 21382 Exp. 08/2019	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Avkare Incorporated
Drug	AvKARE Valsartan and Hydrochlorothiazide 320 mg/25 mg tablets 90-count bottle, Rx Only, Manufactured for: AvKARE, Inc. Pulaski, TN 38478, NDC 42291-888-90	Class II	Lots: 17308 Exp. 09/2018; 18158 Exp. 09/2018; 18539 Exp. 01/2019; 19021 Exp. 01/2019; 19225 Exp. 01/2019; 20033 Exp. 06/2019; 20290 Exp. 06/2019; 20565 Exp. 06/2019; 21369 Exp. 10/2019	CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.	Avkare Incorporated
Drugs	Calcitriol Oral Solution, 1 mcg/mL, 15 mL bottle, Rx Only, Distributed by:	Class III	RV1602RB, Exp 07/2019; RV1604RB, Exp 9/2019;	Subpotency: lower than expected potency result was obtained at the 18 month stability time point.	Validus Pharmaceuticals, Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Ranbaxy Pharmaceuticals Inc. Jacksonville, FL 32257 USA, NDC 63304-241-59		RV1605RB, Exp 10/2019		
Drugs	Azelastine HCl Ophthalmic Solution 0.05%, 6 mL in 10 mL HDPE bottle, 1 bottle per box, Rx only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-718-10	Class III	Lot# 6K89A, 6K90A, 6K92A, exp 9/18	Failed Impurities/Degradation Specifications: out-of-specification (OOS) results for Azelastine N-oxide	Akorn, Inc
Drugs	Oxycodone and Acetaminophen Tablets, USP, 5 mg*/325 mg, 100-count bottle, Rx Only, Manufactured by: Mayne Pharma, Greenville, NC 27834, NDC 68308-841-01.	Class III	Lot: FG01517, Exp. 12/31/2019	Labeling: Incorrect or Missing Lot and/or Exp Date: Lot FG10517 is mislabeled on the primary container with Lot FG01517, shipper labels and invoices contain the correct lot number of FG10517.	Mayne Pharma Inc
Drugs	Rocaltrol (calcitriol) Oral Solution, 1 mcg/mL, 15 mL bottle, Rx only, Distributed by: Validus Pharmaceuticals, LLC Parsippany, NJ 07054 USA, NDC 30698-911-15	Class III	RV1604, Exp 09/2019	Subpotency: lower than expected potency result was obtained at the 18 month stability time point.	Validus Pharmaceuticals, Inc.
Drug	Diltiazem HCl Extended-Release Capsules, USP 120 mg 100-count bottle, Rx only, Mylan	Class III	Batch code # 3093163, expiration date 04/2019	Failed Impurities/Degradation Specifications: Out of specification test results obtained during routine stability testing for related compound.	Mylan Pharmaceuticals Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Pharmaceuticals Inc. Morgantown, WV 26505. NDC 0378-5220-01				
Drug	Tyvaso Inhalation System Patient a) Starter Kit with TYVASO (treprostinil) Inhalation Solution. Treprostinil 1.74 mg/2.9 mL (0.6 mg/mL) (NDC 66302-206-01) b) TD-300/A Replacement Device Kit Material Number RTP3099 RX Only. Manufactured by United Therapeutics Corporation Research Triangle Park, NC 27709	Class III	Lot number a) 2101503, 2101507, 2101523, 2101532, 2101533, EXP 07/31/2019; 2101557, EXP 11/30/2019 b) Lot # 2101504, EXP 4/24/2021; 2101509, 2101522, EXP 5/8/2021; 2101531, EXP 5/15/2021; 2101534, EXP 6/10/2021; 2101543, EXP 6/14/2021; 2101558, EXP 7/26/2021	Defective Delivery System: Water ingress through the lower water cup sensor of the device.	United Therapeutics Corp.
Drug	Argatroban Injection, 250 mg/2.5 mL (100 mg/mL), 2.5 mL Single-use Vial, Rx only, Sterile, Manufactured for: Hospira, Inc, Lake Forest, IL 60045 USA. NDC: 0409-	Class III	Lot: DP602, 10/2018	Failed Impurities/Degradation Specifications; Out of specification stability testing results at the 18 month time point	Pfizer Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	1140-01				
Drug	Pramipexole dihydrochloride extended release tablets, 0.75 mg, packaged in 30-count bottles, Rx only, Manufactured by: Par Pharmaceutical, Chestnut Ridge, NY 10977, NDC 10370-252-11	Class III	Lot #: 29906202, Exp 12/18; 29993102, Exp 2/19; 30366102, 30373103, Exp 4/19; 31940601, Exp 3/20.	Failed impurities/degradation specifications: Finished product contain a known product impurity about current specification levels.	Par Pharmaceutical, Inc.
Drug	Diltiazem HCl Extended-Release Capsules, USP 120 mg 500-count bottle, Rx only, Mylan Pharmaceuticals Inc. Morgantown, WV 26505. NDC 0378-5220-05	Class III	Batch code # 3093163, expiration date 04/2019	Failed Impurities/Degradation Specifications: Out of specification test results obtained during routine stability testing for related compound.	Mylan Pharmaceuticals Inc.

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

CURRENT DRUG SHORTAGES

Morphine PCA Vials

August 24, 2018

Reason for the Shortage

- ICU Medical had morphine PCA vials on allocation due to increased demand.
- Amphastar's morphine PCA vials are not affected by the shortage.

Estimated Resupply Dates

- ICU Medical has morphine PCA vials on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=436

Buprenorphine Hydrochloride Injection

August 24, 2018

Reason for the Shortage

- Pfizer has buprenorphine injection on shortage due to manufacturing delays.
- Par had buprenorphine injection on shortage due to increased demand.

Estimated Resupply Dates

- Pfizer has buprenorphine 0.3 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of June 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=419

Mineral Oil and Petrolatum Ophthalmic Ointment

August 27, 2018

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.
- Novartis did not provide a reason for the shortage.
- Perrigo did not provide a reason for the shortage.
- 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.
- Major has Lubrifresh PM Ointment 3.5 gram tubes on back order and the company cannot estimate a release date.
- Rugby has Artificial Tears 3.5 gram tubes on back order and the company cannot estimate a release date.
- Novartis has Genteal PM ointment in 3.5 gram tubes on back order and the company estimates a release date of early-September 2018.

- Perrigo has Puralube ointment in 3.5 gram and 1 gram tubes on back order and the company estimates release dates in early-September 2018 for the 3.5 gram tubes and early-October 2018 for the 1 gram tubes.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=435

Dorzolamide 2% and Timolol 0.5% Ophthalmic Solution

August 27, 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 dorzolamide 2% and timolol 0.5% ophthalmic solution in 10 mL bottles on allocation.
- 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 late-September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=360

Atropine Sulfate Injection

August 27, 2018

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 and 0.1 mg/mL 10 mL Ansyr syringes available in limited supply. The 0.1 mg/mL 5 mL LifeShield syringes are on back order and the company estimates release dates of October 2018. The 0.05 mg/mL 5 mL Ansyr syringes are available with an expiration date of February 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=46

Methyldopa Tablets

August 28, 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 temporarily discontinued all methyldopa tablet presentations.

- Teva has methyldopa 500 mg tablets temporarily unavailable with no estimated release date.
- Mylan has methyldopa 250 mg tablets and 500 mg tablets in 100 count bottles on back order and the company estimates a release date of late-November 2018 for the 250 mg tablets and early-December 2018 for the 500 mg tablets. The 250 mg tablets and 500 mg tablets in 100 count unit-dose packs are on back order and the company estimates a release date of late-January to early-February 2019 for the 250 mg tablets and mid-February 2019 for the 500 mg tablets.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=462

Mannitol Injection

August 28, 2018

Reason for the Shortage

- American Regent did not provide a reason for the mannitol shortage.
- Baxter did not provide a reason for the mannitol shortage.
- Fresenius Kabi had mannitol on shortage due to increased demand.
- Pfizer has mannitol on shortage due to manufacturing delays.

Estimated Resupply Dates

- American Regent has mannitol 250 mg/mL 50 mL vials on back order and the company cannot estimate a release date.
- Pfizer has mannitol 250 mg/mL 50 mL vials on back order and the company estimates a release date of November 2018.
- BBraun has mannitol 200 mg/mL 250 mL and 500 mL premixed bags on allocation to current customers.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=341

Mafenide Acetate Powder for Solution

August 28, 2018

Reason for the Shortage

- Mylan did not provide a reason for the shortage.
- Par did not provide a reason for the shortage.
- Mafenide acetate cream is not affected by this shortage.

Estimated Resupply Dates

- Par has mafenide acetate 50 gram packets on back order and the company estimates a release date of mid-September 2018.
- Mylan has Sulfamylon 50 gram packets on back order and the company estimates a release date of late-October 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=461

Dopamine Hydrochloride Injection

August 28, 2018

Reason for the Shortage

- American Regent has dopamine on shortage due to manufacturing delays.
- 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

- American Regent has all dopamine presentations on back order and the company cannot estimate a release date.
- Pfizer has dopamine 40 mg/mL 10 mL vials on back order and the company estimates a release date of 2019. The 400 mg/250 mL bags are on back order and the company estimates a release date of November 2018. The 800 mg/500 mL bags are on back order and the company estimates a release date of September 2018. The 40 mg/mL 5 mL vials are on back order and the company estimates a release date of September 2018.

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

Diazepam Injection

August 28, 2018

Reason for the Shortage

- Pfizer has diazepam on shortage due manufacturing delays.

Estimated Resupply Dates

- Pfizer has diazepam 5 mg/mL 2 mL Carpuject syringes on back order and the company estimates a release date of October 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=330

Sincalide Injection

August 29, 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

Potassium Chloride Injection

August 29, 2018

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

- Baxter has potassium chloride 20 mEq/1000 mL in lactated ringers and 5% dextrose on back order and the company cannot estimate a release date.
- Fresenius Kabi has potassium chloride 10 mEq/5 mL, 20 mEq/10 mL, 40 mEq/20 mL, and 60 mEq/30 mL vials on back order and the company estimates a release date of late-October 2018 for the 5 mL vials and 10 mL vials, early-October 2018 for the 20 mL, and late-September 2018 for the 30 mL vials. Check wholesalers for inventory.
- ICU Medical has potassium chloride 20 mEq/100 mL in sterile water on back order and the company cannot estimate a release date.
- Pfizer has potassium chloride 10 mEq/5 mL vials and 40 mEq/20 mL vials on back order and the company estimates a release date in November 2018. The 20 mEq/10 mL vials are on back order and the company estimates a release date in October 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=12

Oxacillin Sodium Injection

August 29, 2018

Reason for the Shortage

- AuroMedics did not provide a reason for the shortage.
- Baxter had oxacillin on shortage due to manufacturing delays.
- Sagent had oxacillin on shortage due to manufacturing delays.
- Wockhardt did not provide a reason for the shortage.

Estimated Resupply Dates

- AuroMedics has oxacillin 1 gram vials on intermittent back order and the company is releasing supplies as they become available.
- Wockhardt has oxacillin 2 gram and 10 gram vials on back order and the company estimates a release date in mid-October 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=377

Methocarbamol Tablets

August 29, 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 tablets on intermittent back order and is shipping product weekly.
- Solco has methocarbamol 500 mg tablets in 100 count and 500 count and 750 mg tablets in 100 count and 500 count on allocation.
- Virtus has all methocarbamol tablets on back order and the company estimates a release date of late-September 2018.

- Hikma has methocarbamol 500 mg in 100 count and 500 count available with short expiration dating. Methocarbamol 750 mg tablets in 100 count and 500 count are 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.
- Bayshore has methocarbamol 500 mg tablets in 100 count and 500 count and 750 mg tablets in 500 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

Dobutamine Injection

August 29, 2018

Reason for the Shortage

- Baxter has dobutamine available.
- Pfizer has dobutamine on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has dobutamine 12.5 mg/mL 20 mL and 40 mL latex-free vials on back order with an estimated release date of 2019. The 12.5 mg/mL 20 mL regular vials in 1 count are on back order and the company estimates a release date of October 2018. The 12.5 mg/mL 20 mL regular vials in 10 count are available in limited supply.
- Pfizer has dobutamine 1 mg/mL in 250 mL bags on back order and the company estimates a release date of November 2018. The dobutamine 2 mg/mL 250 mL bags are on back order and the company estimates a release date of November 2018. The dobutamine 4 mg/mL 250 mL bags are on back order and the company estimates a release date of November 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=296

Desiccated Thyroid Tablets

August 29, 2018

Reason for the Shortage

- Acella has NP Thyroid available.
- Allergan has Armour Thyroid available.
- RLC states the reason for the shortage is increased demand and difficulty obtaining raw materials.

Estimated Resupply Dates

- RLC has Nature-Throid 16.25 mg, 194.4 mg, 260 mg, and 325 mg tablets on back order and the company cannot estimate a release date. Westhroid presentations are also on back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=350

Ciprofloxacin Ophthalmic Solution

August 29, 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 allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=443

Mepivacaine Injection
August 30, 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 cannot estimate a release date. The 1% Polocaine-MPF 30 mL vials are on back order and the company estimates a release date of mid-September 2018. The 1% Polocaine 50 mL vials are on back order and the company estimates a release date of mid-October 2018.
- 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 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=331

Gentamicin Sulfate Ophthalmic Ointment
August 30, 2018

Reason for the Shortage
- Akorn had 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 cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=412

Scopolamine Transdermal System
August 31, 2018

Reason for the Shortage
- GlaxoSmithKline has Transderm Scop patches available.
- Perrigo did not provide a reason for the shortage.

Estimated Resupply Dates
- Perrigo has scopolamine patches on back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=442

Rocuronium Injection

August 31, 2018

Reason for the Shortage

- Fresenius Kabi has rocuronium available.
- Pfizer has rocuronium on shortage due to manufacturing delays.
- Sagent has rocuronium available.
- AuroMedics launched rocuronium in mid-2017.
- Athenex launched rocuronium in mid-2018.

Estimated Resupply Dates

- AuroMedics has rocuronium 10 mg/mL 5 mL vials on intermittent back order with regular releases.
- Pfizer has rocuronium 10 mg/mL 5 mL vials available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=290

Isocarboxazid Tablets

August 31, 2018

Reason for the Shortage

- Validus has Marplan tablets on shortage due to manufacturing delays.

Estimated Resupply Dates

- Validus has Marplan on back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=411

Furosemide Tablets

August 31, 2018

Reason for the Shortage

- Major discontinued furosemide tablets in early-2018.
- Mylan and Teva 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

- Mylan has furosemide 40 mg tablets in 100 count and 1000 count on back order and the company estimates a release date of late-September 2018.
- Hikma has furosemide 40 mg tablets in 100 count bottles on allocation.

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

Diltiazem Hydrochloride Injection

August 31, 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.
- 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 and 25 mL vials available in limited supply. The 10 mL vials are on allocation.
- Hikma has diltiazem 5 mg/mL 10 mL and 25 mL vials on allocation. The 5 mL vials are on back order and the company estimates a release date of early- to mid-September 2018 for the 5 mL vials.
- Pfizer has 100 mg ADD-Vantage vials on back order and the company estimates a release date of September 2018. The 5 mg/mL 5 mL and 10 mL vials are 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

Cefuroxime Sodium Injection

August 31, 2018

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.

Estimated Resupply Dates

- Sagent has cefuroxime 750 mg vials on back order and the company cannot estimate a release date.
- Hikma has cefuroxime 7.5 gram vials on back order and the company estimates a release date of September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=13

Ceftazidime Injection

August 31, 2018

Reason for the Shortage

- Pfizer has Tazicef available.
- Sagent had ceftazidime injection on shortage due to manufacturing delays.
- Sandoz discontinued ceftazidime 1 gram and 2 gram vials in 2015. Sandoz discontinued the 6 gram vials in early 2016.
- BBraun had ceftazidime on allocation due to increased demand.
- Teligent discontinued Fortaz 2 gram vials, 6 gram vials, and both 1 gram/50 mL and 2 gram/50 mL premixes in February 2018.
- WG Critical Care has ceftazidime available.

Estimated Resupply Dates

- BBraun has ceftazidime 1 gram/50 mL and 2 gram/50 mL premixed bags on allocation.
- Teligent has Fortaz 500 mg vials 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=63

Calcium Chloride Injection

August 31, 2018

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 100 mg/mL 10 mL vials available in limited supply.
- Pfizer has calcium chloride 100 mg/mL 10 mL Ansyr syringes and 100 mg/mL 10 mL LifeShield syringes on back order and the company estimates a release date of November 2018 for the Ansyr syringes and September 2018 for the LifeShield syringes.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=48

Calcitriol Injection

August 31, 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

Bumetanide Injection

August 31, 2018

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 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=307

Phenytoin Sodium

September 2, 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 vials and 50 mg/mL 5 mL vials on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=406

Labetalol Injection

September 2, 2018

Reason for the Shortage

- Akorn has labetalol injection available.[1]
- Alvogen has labetalol injection available.[2]
- Pfizer has labetalol injection on shortage due to manufacturing delays.[3]
- Hikma has labetalol injection available.[4]

Estimated Resupply Dates

- Hikma has labetalol 5 mg/mL 40 mL vials available with an expiration date of May 2019.
- Pfizer has labetalol 5 mg/mL 4 mL syringes on back order and the company estimates a release date of September 2018. The 20 mL and 40 mL vials are on back order and the company estimates a release date of November 2018 for the 20 mL vials and September 2018 for the 40 mL vials.[3]

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=286

Hydroxyethyl Starch in Sodium Chloride Injection

September 2, 2018

Reason for the Shortage

- BBraun did not provide a reason for the shortage.
- Pfizer did not provide a reason for the shortage of 6% hetastarch in 0.9% sodium chloride injection.
- Pfizer has Voluven available.

Estimated Resupply Dates

- BBraun has Hespan 500 mL bags on back order and the company cannot estimate a release date.
- Pfizer has 6% hetastarch in 0.9% sodium chloride injection in 500 mL bags on back order and the company estimates a release date of October 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=454

Sterile Water for Injection - Small Volume Vials

September 3, 2018

Reason for the Shortage

- American Regent has limited availability of sterile water for injection.
- Fresenius Kabi has sterile water on shortage due to increased demand.
- Pfizer has sterile water for injection in vials on shortage due to increased demand.

Estimated Resupply Dates

- American Regent has sterile water for injection 20 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has sterile water for injection 5 mL, 20 mL, and 50 mL vials on back order and the company estimates a release date of mid-to late-September 2018 for the 5 mL vials, early- to mid-October 2018 for the 20 mL vials, and late-October to early-November 2018 for the 50 mL vials. 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 20 mL, 50 mL, and 100 mL vials on back order and the company estimates a release date of September 2018 for the 50 mL and 100 mL vials and October 2018 for the 20 mL vials. The 10 mL vials are available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=375

Sodium Acetate Injection

September 4, 2018

Reason for the Shortage

- American Regent has had sodium acetate on long-term back order for several years.
- Fresenius Kabi had sodium acetate on shortage due to increased demand.
- Pfizer had sodium acetate 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=317

Pamidronate Disodium Injection

September 4, 2018

Reason for the Shortage

- Areva has pamidronate powder for injection available.
- Mylan Institutional did not provide a reason for the shortage.
- Pfizer has pamidronate on shortage due to manufacturing delays.

Estimated Resupply Dates

- Mylan Institutional has pamidronate 3 mg/mL and 9 mg/mL 10 mL vials on back order and the company estimates a release date of late-October to early-November 2018.
- Pfizer has pamidronate 3 mg/mL 10 mL vials available in limited supply. The 6 mg/mL 10 mL vials are on back order and the company estimates a release date of October 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=402

Multiple Vitamins for Infusion

September 4, 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 October 2018. There is limited short-dated product available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=69

Multiple Electrolytes Large Volume Solutions for Injection

September 4, 2018

Reason for the Shortage

- Baxter has Plasma-Lyte 148 and Plasma-Lyte A presentations available.
- Pfizer had Normosol-R presentations on back order due to manufacturing delays.

Estimated Resupply Dates

- ICU Medical has Normosol-R pH 7.4 in 500 mL bags 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=389

Etoposide Solution for Injection

September 4, 2018

Reason for the Shortage

- Accord has etoposide 20 mg/mL 5 mL and 25 mL vials on allocation and 50 mL vials on back order due to increased demand.
- Fresenius Kabi has etoposide on back order due to increased demand.
- Teva has Toposar on allocation due to increased demand.
- West-Ward did not provide a reason for the shortage.
- Etoposide phosphate powder for injection (Etopophos) is unaffected by this shortage.

Estimated Resupply Dates

- All marketed presentations are available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=369

Epinephrine Injection

September 4, 2018

Reason for the Shortage

- Amphastar stopped distributing epinephrine 1 mg/mL 30 mL vials on May 10, 2017. They are continuing to supply 0.1 mg/mL 10 mL syringes. These are on shortage due to increased demand.[1]
- Pfizer stopped distributing epinephrine 1 mg/mL presentations on May 10, 2017.[2]
- BPI has epinephrine 1 mg/mL 2 mL ampules available.[3]
- Par has Adrenalin 1 mg/mL 1 mL and 30 mL vials available.[4]

Estimated Resupply Dates

- Amphastar has epinephrine 0.1 mg/mL 10 mL syringes on allocation.[1]
- Pfizer has epinephrine 0.1 mg/mL 10 mL syringes on back order and the company estimates a release date of September 2018.[2]
- Snap Medical Industries has the Epinephrine Snap-V Kit available. Each kit contains an epinephrine 1 mg/mL 1 mL vial, (3) 1 mL luer lock syringes, and (3) 23-gauge 1-inch needles.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=313

Epinephrine Auto-Injectors

September 4, 2018

Reason for the Shortage

- Impax was not able to provide a reason for the shortage.
- Mylan has EpiPen on shortage due to supply constraints.

Estimated Resupply Dates

- Impax has epinephrine 0.15 mg/0.15 mL and 0.3 mg/0.3 mL auto-injectors on back order and the company estimates a release date of mid-September 2018.
- Mylan has Epipen, EpiPen Jr, and their authorized generic presentations on intermittent back order with regular releases.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=420

50% Dextrose Injection

September 4, 2018

Reason for the Shortage

- Amphastar has 50% dextrose injection available.
- 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 October 2018. The 50% dextrose 50 mL Ansyr syringes are available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=306

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

September 4, 2018

Reason for the Shortage

- ICU Medical states the shortage is due to increased demand and manufacturing delays. ICU Medical discontinued the 500 mL VisIV bags in 2011 due to leaking around the administration and medications ports.
- ICU Medical is now the IV fluid business of Pfizer after the acquisition of Hospira.
- Baxter is not currently marketing 5% dextrose PVC/DEHP-free bags.
- BBraun has 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags on shortage due to manufacturing delays.

Estimated Resupply Dates

- BBraun has 5% dextrose 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags on allocation to current customers.
- ICU Medical has 5% dextrose in 100 mL PVC/DEHP-free bags 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=314

0.9% Sodium Chloride Large Volume Bags

September 4, 2018

Reason for the Shortage

- Baxter discontinued 0.9% sodium chloride 250 mL and 500 mL AVIVA bags. The Viaflex bags and Viaflo bags are available.[1]
- BBraun did not provide a reason for the shortage.[2]
- ICU Medical cited increased demand as the reason for the shortage.[3]
- Fresenius Kabi is no longer importing product.[8]
- Baxter has received FDA approval for 0.9% sodium chloride in Viaflo containers manufactured in an FDA-approved facility in Spain. Additional information about this product is available at: http://www.baxter.com/information/saline_supply.html.

Estimated Resupply Dates

- BBraun has 0.9% sodium chloride 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags on allocation to current customers.[2]
- ICU Medical has 0.9% sodium chloride 150 mL, 250 mL, and 500 mL bags on back order and the company estimates a release date in late-September 2018. The 250 mL PVC/DEHP-free bags are on back order and the company estimates a release date in mid-September 2018. All other presentations are on allocation. [3]

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=76

0.9% Sodium Chloride 10 mL, 20 mL, and 50 mL Preservative Free Vials and Syringes

September 4, 2018

Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has 0.9% sodium chloride preservative-free vials on shortage due to manufacturing delays.

Estimated Resupply Dates

- Fresenius Kabi has 0.9% sodium chloride preservative free 10 mL vials on back order and the company estimates a release date of late-September 2018.
- Pfizer has 0.9% sodium chloride preservative free 10 mL LifeShield syringes on back order and the company estimates a release date of September 2018. The 10 mL vials are available in limited supply. The 20 mL and 50 mL vials are on back order and the company estimates a release date of October 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=332

Lorazepam Injection

September 5, 2018

Reason for the Shortage

- Bedford discontinued lorazepam injection in May, 2011.[1]
- Hikma has product on shortage due to manufacturing delays.[2]
- Pfizer has product on shortage due to increased demand and manufacturing delays. Pfizer discontinued 4 mg/mL 10 mL vials in December 2017.[3]
- Akorn has not provided a reason for the shortage.[4]

- Amphastar has product available.[5]

Estimated Resupply Dates

- Hikma has lorazepam 2 mg/mL 10 mL vials on intermittent back order and the company is releasing supplies as they become available. The 4 mg/mL 10 mL vials are on back order and the company estimates a release date of mid- to late-September 2018.[2]
- Hikma has Ativan 2 mg/mL 10 mL vials on back order and the company estimates a release date of October 2018. Ativan 4 mg/mL 10 mL vials are on back order and the company estimates a release date of mid- to late-September 2018.[2]
- Pfizer has lorazepam 2 mg/mL 1 mL Carpuject syringes on allocation. The 2 mg/mL 10 mL vials are on back order and the company estimates a release date of November 2018. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of October 2018. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 2019.[3]

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

Levetiracetam Injection

September 5, 2018

Reason for the Shortage

- American Regent did not provide a reason for the shortage.
- Athenex has product available.
- AuroMedics did not provide a reason for the shortage.
- Fresenius Kabi has product available.
- Mylan has product available.
- Pfizer has product available.
- Sagent has product available.
- Sun Pharma did not provide a reason for the shortage.
- UCB has product available.
- Hikma has product available.
- X-Gen has product available.

Estimated Resupply Dates

- American Regent has levetiracetam 100 mg/mL 5 mL vials on back order and the company cannot estimate a release date.
- AuroMedics has levetiracetam 5 mg/mL 100 mL, 10 mg/mL 100 mL, and 15 mg/mL 100 mL premixed bags on back order and the company cannot estimate a release date. The 100 mg/mL 5 mL vials are on intermittent back order and the company is releasing supplies as they become available.
- Sun Pharma has levetiracetam 100 mg/mL 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=84

Leuprolide Acetate 14-Day Kit

September 5, 2018

Reason for the Shortage

- Sun Pharma did not provide a reason for the shortage.

- Sandoz states the reason for the shortage was increased demand.
- Teva is not currently marketing leuprolide injection.

Estimated Resupply Dates

- Sun Pharma has leuprolide acetate 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=81

Heparin Injection

September 5, 2018

Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer did not provide a reason for the shortage.
- Sagent had heparin on shortage due to manufacturing delay.
- Hikma did not provide a reason for the shortage.

Estimated Resupply Dates

- Fresenius Kabi has heparin 10,000 unit/mL 4 mL vials available as short-dated product (<7 months expiration date).
- 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 in September to October 2018.
- Pfizer has 5,000 unit/mL 1 mL Carpuject syringes on back order and the company estimates a release date of 2019. The 1,000 unit/mL 10 mL and 30 mL vials, 5,000 unit/mL 10 mL vials, and 10,000 unit/mL 1 mL vials are on back order and the company cannot estimate a release date. The 10,000 unit/mL 0.5 mL carpuject syringes, 10,000 unit/mL 1 mL vials, and 5,000 unit/mL 1 mL vials are available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=353

Dexmedetomidine Hydrochloride Injection

September 5, 2018

Reason for the Shortage

- Akorn did not provide a reason for the shortage.
- 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.

Estimated Resupply Dates

- Hikma has 100 mcg/mL 2 mL vials on allocation.

- Pfizer has Precedex 4 mcg/mL 50 mL and 100 mL premixed bottles on back order and the company estimates a release date of September 2018. The 4 mcg/mL 20 mL vials are also on back order and the company estimates a release date in September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=398

Ciprofloxacin Injection

September 5, 2018

Reason for the Shortage

- Pfizer has ciprofloxacin injection on shortage due to manufacturing delays.
- Baxter (formerly Claris) has ciprofloxacin injection available.

Estimated Resupply Dates

- Pfizer has ciprofloxacin 2 mg/mL 200 mL premixed bags on back order and the company estimates a release date of September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=396

Ceftriaxone Sodium Injection

September 5, 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 relaunched their ceftriaxone presentations in October 2017.

Estimated Resupply Dates

- Lupin has all ceftriaxone presentations on allocation.
- Pfizer has ceftriaxone 1 gram ADD-Vantage vials, 2 gram ADD-Vantage vials, and 10 gram vials on allocation.
- Sagent has ceftriaxone 2 gram and 10 gram vials on back order and the company estimates a release date of September 2018.
- Wockhardt has all ceftriaxone presentations on back order and the company cannot estimate a release date.
- Hikma has ceftriaxone 500 mg and 1 gram vials on back order and the company cannot estimate a release date. The 2 gram vials are on allocation.

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

0.9% Sodium Chloride Small Volume Bags (< 150 mL)

September 5, 2018

Reason for the Shortage

- Baxter had 0.9% sodium chloride small volume bags on shortage due to manufacturing delays.
- BBraun has 0.9% sodium chloride small volume bags on shortage due to increased demand.
- ICU Medical has 0.9% sodium chloride small volume bags on shortage due to increased demand.

Estimated Resupply Dates

- BBraun has all 0.9% sodium chloride small volume bags on allocation to current customers only.
- ICU Medical has 0.9% sodium chloride 50 mL bags, 100 mL VisIV bags, and 100 mL bags on back order and the company estimates a release date in late-September 2018. The 25 mL and 100 mL bags are on back order and the company estimates a release date in mid- to late-September 2018. The 50 mL preservative-free bags are on back order with an estimated release date of early-October 2018.
- Pfizer has 0.9% sodium chloride 50 mL Add-Vantage bags and 100 mL Add-Vantage bags available in limited quantities. The 50 mL preservative-free vials are on back order and the company estimates a release date of September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=352

Norepinephrine Bitartrate Injection

September 6, 2018

Reason for the Shortage

- Baxter did not provide a reason for the shortage.
- Pfizer has Levophed on shortage due to manufacturing delays.
- Teva has norepinephrine injection on allocation due to increased demand.

Estimated Resupply Dates

- Pfizer has Levophed 1 mg/mL 4 mL ampules on back order and the company estimates a release date of 2020. The 4 mL vials are available in limited supply.
- Teva has norepinephrine 1 mg/mL 4 mL vials on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=292

Metronidazole Hydrochloride Injection

September 6, 2018

Reason for the Shortage

- Pfizer has metronidazole injection on shortage due to manufacturing delay.
- BBraun did not provide a reason for the metronidazole injection shortage.

Estimated Resupply Dates

- Baxter has metronidazole 100 mL bags (NDC 36000-0001-24) on back order and the company cannot estimate a release date.
- BBraun has metronidazole 100 mL bags on allocation to current customers.
- Pfizer has metronidazole 100 mL bags in 24 count and 80 count available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=316

Midodrine Tablets

September 7, 2018

Reason for the Shortage

- Impax discontinued midodrine tablets in July 2018.
- Mylan has midodrine tablets available.
- Sandoz discontinued midodrine tablets in mid-2018.

- Upsher-Smith did not provide a reason for the shortage.

Estimated Resupply Dates

- Upsher-Smith has midodrine 2.5 mg, 5 mg, and 10 mg tablets in 100-count bottles on intermittent back order with regular releases. Product is being allocated upon release.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=439

Metoprolol Injection

September 7, 2018

Reason for the Shortage

- Alvogen has metoprolol injection available.[1]
- American Regent has had metoprolol injection on long-term back order for several years.[2]
- Athenex has metoprolol injection available.[3]
- Baxter did not provide a reason for the shortage.[4]
- Fresenius Kabi has metoprolol injection on shortage due to increased demand.[5]
- Mylan Institutional acquired metoprolol injection from Sagent. They discontinued metoprolol injection in March 2018.[6]
- Pfizer has metoprolol injection on shortage due to manufacturing delays.[7]
- Hikma did not provide a reason for the shortage.[8]

Estimated Resupply Dates

- Baxter (formerly Claris) has metoprolol 1 mg/mL 5 mL vials on back order and the company cannot estimate a release date.[4]
- Pfizer has metoprolol 1 mg/mL 5 mL ampules and 1 mg/mL 5 mL Carpuject syringes on back order and the company estimates a release date of 2019. The 1 mg/mL 5 mL vials are available in limited supply.[7]
- Hikma has metoprolol 1 mg/mL 5 mL vials on allocation. The 1 mg/mL 10 mL vials are on back order and the company estimates a release date of late-September to early-October 2018.[8]

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

Meperidine Hydrochloride Injection

September 7, 2018

Reason for the Shortage

- Pfizer has Demerol injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Demerol 100 mg/mL 20 mL vials and on back order and the company estimates a release date of March 2019. The 25 mg/mL 1 mL Carpuject syringes, 50 mg/mL 1 mL Carpuject syringes, 75 mg/mL 1 mL Carpuject syringes, and 100 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of March 2019. The 50 mg/mL 0.5 mL ampules are on back order and the company estimates a release date of early-October 2018. The 50 mg/mL 1 mL ampules are on back order and the company estimates a release date of late-September 2018. The 50 mg/mL 2 mL ampules are on back order and the company estimates a release date of November 2018. The 50 mg/mL 30 mL vials are on back order and the company estimates a release date of December 2018. The 50 mg/mL 1.5 mL ampules are on

back order and the company estimates a release date of October 2018. The 100 mg/mL 1 mL ampules are on back order and the company estimates a release date of October 2018.
https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=347

Leucovorin Calcium Injection
September 7, 2018

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 vials on back order and the company estimates a release date of mid- to late-September 2018.
- Hikma has leucovorin 200 mg and 350 mg vials on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=35

Hypromellose Ophthalmic Solution
September 7, 2018

Reason for the Shortage
- Akorn has hypromellose ophthalmic solution on shortage due to lack of raw materials.1
- HUB Pharmaceuticals has hypromellose ophthalmic solution on long-term back order and did not provide a reason.2

Estimated Resupply Dates
- Akorn has Gonak 2.5% ophthalmic solution 15 mL bottles on back order and the company cannot estimate a release date.1
- HUB Pharmaceuticals has Goniovisc 2.5% ophthalmic solution 15 mL bottles on long-term back order and the company cannot estimate a release date.2

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=437

Heparin Sodium Premixed Bags
September 7, 2018

Reason for the Shortage
- Baxter has heparin on shortage due to manufacturing delays.
- BBraun did not provide a reason for the shortage.
- 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 late-September 2018.
- BBraun has all heparin premixed bags on allocation.
- Pfizer has heparin 12,500 units/250 mL 0.45% sodium chloride, 25,000 units/500 mL 0.45% sodium chloride, 1000 units/500 mL 0.9% sodium chloride, and 2000 units/1000 mL 0.9%

sodium chloride premixed bags on back order and the company estimates a release date of September 2018. The 25,000 units/250 mL 5% dextrose premixed bags are on back order and the company estimates a release date of November 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=468

Famotidine Injection

September 7, 2018

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.[1]
- Hikma did not provide a reason for the shortage.[2]
- Pfizer launched famotidine injections in March 2012.[3]
- Mylan Institutional acquired famotidine injections from Pfizer on December 6, 2013.[4]
- Fresenius Kabi did not provide a reason for the shortage.[5]
- Baxter has famotidine premixed bags available.[6]

Estimated Resupply Dates

- Fresenius Kabi has famotidine 20 mL vials on back order and the company estimates a release date of mid- to late-September 2018. Check wholesalers for inventory.[5]
- Mylan Institutional has famotidine 2 mL, 4 mL, and 20 mL vials on back order and the company estimates a release date of late-October 2018 for the 2 mL and 20 mL vials and late-December 2018 for the 4 mL vials.[4]
- Hikma has famotidine 4 mL and 20 mL vials on back order and the company estimates a release date of September 2018 for the 4 mL vials and late-September to early-October 2018 for the 20 mL vials.[2]

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

Enoxaparin Sodium Injection

September 7, 2018

Reason for the Shortage

- Actavis has enoxaparin available.
- Amphastar has enoxaparin available.
- 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.
- Winthrop did not provide a reason for the shortage.

Estimated Resupply Dates

- Fresenius Kabi has enoxaparin 30 mg/0.3 mL and 40 mg/0.4 mL prefilled syringes on back order and the company estimates a release date of early- to mid-October 2018 for the 30 mg/0.3 mL syringes and mid-October 2018 for the 40 mg/0.4 mL syringes. Check wholesalers for inventory. Enoxaparin 100 mg/mL 1 mL and 150 mg/mL 1 mL prefilled syringes are available with short expiration dating (< 6 months for the 150 mg/mL 1 mL syringes and < 9 months for the 100 mg/mL 1 mL syringes).
- 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 presentations on allocation.

- Winthrop has all enoxaparin presentations on allocation.

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

Cefotaxime Sodium Injection

September 7, 2018

Reason for the Shortage

- Hospira has discontinued Claforan. Sanofi-Aventis manufactured Claforan for Hospira and is no longer making the product.
- Baxter discontinued Claforan in late-2015.
- Hikma has cefotaxime on shortage due to manufacturing and issues with raw material.

Estimated Resupply Dates

- Hikma has cefotaxime 500 mg, 1 gram, 2 gram, and 10 gram vials 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=51

Acetylcysteine Oral and Inhalation Solution

September 7, 2018

Reason for the Shortage

- American Regent has acetylcysteine oral and inhalation solution on shortage due to manufacturing delays.
- 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 10 mL and 200 mg/mL 10 mL and 30 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has acetylcysteine solution 200 mg/mL 4 mL and 10 mL vials on back order and the company estimates a release date of late-September 2018. The 100 mg/mL 4 mL and 10 mL vials are on back order and the company estimates a release date of late-September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=43

Torsemide Injection

September 10, 2018

Reason for the Shortage

- Roche discontinued Demadex injection for business reasons. Demadex tablets are not affected by this shortage.
- American Regent has torsemide on shortage due to manufacturing delays.

Estimated Resupply Dates

- American Regent has torsemide injection 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=168

Daptomycin Injection

September 10, 2018

Reason for the Shortage

- Fresenius Kabi has daptomycin available.
- Mylan Institutional has daptomycin available.
- Pfizer has daptomycin on shortage due to manufacturing delays.
- Teva has daptomycin on shortage due to increased demand.
- Merck has Cubicin and Cubicin RF available.

Estimated Resupply Dates

- Pfizer has daptomycin 500 mg vials on back order and the company cannot estimate a release date.
- Teva has daptomycin 500 mg vials on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=467

Carbidopa and Levodopa Extended-Release Tablets

September 10, 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 50 mg/200 mg extended-release tablets in 100 count unit-dose packs on back order and the company estimates a release date of early-November 2018. The 25 mg/100 mg extended release tablets in 100 count unit-dose packs are on back order and the company estimates a release date of early-October 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-September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=349

Tobramycin Sulfate Injection

September 11, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Akorn has tobramycin 40 mg/mL 2 mL and 30 mL vials on back order and the company cannot estimate a release date.
- 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.
- Pfizer has tobramycin 40 mg/mL 2 mL vials on back order and the company estimates a release date of November 2018.
- Teva has temporarily discontinued tobramycin 40 mg/mL 2 mL vials.
- Fresenius Kabi has tobramycin 40 mg/mL 2 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=164

Thiothixene Capsules

September 11, 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 early- to mid-October 2018 for the 1 mg capsules, mid-October 2018 for the 2 mg capsules, late-October to early-November 2018 for the 5 mg capsules, and mid-November 2018 for the 10 mg capsules.
- Mylan Institutional has thiothixene 2 mg and 10 mg capsules in 100 count unit-dose blister packs on back order and the company estimates a release date of mid-November 2018 for the 2 mg capsules and early-January 2019 for the 10 mg capsules.

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

Sodium Bicarbonate Injection

September 11, 2018

Reason for the Shortage

- Amphastar has sodium bicarbonate injection available.[1]
- Pfizer has sodium bicarbonate injection on shortage due to manufacturing delays.[2]
- Fresenius Kabi has sodium bicarbonate injection temporarily available.[3]

Estimated Resupply Dates

- Pfizer has sodium bicarbonate 4.2% 10 mL LifeShield syringes, 7.5% 50 mL syringes, and 8.4% 50 mL syringes available in limited supply. The 8.4% 10 mL syringes are on back order and the company estimates a release ate of September 2018. The 8.4% 50 mL vials are on back order and the company estimates a release date of November 2018.[2]
- Pfizer has Neut 4% 5 mL vials on back order and the company estimates a release date of November 2018.[2]

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=293

Ranitidine Injection

September 11, 2018

Reason for the Shortage

- Teligent has Zantac IV on shortage due to production delays.
- Zydus has ranitidine injection available.

Estimated Resupply Dates

- Teligent has Zantac 25 mg/mL 2 mL and 40 mL (NDC 52565-0096-01) vials on back order and the company estimates a release date of 4th quarter 2018. Zantac 25 mg/mL 6 mL and 40 mL vials (NDC 24987-0364-01) are available but are short-dated.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=426

Potassium Phosphate Injection

September 11, 2018

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 has potassium phosphate injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has potassium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of November 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=305

Nitrofurantoin Oral Suspension

September 11, 2018

Reason for the Shortage

- Amneal has nitrofurantoin oral suspension available.
- Casper Pharma did not provide a reason for the Furadantin shortage.
- Lupin is no longer manufacturing this product.
- Nostrum is no longer manufacturing this product.
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates

- Casper has short-dated Furadantin suspension available with an expiration date of May 2019.
- Teva 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

Mitomycin Kit for Ophthalmic Use

September 11, 2018

Reason for the Shortage

- Mobias Therapeutics did not provide a reason for the shortage.

Estimated Resupply Dates

- Mobias Therapeutics states that it has Mitosol Kits available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=463

Ketamine Injection

September 11, 2018

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

- Mylan Institutional has ketamine 10 mg/mL 20 mL on back order and the company estimates a release date of mid- to late-September 2018. The 50 mg/mL 10 mL vials are on back order and the company estimates a release date of mid- to late-September 2018. The 100 mg/mL 10 mL vials are on back order and the company estimates a release date of late-January 2019.
- Pfizer has ketamine 50 mg/mL 10 mL vials and 100 mg/mL 5 mL vials on back order and the company estimates a release date of 2019.
- Hikma has ketamine 50 mg/mL 10 mL vials and 100 mg/mL 5 mL vials on allocation.
- Par has Ketalar 10 mg/mL 20 mL vials, 50 mg/mL 10 mL vials, and 100 mg/mL 5 mL vials on back order and the company estimates a release date of mid- to late-September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=391

Hydroxocobalamin Injection

September 11, 2018

Reason for the Shortage

- Meridian Medical Technologies reports that the shortage is due to manufacturing delays and increased demand.1

Estimated Resupply Dates

- Meridian Medical Technologies has hydroxocobalamin injection 5 gram vials on intermittent back order and the company estimates a release date of late-October/early-November 2018.1

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=446

Dexrazoxane Injection

September 11, 2018

Reason for the Shortage

- Cumberland Pharmaceuticals relaunched Totect in late-July 2017.
- Mylan Institutional has dexrazoxane available.
- Pfizer states manufacturing delay as the reason for the shortage.
- West-Ward has dexrazoxane available.

Estimated Resupply Dates

- Pfizer has Zinecard 250 mg vials available in limited supply. The 500 mg 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=107

Amiodarone Injection

September 11, 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.

Estimated Resupply Dates

- Fresenius Kabi has amiodarone 50 mg/mL 9 mL vials available with an expiration date of <8 months.
- Hikma has amiodarone 50 mg/mL 3 mL in 10 count available with an expiry of December 2018.
- Mylan Institutional has amiodarone 50 mg/mL 3 mL and 9 mL vials on back order and the company estimates a release date of late-September 2018 for the 3 mL vials and mid-September 2018 for the 9 mL vials.
- Sagent has 50 mg/mL 3 mL vials available with an expiry of February 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=374

Procainamide Hydrochloride Injection

September 12, 2018

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

- Pfizer has procainamamide 100 mg/mL 10 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=469

Ondansetron Hydrochloride Injection

September 12, 2018

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 has ondansetron on shortage due to increased demand.
- 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 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 and 20 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has ondansetron 2 mg/mL 20 mL vials on back order and the company cannot estimate release dates. The 2 mg/mL 2 mg/mL 2 mL prefilled syringes are on back order and the company estimates release dates of late-October 2018.
- Heritage has all ondansetron presentations on allocation.
- Hikma has ondansetron 2 mg/mL 20 mL vials in single count (NDC 00143-9890-01) and 10 count on allocation. The 2 mg/mL 20 mL vials (NDC 00641-6079-01) are on back order and the company estimates a release date of September to October 2018. The 2 mg/mL 2 mL vials are on back order and the company estimates a release date of September 2018.
- Mylan Institutional has ondansetron 2 mg/mL 20 mL vials on back order and the company cannot estimate a release date.
- Pfizer has ondansetron 2 mg/mL 2 mL vials on back order and the company estimates a release date of September 2018. The 2 mg/mL 20 mL vials are on back order and the company estimates a release date of November 2018. The 2 mg/mL 2 mL iSecure syringes are on back order and the company estimates a release date of 2019.
- Sagent has ondansetron 2 mg/mL 2 mL vials on back order and the company estimates a release date of October 2018. The 2 mg/mL 20 mL 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=405

Ketorolac Injection

September 12, 2018

Reason for the Shortage

- Alvogen did not provide a reason for the shortage.[1]
- Amphastar did not provide a reason for the shortage.[2]
- Athenex did not provide a reason for the shortage.[3]
- BD RX is now part of Fresenius Kabi.[4]
- Fresenius Kabi has most ketorolac presentations available.[5]
- Pfizer has ketorolac injection on back order due to manufacturing delays.[6]
- Sagent states the reason for the shortage is manufacturing delay.[7]
- Hikma did not provide a reason for the shortage.[8]
- Ben Venue closed its plant in Bedford, Ohio in July 2014.[9]
- Virtus has ketorolac injection available.[10]
- FDA imposed an import ban in mid-2013 on several Wockhardt products including ketorolac.[11]
- Sprix Nasal Spray is not affected by this shortage.[12]

Estimated Resupply Dates

- Alvogen has 15 mg/mL 1 mL vials and 30 mg/mL 1 mL vials on back order with unknown release dates.1
- Amphastar has ketorolac 30 mg/mL 1 mL vials on back order and the company cannot estimate a release date.[2]
- Athenex has ketorolac 15 mg/mL 1 mL vials on back order and the company estimates a release date of October 2018.[3]

- Fresenius Kabi has ketorolac 30 mg/mL 1 mL prefilled syringes available with short expiration dating (< 7 months).[5]
- 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 2019.[6]
- Sagent has ketorolac 15 mg/mL 1 mL vials, 30 mg/mL 1 mL vials, and 30 mg/mL 2 mL vials for intramuscular injection on back order and the company cannot estimate a release date.[7]
- Hikma has ketorolac 15 mg/mL and 30 mg/mL 1 mL vials on back order and the company estimates a release date of mid-September 2018.[8]

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=113

Hepatitis B Vaccine (Recombinant)

September 12, 2018

Reason for the Shortage

- Merck has Recombivax HB on shortage due to increase in global demand.
- 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 2018.
- Merck has Recombivax HB pediatric/adolescent formulation syringes and pediatric/adolescent vials on back order and the company estimates this will continue through 2018. 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 2018.

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

Hepatitis A Virus Vaccine Inactivated

September 12, 2018

Reason for the Shortage

- Merck did not provide a reason for the Vaqta shortage.
- GlaxoSmithKline has Havrix available.
- GlaxoSmithKline discontinued the Havrix adult vials in November 2017.

Estimated Resupply Dates

- 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

Estradiol Valerate Injection

September 12, 2018

Reason for the Shortage

- Perrigo did not provide a reason for the shortage.

Estimated Resupply Dates

- Perrigo has estradiol valerate 40 mg/mL 5 mL vials available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=424

Diclofenac 0.1% Ophthalmic Solution

September 12, 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.
- Sandoz has diclofenac 0.1% ophthalmic solution in 2.5 mL bottles on back order and the company estimates a release date of mid-September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=395

Atenolol and Chlorthalidone Tablets

September 12, 2018

Reason for the Shortage

- Almatica Pharma did not provide a reason for the shortage.
- Mylan has discontinued the production of atenolol/chlorthalidone tablets.

Estimated Resupply Dates

- Almatica Pharma has atenolol/chlorthalidone (Tenoretic) 50 mg/25 mg tablets on back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=449

5% Dextrose Injection

September 12, 2018

Reason for the Shortage

- Baxter has 5% dextrose injection available.
- ICU Medical states the shortage is due to increased demand.
- Pfizer states that the shortage is due to increased demand.
- ICU Medical is now the IV fluid business of Pfizer after the acquisition of Hospira. Pfizer continues to market the ADD-vantage product.

Estimated Resupply Dates

- Pfizer has 5% dextrose 250 mL ADD-Vantage bags available in limited supply.
- ICU Medical has 5% dextrose 250 mL 2 port bags on back order and the company cannot estimate a release date.

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

2% Lidocaine Hydrochloride Topical Jelly

September 12, 2018

Reason for the Shortage

- Akorn has 2% lidocaine jelly on shortage due to increased demand.
- Teva discontinued lidocaine jelly in early-2018.
- Glydo and Uro-Jet prefilled syringes are not affected by this shortage.

Estimated Resupply Dates

- Akorn has 2% lidocaine jelly 5 mL and 30 mL tubes on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=400

Octreotide Injection

September 13, 2018

Reason for the Shortage

- Fresenius Kabi has octreotide available.
- Mylan Institutional has octreotide available.
- Sagent has octreotide on shortage due to manufacturing delays.
- 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.
- Hikma did not provide a reason for the shortage.

Estimated Resupply Dates

- Fresenius Kabi has octreotide 50 mcg/mL 1 mL vials on back order and the company cannot estimate a release date.
- Hikma has all presentations available but with short expiration dating.
- Sagent has 500 mcg/mL 1 mL vials on back order and the company estimates a release date of October 2018.
- 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

Indomethacin Capsules

September 13, 2018

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 in 100 count on back order and the company estimates a release date of mid-September 2018.
- Glenmark has indomethacin 50 mg capsules in 100 count and 500 count capsules on back order and the company estimates a release date of September 2018. The 25 mg capsules in 1000 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=235

Fluorescein Sodium Ophthalmic Strips

September 13, 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 cannot estimate a release date. 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

Cefazolin Injection

September 13, 2018

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 most cefazolin products available.
- 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 back order and the company estimates a release date of mid-September 2018.
- Fresenius Kabi has cefazolin 500 mg vials and 1 gram vials on back order and the company estimates a release date of mid- to late-November 2018. The 20 gram bulk vials are on back order and the company cannot estimate a release date. The 10 gram vials are available with an expiration date of <2 months.
- Pfizer has 1 gram and 10 gram vials on back order and the company estimates a release date of 2019.

- Sagent has cefazolin 500 mg, 1 gram, and 10 gram vials on back order and the company estimates a release date of December 2018 for the 500 mg vials, October 2018 for the 1 gram vials, and September 2018 for the 10 gram vials.
- Sandoz has cefazolin 500 mg and 1 gram vials on back order and the company estimates a release date of mid- to late-September 2018.
- Hikma has cefazolin 500 mg and 1 gram vials on allocation. The 10 gram vials are on back order and the company estimates a release date of mid-September 2018.
- WG Critical Care has cefazolin 1 gram vials on intermittent back order and the company is releasing product as it becomes available. The 10 gram vials are on back order and the company estimates a release date of October 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=432

Alpha-1 Proteinase Inhibitor

September 13, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- CSL Behring has Zemaira 1 mg vials available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=452

Methylphenidate Extended-Release Oral Suspension and Chewable Tablets

September 14, 2018

Reason for the Shortage

- Pfizer has Quillivant XR on shortage due to manufacturing delays.
- Pfizer has QuillChew ER chewable tablets available.

Estimated Resupply Dates

- Pfizer has Quillivant XR 5 mg/mL extended-release oral suspension in 60 mL bottles, 120 mL bottles, 150 mL bottles, and 180 mL bottles on back order and the company cannot estimate a release date. There is limited supply of short-dated 180 mL bottles with an expiration date of March 2019.

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

Ropivacaine Injection

September 16, 2018

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 2 mg/mL 100 mL premixed bags on back order and the company estimates a release date of mid-October 2018.The 2 mg/mL 20 mL vials are on back order and the company estimates a release date of late-September 2018. The 5 mg/mL 30 mL Steripak ampules are on back order and the company estimates a release date of late-October 2018. The 5 mg/mL 100 mL bottles are on back order and the company estimates a release date of early-October 2018. Check wholesalers for inventory.

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

Pyridoxine Hydrochloride Injection

September 16, 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 on back order and the company estimates a release date of late-September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=450

Protamine Injection

September 16, 2018

Reason for the Shortage

- Fresenius Kabi has protamine on a short-term shortage due to increased demand.

Estimated Resupply Dates

- Fresenius Kabi has protamine 10 mg/mL 5 mL and 25 mL vials on back order and the company estimates a release date of mid- to late-September 2018. Check wholesalers for inventory.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=453

Promethazine Injection

September 16, 2018

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 September 2018. The 25 mg/mL 1 mL vials are on allocation. The 50 mg/mL 1 mL ampules are on back order and the company estimates a release date of late-September to mid-October 2018. There are short-dated 50 mg/mL 1 mL vials available with an expiration date of August 2019.
- Hikma has Phenergan 25 mg/mL 1 mL vials on back order and the company estimates a release date of mid-September 2018. The 25 mg/mL 1 mL ampules are on back order and the company

estimates a release date of late-September to mid-October 2018. There are short-dated 25 mg/mL 1 mL vials available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=460

Nalbuphine Injection

September 16, 2018

Reason for the Shortage

- Pfizer has nalbuphine or shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has nalbuphine 20 mg/mL 1 mL ampules available in limited supply. The 10 mg/mL 10 mL vials are on back order and the company estimates a release date of October 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=409

Morphine Injection

September 16, 2018

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.[1-2]
- Astramorph injection has been unavailable since 2012. Fresenius Kabi changed manufacturing sites and cannot estimate if Astramorph will return.[2]
- Pfizer states the shortage is due to manufacturing delays. Pfizer discontinued morphine ADD-Vantage vials in January 2017.[3]
- Pfizer anticipates 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. Pfizer expects the shortage of prefilled syringe products to recover by late-first quarter 2018.[3]
- Hikma did not provide a reason for the shortage. West-Ward is not actively marketing the 15 mg/mL 1 mL vials or the 8 mg/mL 1 mL vials (NDC 00641-6075-25). They are still marketing the 8 mg/mL 1 mL vials with NDC 00641-6126-25.[4]

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- to mid-October 2018. The morphine 4 mg/mL 1 mL syringes are on back order and the company estimates a release date of 1st quarter 2019. The morphine 5 mg/mL 1 mL syringes are on back order and the company cannot estimate a release date. The 2 mg/mL 1 mL vials are on back order and the company estimates a release date of mid-to late-September 2018. The 5 mg/mL 1 mL vials and 8 mg/mL 1 mL vials are on back order and the company cannot estimate a release date. The 10 mg/mL 1 mL vials are on back order and the company cannot estimate a release date. Check wholesalers for inventory.[2]
- Pfizer has morphine 2 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of early-October 2018. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company cannot estimate a release date. The 2 mg/mL 1 mL iSecure syringes, 4 mg/mL 1 mL iSecure syringes, 8 mg/mL 1 mL Carpuject syringes, 8 mg/mL 1 mL iSecure syringes, 10 mg/mL 1 mL iSecure syringes, and 10 mg/mL 1 mL Carpuject syringes are on back order and the

company estimates a release date of June 2019. The 50 mg/mL 50 mL vials are on back order and the company estimates a release date of October 2018.[3]
- Hikma has morphine 4 mg/mL, 8 mg/mL, and 10 mg/mL 1 mL vials on allocation. Infumorph 10 mg/mL 20 mL ampules and 25 mg/mL 20 mL ampules are on back order and the company cannot estimate a release date. Duramorph 1 mg/mL 10 mL ampules are on allocation. Duramorph 0.5 mg/mL 10 mL ampules are on allocation.[4]

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=41

Metoclopramide Injection

September 16, 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 late-October 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=338

Lidocaine with Epinephrine Injection

September 16, 2018

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 early- to mid-October 2018. The 1% Xylocaine with epinephrine (1:200,000) 10 mL vials is on back order and the company estimates a release date of early- to mid-October 2018. The 1% Xylocaine with epinephrine (1:200,000) 20 mL vials are on back order and the company estimates release dates of late-September 2018. The 1% Xylocaine with epinephrine (1:200,000) 50 mL vials is on back order and the company estimates release dates of mid- to late-September 2018. 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-September 2018. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs is 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 is 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 and 30 mL vials are on back order and the company estimates a release date of early-November 2018 for the 10 mL vials and early- to mid-October 2018 for the 30 mL vials. The 2% Xylocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates a release date of mid-October 2018. The 2% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials are on back order and the company estimates a release date of early-October 2018. 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 0.5% lidocaine with epinephrine (1:200,000) 50 mL vials on back order and the company estimates a release date of 1st quarter 2019. The 1% lidocaine with epinephrine (1:100,000) 30 mL and 50 mL vials are on back order and the company estimates a release date of September 2018. The 1% lidocaine with epinephrine (1:100,000) 20 mL vials are on back order and the company estimates a release date of October 2018.The 1.5% lidocaine with epinephrine (1:200,000) 30 mL vials are on back order and the company estimates a release date of November 2018. The 1.5% lidocaine with epinephrine (1:200,000) 5 mL ampules are on back order and the company estimates a release date of 2019. The 2% lidocaine with epinephrine (1:100,000) 20 mL vials are available in limited supply. 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 November 2018 for the 30 mL vials and October 2018 for the 50 mL vials. The 2% lidocaine with epinephrine (1:200,000) 20 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=98

Lidocaine Injection

September 16, 2018

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

- AuroMedics has 1% lidocaine 2 mL and 5 mL ampules and 2 mL, 5 mL, and 30 mL vials on intermittent back order and the company is releasing product as it becomes available. AuroMedics has 2% lidocaine 2 mL ampules and 2 mL and 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 0.5% Xylocaine 50 mL MPF vials are on back order and the company estimates a release date of late-September 2018. The 1% lidocaine 2 mL and 10 mL vials are on back order and the company estimates a release date of late-October 2018 for the 2 mL vials and mid-October 2018 for the 10 mL vials. The 1% Xylocaine 20 mL and 50 mL vials are on back order and the company estimates a release date of late-September 2018. The 1% Xylocaine-MPF 2 mL, 5 mL, and 30 mL vials are on back order and the company estimates a release date of mid- to late-September 2018 for the 2 mL and 5 mL vials and early-October 2018 for the 30 mL vials. The 1% Xylocaine-MPF 10 mL vial sterile packs are on back order and the company estimates a release date of early-October 2018. The 1% Xylocaine-MPF 30 mL vial sterile packs are on back order and the company cannot estimate a release date. The 2% Xylocaine 10 mL, 20 mL, and 50 mL vials are on back order and the company estimates a release date of late-October 2018 for the 10 mL vials, early-October 2018 for the 20 mL vials, and mid-October 2018 for the 50 mL vials. The 2% Xylocaine-MPF 2 mL and 5 mL vials are on back order and the company estimates a release date of early-October 2018 for the 2 mL vials and late-September 2018 for the 5 mL

vials. The 2% Xylocaine-MPF 10 mL ampules are on back order and the company estimates a release date of early-October 2018.The 2% lidocaine 5 mL preservative free vials are on back order and the company estimates a release date of mid- to late-September 2018. The 2% lidocaine 2 mL vials are on back order and the company estimates a release date of late-October to early-November 2018. Check wholesalers for inventory.

- Pfizer has 0.5% lidocaine 50 mL tear top vials on back order and the company estimates a release date of December 2018. The 0.5% lidocaine flip top vials are on back order and the company estimates a release date of February 2019. The 1% lidocaine 2 mL preservative-free ampules on back order and the company estimates a release date of October 2018. The 1% lidocaine 5 mL preservative-free ampules are on back order and the company estimates a release date of 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 October 2018. The 1% lidocaine 50 mL vials are on back order and the company estimates a release date of October 2018. The 1% lidocaine 5 mL Lifeshield syringes are on back order and the company estimates a release date of December 2018. The 1% lidocaine 5 mL Ansyr syringes are on back order and the company estimates a release date of November 2018.The 2% lidocaine 2 mL preservative-free ampules are on back order and the company estimates a release date of September 2018. The 2% lidocaine 10 mL ampules are on back order and the company estimates a release date of September 2018. The 2% lidocaine 5 mL vials are on back order and the company estimates a release date of 2019. The 2% lidocaine 20 mL and 50 mL vials are on back order and the company estimates a release date of September 2018 for the 20 mL vials and October 2018 for the 50 mL vials. The 2% lidocaine 5 mL Lifeshield syringes are on back order and the company estimates a release date of December 2018. The 2% lidocaine 5 mL Ansyr syringes are on back order and the company estimates a release date of September 2018. The 4% lidocaine 5 mL ampules are on back order and the company estimates a release date of December 2018.
- Hikma has 1% lidocaine 5 mL preservative-free vials on back order and the company estimates a release date of late-September to mid-October 2018. The 1% lidocaine 50 mL vials are on allocation. The 2% lidocaine 5 mL preservative-free vials are on back order and the company estimates a release date of late-September to mid-October 2018. The 2% lidocaine 50 mL vials are on back order and the company estimates a release date of October to November 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=88

Hydralazine injection

September 16, 2018

Reason for the Shortage

- Akorn has product on back order due to increased demand.
- American Regent did not provide a reason for the shortage.
- 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 cannot estimate a release date.
- American Regent has hydralazine 20 mg/mL 1 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of mid- to late-September 2018.

- X-Gen has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of late-September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=431

Dexamethasone Sodium Phosphate Injection

September 16, 2018

Reason for the Shortage

- American Regent has dexamethasone sodium phosphate on shortage due to manufacturing delays.
- 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

- American Regent has dexamethasone sodium phosphate 4 mg/mL products on back order and the company cannot estimate a release date.
- 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.
- Fresenius Kabi has dexamethasone sodium phosphate 4 mg/mL 1 mL prefilled syringes on back order and the company estimates a release date of 4th quarter 2018. The 10 mg/mL 1 mL preservative-free vials are on back order and the company estimates a release date of mid- to late-September 2018. The 10 mg/mL 10 mL vials are on back order and the company estimates a release date of mid- to late-September 2018. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of mid- to late-September 2018.
- 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. The 10 mg/mL 1 mL vials are on back order and the company estimates a release date of early-September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=140

Deferoxamine Injection

September 16, 2018

Reason for the Shortage

- Fresenius Kabi has deferoxamine on shortage due to increased demand.
- Pfizer has deferoxamine on shortage due to manufacturing delays.
- Novartis has Desferal on shortage due to increased demand.
- Alvogen launched deferoxamine injection in mid-2018.
- Apo-Pharma launched deferoxamine injection in mid-2018.

Estimated Resupply Dates

- Pfizer has deferoxamine 500 mg and 2 gram vials on back order and the company estimates a release date of September 2018 for the 500 mg vials and November 2018 for the 2 gram vials.
- Novartis has Desferal 500 mg vials on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=393

Chloroprocaine Hydrochloride Injection

September 16, 2018

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

- Hikma has chloroprocaine hydrochloride 20 mg/mL 20 mL preservative-free vials and 30 mg/mL 20 mL preservative-free vials on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=455

Calcium Gluconate Injection

September 16, 2018

Reason for the Shortage

- American Regent has calcium gluconate on shortage due to manufacturing delays.
- Fresenius Kabi has calcium gluconate available with alternating short-dating due to manufacturing process of the vials.

Estimated Resupply Dates

- American Regent has calcium gluconate 100 mg/mL 50 mL and 100 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has calcium gluconate 100 mg/mL 10 mL, 50 mL, and 100 mL vials on back order and the company estimates a release date of late-September 2018. Check wholesalers for inventory.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=150

Bupivacaine with Epinephrine Injection

September 16, 2018

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 mid- to late-September 2018. The 0.25% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of mid- to late-September 2018. The 0.25% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of mid- to late-September 2018. The 0.5% Sensorcaine-MPF with epinephrine 10 mL vials are on back order and the company estimates a release date of early-October 2018. The 0.5% Sensorcaine-MPF with epinephrine 30 mL sterile packs is on back order and the company cannot estimate a release date. The 0.5% Sensorcaine with epinephrine 50 mL vials is on back order and the company estimates a release date of mid- to late-September 2018.

- 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 2019. The 0.25% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 2019. The 0.5% bupivacaine with epinephrine 10 mL preservative-free vials are on back order and the company estimates a release date of 2019. The 0.5% bupivacaine with epinephrine 30 mL preservative-free vials are on back order and the company estimates a release date of October 2018. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 2019.
- Pfizer has 0.25% Marcaine with epinephrine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of 2019. The 0.25% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 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 2019. The 0.5% Marcaine with epinephrine 50 mL vials are 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=261

Remifentanil Injection

September 17, 2018

Reason for the Shortage

- Mylan Institutional did not provide a reason for the shortage.
- Fresenius Kabi launched generic remifentanil in January 2018.

Estimated Resupply Dates

- Mylan Institutional has Ultiva 1 mg, 2 mg, and 5 mg vials on back order and the company estimates a release date of mid-October 2018 for the 1 mg and 2 mg vials and mid-November 2018 for the 5 mg vials.
- Fresenius Kabi has remifentanil 1 mg, 2 mg, and 5 mg vials on back order and the company estimates a release date of late-September for the 1 mg and 2 mg vials and cannot estimate a release date for the 5 mg vials.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=371

Orphenadrine Citrate Injection

September 17, 2018

Reason for the Shortage

- Akorn did not provide a reason for the shortage.
- Hikma did not provide a reason for the shortage.

Estimated Resupply Dates

- Akorn has orphenadrine 30 mg/mL 2 mL vials on back order and the company cannot estimate a release date.
- Hikma has orphenadrine 30 mg/mL 2 mL vials on back order and the company estimates a release date of late-September to mid-October 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=471

Indocyanine Green

September 17, 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

Granisetron Hydrochloride Injection

September 17, 2018

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 granisetron 1 mg/mL 1 mL and 4 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has granisetron injection 1 mg/mL 4 mL vials on back order and the company estimates a release date of late-September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=428

Fentanyl Citrate Injection

September 17, 2018

Reason for the Shortage

- Akorn has fentanyl injection on shortage due to increased demand.
- Hikma has fentanyl injection on shortage due to supply and demand issues.
- 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 ampules in 10 count and 25 count, and 5 mL ampules in 10-count and 25-count on allocation.
- Hikma has fentanyl 50 mcg/mL 2 mL, 20 mL, and 50 mL vials on allocation. The 5 mL vials are on back order and the company estimates a release date of September 2018. The 2 mL, 5 mL, and 20 mL ampules are on back order and the company cannot estimate a release date.
- Pfizer has fentanyl 50 mcg/mL 2 mL ampules on back order and the company estimates a release date of October 2018. The 5 mL ampules are on back order and the company estimates a release date of early-September 2018. The 2 mL Carpuject syringes are on back order and the company estimates a release date of June 2019. The 2 mL and 20 mL vials are on back order and the company estimates a release date of September 2018 for the 2 mL vials and mid-October 2018 for the 20 mL vials. The 5 mL and 50 mL vials are available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=315

Bupivacaine Injection

September 17, 2018

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 mid- to late-September 2018. The 0.25% 30 mL preservative-free vials are on back order and the company estimates a release date of mid- to late-September 2018. The 0.25% 50 mL vials are on back order and the company estimates a release date of early-October 2018. The 0.5% Sensorcaine 10 mL preservative-free vials are on back order and the company estimates release dates of late-September 2018. The 0.5% Sensorcaine 30 mL preservative-free vials are on back order and the company estimates release dates of late-October to early-November 2018. The 0.5% Sensorcaine 50 mL vials are on back order and the company estimates a release date of late-September 2018. The 0.75% 10 mL preservative-free vials are on back order and the company estimates a release date of mid-November 2018. The 0.75% 30 mL preservative-free vials are on back order and the company estimates a release date of early-October 2018. 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 November 2018 for the 10 mL vials and December 2018 for the 30 mL vials. The 0.25% bupivacaine 50 mL vials are on back order and the company estimates release dates of October 2018. The 0.5% bupivacaine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of December 2018 for the 10 mL vials and September 2018 for the 30 mL vials. The 0.5% bupivacaine 50 mL vials are on back order and the company estimates a release date of December 2018. The 0.75% bupivacaine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of December 2018 for the 10 mL vials and November 2018 for the 30 mL vials. The bupivacaine 0.75% in 8.25% dextrose 2 mL ampules are on back order and the company estimates a release date of October 2018.
- Pfizer has all Marcaine presentations on back order and the company estimates a release date of 2019 except for the Marcaine 0.75% in 8.25% dextrose 2 mL ampules are on back order and the company estimates a release date of October 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=172

Ampicillin Sodium and Sulbactam Sodium Injection

September 17, 2018

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 and 3 gram vials on back order and the company estimates a release date of October to November 2018 for the 1.5 gram vials and late-September to mid-October 2018 for the 3 gram vials.
- Mylan Institutional has ampicillin sulbactam 15 gram vials on back order and the company estimates a release date of late-October 2018.
- Pfizer has Unasyn 3 gram ADD-Vantage vials available in limited supply. The 1.5 gram vials, 3 gram vials, and 15 gram bulk vials are on back order and the company estimates a release date of October 2018.
- 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 November 2018 for the 1.5 gram vials and January 2019 for the 3 gram vials.
- WG Critical Care has ampicillin sulbactam 3 gram and 15 gram vials on back order and the company estimates a release date of late-September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=159

Aminocaproic Acid Injection

September 17, 2018

Reason for the Shortage

- Pfizer has aminocaproic acid on shortage due to manufacturing delays. [1]

Estimated Resupply Dates

- Pfizer has aminocaproic acid 250 mg/mL 20 mL vials available in limited supply.[1]

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=346

Albuterol Inhalation Solution

September 17, 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 back order and the company cannot estimate a release date.

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

23.4% Sodium Chloride Injection

September 17, 2018

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 mL, and 200 mL vials on back order and the company estimates a release date of early- to mid-September 2018 for the 30 mL vials and late-September 2018 for the 100 mL and 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 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=336

Sodium Phosphate Injection

September 18, 2018

Reason for the Shortage

- American Regent has sodium phosphate injection on shortage due to manufacturing delay.[1]
- Fresenius Kabi states the reason for the shortage is increased demand.[2]
- Pfizer has sodium phosphate injection on shortage due to manufacturing delay.[3]

Estimated Resupply Dates

- American Regent has sodium phosphate 3 mmol/mL 5 mL, 15 mL, and 50 mL vials on back order and the company cannot estimate a release date.[1]
- Fresenius Kabi has sodium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of early- to mid-October 2018.[2]
- Pfizer has sodium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of 2019.[3]

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=227

Potassium Acetate Injection

September 18, 2018

Reason for the Shortage

- American Regent has not had product available for several years. It is unclear if they will market potassium acetate again in the future.
- Pfizer has potassium acetate on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has potassium acetate 2 mEq/mL 50 mL vials available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=344

Polyvinyl Alcohol (Artificial Tears) Ophthalmic Solution

September 18, 2018

Reason for the Shortage

- Akorn did not provide a reason for the shortage.
- Altaire is planning to launch Activeyes polyvinyl alcohol drops in November 2018.
- 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

- Rugby has Artificial Tears ophthalmic drops on back order and the company cannot estimate a release date.
- 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.
- Altaire plans to launch Activeyes polyvinyl alcohol ophthalmic drops in November 2018.
- Ocusoft has Tears Again ophthalmic drops in 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=451

Penicillin G Procaine Injection

September 18, 2018

Reason for the Shortage

- Pfizer has 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 on back order and the company estimates a release date of November 2018 for the 1 mL syringes and September 2018 for the 2 mL syringes.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=240

Melphalan Tablets

September 18, 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

Fluorouracil Injection

September 18, 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 has fluorouracil injection on shortage due to manufacturing delays.
- Teva has fluorouracil injection on allocation due to increased demand.

Estimated Resupply Dates

- Accord has fluorouracil 50 mg/mL 100 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has fluorouracil 50 mg/mL 50 mL vials on back order and the company estimates a release date of mid- to late-September 2018.
- Sagent has fluorouracil 50 mg/mL 100 mL vials on allocation.
- Teva has Adrucil 50 mg/mL 10 mL, 50 mL, and 100 mL vials on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=401

Buspirone Tablets

September 18, 2018

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

- Mylan Institutional has buspirone 5 mg tablets in 100 count unit-dose packs on back order and the company estimates a release date of early-December 2018. The 15 mg tablets in 100 count unit-dose packs are on back order and the company cannot estimate a release date.
- Mylan has all buspirone presentations in bottles on back order and the company cannot estimate a release date.
- Teva has buspirone 5 mg tablets in 100 count on back order and the company estimates a release date of early-October 2018. The 5 mg tablets in 500 count, 10 mg in 500 count, and 30 mg in count are on back order and the company estimates a release date of late-October 2018. The 15 mg in 100 count are back order and the company estimates a release date of early-October 2018.

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

Amino Acids in Dextrose

September 18, 2018

Reason for the Shortage

- Baxter had all Clinimix presentations on allocation due to delays because of the hurricane in Puerto Rico.
- Baxter is not currently marketing the following presentations: Clinimix 4.25%/20% 2000 mL bags, Clinimix 4.25%/25% 1000 and 2000 mL bags, and Clinimix 5%/25% 2000 mL bags.

Estimated Resupply Dates

- Baxter has Clinimix presentations available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=355

Amino Acid Products with Electrolytes and Calcium

September 18, 2018

Reason for the Shortage

- Baxter had Clinimix E with electrolytes plus calcium presentations on allocation due to delays because of the hurricane in Puerto Rico.
- To help alleviate the critical drug shortages resulting from the aftermath of Hurricane Maria, FDA has allowed Baxter to temporarily import the following amino acid products: Clinimix N9G15E, Clinimix N9G20E, and Clinimix N14G30E solutions for infusion. Additional information can be found in the Dear Healthcare Professional Letter. https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM584414.pdf

Estimated Resupply Dates

- N/A

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=354

Magnesium Sulfate Injection

September 19, 2018

Reason for the Shortage

- American Regent has had magnesium sulfate 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 has magnesium sulfate injection on shortage due to increased demand for the product.

Estimated Resupply Dates

- Fresenius Kabi has magnesium sulfate 500 mg/mL 2 mL, 10 mL, 20 mL and 50 mL vials on back order and the company estimates a release date of early- to mid-October 2018 for the 2 mL vials and 10 mL vials, mid- to late-September 2018 for the 20 mL vials and 50 mL vials. The 40 mg/mL 50 mL, 100 mL, and 500mL premixed bags are on back order and the company estimates a release date of mid- to late-September 2018 for the 50 mL and 100 mL premixed bags and mid- to late-November 2018 for the 500 mL premixed bags. The 80 mg/mL 50 mL premixed bags are on back order and the company estimates a release date of mid- to late-November 2018. The 10 mg/mL 100 mL premixed bags are on back order and the company estimates a release date of mid- to late-September 2018.
- 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 of November 2018. The magnesium sulfate 10 mg/mL 100 mL bags are on back order and the company estimates a release date of October 2018. The magnesium sulfate 40 mg/mL 50 mL, 100 mL, 500 mL, and 1000 mL bags are on back order and the company estimates a release date of October 2018 for the 50 mL bags, November 2018 for the 100 mL

and 500 mL bags, and September 2018 for the 1000 mL bags. The 80 mg/mL 50 mL bags are on back order and the company estimates a release date of December 2018.
- WG Critical Care has magnesium sulfate 40 mg/mL 50 mL premixed bags on back order and the company estimates a release date of October 2018. Check wholesalers for inventory.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=21

Alcohol Dehydrated Injection (Ethanol)

September 19, 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

Vancomycin Hydrochloride Injection

September 20, 2018

Reason for the Shortage

- Alvogen has vancomycin injection available.[1]
- Athenex has vancomycin injection available.[2]
- Pfizer has vancomycin vials on back order due to manufacturing delays.[3]
- Fresenius Kabi has vancomycin injection on shortage due to increased demand.[4]
- Mylan Institutional has vancomycin injection available.[5]
- Sagent has vancomycin injection on shortage due to manufacturing delays and increased demand.[8]
- Baxter has vancomycin injection available.[6]
- Samson Medical Technologies has vancomycin injection available.[7]

Estimated Resupply Dates

- Fresenius Kabi has vancomycin 5 gram and 10 gram vials on intermittent back order with regular releases. The 750 mg vials are on back order and the company estimates a release date of early-October 2018.
- Pfizer has vancomycin 500 mg vials, 500 mg ADD-Vantage vials, and 1 gram vials available in limited supply. The 750 mg vials are on back order and the company estimates release dates of October 2018. The 5 gram vials are on back order and the company estimates release dates of October 2018. The 750 mg ADD-Vantage vials are on back order and the company estimates a release date of November 2018. The 1 gram ADD-Vantage vials are on back order and the company estimates a release date of October 2018. The 10 gram vials are on back order and the company cannot estimate a release date.
- Sagent has vancomycin 5 gram and 10 gram vials on back order and the company estimates release dates of September 2018 for the 5 gram vials and October 2018 for the 10 gram vials.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=25

Sodium Polystyrene Sulfonate Oral or Rectal Suspension

September 20, 2018

Reason for the Shortage

- CMP Pharma did not provide a reason for the shortage.
- 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 did not provide a reason for the shortage.

Estimated Resupply Dates

- Hikma has sodium polystyrene sulfonate suspension in 60 ml and 120 mL bottles on back order and the company cannot estimate a release date. The 500 mL bottles are on allocation.
- CMP Pharma has SPS Suspension 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=430

Rosuvastatin Calcium Tablets

September 20, 2018

Reason for the Shortage

- Aurobindo, Biocon, Glenmark, Mylan, Sandoz, and Rising did not provide a reason for the shortage.

Estimated Resupply Dates

- Aurobindo has rosuvastatin tablets on back order and the company estimates a release date in mid-September 2018.
- Biocon has rosuvastatin tablets in limited supply.
- Glenmark has rosuvastatin 5 mg tablets on back order and the company estimates a release date in late-September 2018. The 10 mg and 20 mg tablets are on back order and the company estimates a release date in early-October 2018. The 40 mg tablets are on back order and the company estimates a release date in late-September to early-October 2018.
- Mylan has rosuvastatin tablets on back order and the company cannot estimate a release date.
- Rising has rosuvastatin 5 mg tablets in 90 count bottles on allocation. The 10 mg tablets in 90 count and 40 mg in 30 count and 90 count are on back order and the company estimates a release date in September 2018. The 20 mg tablets in 90 count bottles are on back order and the company cannot estimate a release date.
- Sandoz has rosuvastatin tablets on back order and the company estimates a release date in mid-October 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=473

Piperacillin and Tazobactam Injection

September 20, 2018

Reason for the Shortage

- Apotex temporarily discontinued piperacillin/tazobactam in April 2018.

- AuroMedics and Sandoz 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.
- Sandoz has piperacillin/tazobactam available.
- 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.
- Auromedics has piperacillin/tazobactam 3.375 gram vials on intermittent back order and the company is releasing supplies as they become available.
- Baxter has Zosyn frozen premixed bags on allocation with intermittent delivery of product.
- 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. Pfizer has piperacillin/tazobactam 2.25 gram vials on back order and the company estimates a release date of November 2018.
- Mylan has piperacillin/tazobactam 3.375 gram vials on back order and the company estimates a release date in late-September 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=158

Penicillamine

September 20, 2018

Reason for the Shortage

- Mylan did not provide a reason for the shortage.

Estimated Resupply Dates

- Mylan has Depen tablets available for emergency drop shipment only. The company estimates that more supply will be available mid-March 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=379

Hydromorphone Hydrochloride Injection

September 20, 2018

Reason for the Shortage

- Akorn has hydromorphone injection on shortage due to increased demand.[1]

- Fresenius Kabi has Dilaudid syringes on shortage due to increased demand. They are focusing their product on the 0.5 mg strength. The launched hydromorphone vials in late-June 2018.[2]
- Pfizer did not provide a reason for the shortage.[3]
- Purdue discontinued Dilaudid and Dilaudid HP in May 2017 for marketing reasons.[4]
- Teva did not provide a reason for the shortage.[5]
- Hikma did not provide a reason for the shortage.[6]

Estimated Resupply Dates

- Akorn has hydromorphone 10 mg/mL 1 mL ampules, 5 mL ampules, and 50 mL vials on intermittent back order and the company is allocating product upon release.[1]
- Fresenius Kabi has Dilaudid 1 mg/mL 0.5 mL syringes on back order and the company estimates a release date of early-October 2018. The 1 mg/mL 1 mL syringes are on back order and the company estimates a release date of late-September 2018. 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, 2 mg/mL 1 mL vials, and 10 mg/mL 1 mL vials are on back order and the company estimates a release date of mid- to late-September 2018. The hydromorphone 4 mg/mL 1 mL vials and 10 mg/mL 5 mL vials are on back order and the company cannot estimate a release date.[2]
- Hikma has hydromorphone 2 mg/mL 20 mL vials on back order and the company estimates a release date of early- to mid-October 2018.[6]
- Pfizer has 2 mg/mL 1 mL vials on back order and the company estimates a release date of September 2018. The 10 mg/mL 1 mL vials are on back order and the company estimates a release date of late-September 2018. The 10 mg/mL 5 mL vials are on back order and the company estimates a release date of mid-October 2018. The 1 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of early-October 2018. The 10 mg/mL 50 mL vials and 0.5 mg/0.5 mL 0.5 mL iSecure syringes are on back order and the company estimates a release date of March 2019. The 2 mg/mL 1 mL Carpuject syringes, 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 cannot estimate a release date. The 1 mg/mL 1 mL iSecure syringes, 2 mg/mL 1 mL iSecure syringes, 2 mg/mL 1 mL, and 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of June 2019.[3]
- Teva has hydromorphone 10 mg/mL 1 mL, 5 mL, and 50 mL vials on intermittent back order and the company is allocating product upon release.[5]

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=329

Fluconazole Injection

September 20, 2018

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.
- Renaissance Lakewood Pharmaceuticals bought fluconazole in sodium chloride premixed bags from Claris Lifescience.
- Sagent has new NDC numbers for fluconazole in sodium chloride premixed bags.

Estimated Resupply Dates

- Baxter has 200 mg/100 mL in 0.9% sodium chloride on back order and the company cannot estimate a release date. The 400 mg/200 mL in 0.9% sodium chloride premixed bags are on allocation.
- 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 in November 2018. The 200 mg/100 mL in 5% dextrose is on back order and the company cannot estimate a release date.
- Renaissance Lakewood has all fluconazole injection presentations on back order. The company plans to launch fluconazole injection with new NDC numbers in October or November 2018.
- Sagent has fluconazole injection 400 mg/200 mL in 0.9% sodium chloride on back order and the company has an estimated release date of October 2018. The 200 mg/100 mL in 0.9% sodium chloride is on allocation.

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

Diphenhydramine Injection

September 20, 2018

Reason for the Shortage

- Pfizer has diphenhydramine injection on shortage due to manufacturing delays.
- Hikma did not provide a reason for the shortage.
- Fresenius Kabi has diphenhydramine injection on shortage due to a short-term manufacturing delay.

Estimated Resupply Dates

- Fresenius Kabi has diphenhydramine 50 mg/mL 1 mL vials on back order and the company estimates a release date of September 2018. The 50 mg/mL 1 mL syringes are on back order and the company cannot estimate a release date.
- Hikma has diphenhydramine 50 mg/mL 1 mL vials on back order and the company estimates a release date of early-October 2018.
- Pfizer has diphenhydramine 50 mg/mL 1 mL vials 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=456

Chlorothiazide Sodium Injection

September 20, 2018

Reason for the Shortage

- Akorn had chlorothiazide injection on shortage due to manufacturing delays.
- Sagent had chlorothiazide injection on shortage due to increased demand.
- Sun Pharma has chlorothiazide injection available.

Estimated Resupply Dates

- N/A

Aminophylline Injection

September 20, 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 on back order and the company estimates a release date of October 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=407

*Please refer to ASHP website for more information at:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/