



Drug Information Update

November 2018

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NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
TESTOSTERONE	20.25 MG/1.25 GRAM (1.62 %) 40.5 MG/2.5 GRAM (1.62 %) GEL PACKET	ZYDUS, PERRIGO	ANDROGEL
GUAIFENESIN/HYDROCODONE	200 MG-2.5 MG/5 ML SOLUTION	BURKE THERAPEUT	OBREDON
DEXCHLORPHENIRAMINE MALEATE	2 MG/5 ML SYRUP	TEVA, PRASCO LABS	RYCLORA
CLOBAZAM	10 MG, 20 MG TABLET 2.5MG/ML ORAL SUSP	BIONPHARMA INC. MYLAN, WEST-WARD/HIKMA ZYDUS PHARMACEUTICALS	ONFI
GLYCOPYRROLATE	1.5 MG TABLET	FOXLAND PHARMACEUTICALS	GLYCATE
VARDENAFIL HCL	2.5 MG, 5 MG, 10 MG, 20 MG TABLET	LANNETT CO. INC ZYDUS PHARMACEUTICALS	LEVITRA
SUMATRIPTAN SUCCINATE	6 MG/0.5 ML SYRINGE	MYLAN	SUMATRIPTAN SUCCINATE
MOLINDONE HCL	5 MG, 10 MG, 25 MG TABLET	EPIC PHARMA LLC	MOLINDONE
ZOLEDRONIC ACID/MANNITOL-WATER	4 MG/100 ML PGGYBK BTL	ATHENEX PHARMACEUTICALS	ZOMETA
MICONAZOLE NITRATE/ZINC OX/PET	0.25 %-15 %-81.35 % SOLUTION	MYLAN	VUSION
MINOCYCLINE HCL	55 MG TABLET	OCEANSIDE PHARMACEUTICALS	SOLODYN
SALIVA SUBSTITUTE COMBO NO.3	SPRAY/PUMP	3M ESPE DENTAL	AQUORAL
AZELAIC ACID	15% GEL	SANDOZ	FINACEA
GELATIN SPONGE, ABSORB/PORCINE	100 SPONGE	ETHICON	GELFOAM

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
DIRECT FACTOR XA INHIBITORS	XARELTO	RIVAROXABAN	2.5 MG TABLET	New Strength
EYE ANTIBIOTIC, GLUCOCORTICOID AND NSAID COMB.	PREDNISOLONE PHOS-GATIFLO-BROM	PREDNISOLN SP/ GATIFLOX/BROMFEN	1 %-0.5 % DROPS	New Entity; Compounded ophthalmic from outsource facility
EYE ANTIBIOTIC AND GLUCOCORTICOID COMBINATIONS	PREDNISOLONE PHOS-GATIFLOXACIN	PREDNISOLONE SOD PH/GATIFLOXAC	1 %-0.5 % DROPS	New Entity; Compounded ophthalmic from outsource facility
ANTISERA	PANZYGA	IMMUN GLOB G(IGG)-IFAS/GLYCINE	0.1 G/ML VIAL	New Entity; Pricing effective 11/12/2018
ANTINEOPLASTIC-CD22 DIRECT ANTIBODY/CYTOTOXIN CONJ	LUMOXITI	MOXETUMOMAB PASUDOTOX-TDFK	1 MG VIAL	New Entity
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	TALZENNA	TALAZOPARIB TOSYLATE	0.25 MG, 1 MG CAPSULE	New Entity; Pricing effective 10/29/2018
IMMUNOSUPPRESSIVES	ZORTRESS	EVEROLIMUS	1 MG TABLET	New Strength
VACCINE/TOXOID PREPARATIONS,COMBINATIONS	PENTACEL ACTHIB COMPONENT	HIB CONJ-TET,COMPONENT 2OF2/PF	10 MCG VIAL	GCN change
VACCINE/TOXOID PREPARATIONS,COMBINATIONS	PENTACEL DTAP-IPV COMPONENT	DTAP-IPV COMPONENT 1 OF 2/PF	15 Lf-5 Lf-20 MCG-(40 D-ANTIGEN U/8D ANTIGEN U/32D ANTIGEN U) VIAL	GCN change
INTERLEUKIN-4(IL-4) RECEPTOR ALPHA ANTAGONIST, MAB	DUPIXENT	DUPILUMAB	200MG/ 1.14 SYRINGE	New Strength
AMYLOIDOSIS AGENTS-TRANSTHYRETIN (TTR) SUPPRESSION	TEGSEDI	INOTERSEN SODIUM	284 MG/1.5 SYRINGE	New Entity; Pricing will be effective 11/14/2018

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
WOUND HEALING AGENTS, LOCAL	BPCO	BALSAM PERU/CASTOR OIL	OINT	Medical Device
EYE MYDRIATIC AND NSAID COMBINATIONS	MYDRIATIC4 (TROP-PROP-PE-KTRLC)	TROPIC/PROPARACAI/PE/KETOR/WAT	1-0.5-2.5% DROPS	New Combination; Compounded ophthalmic from outsource facility
ANTIVIRALS, GENERAL	XOFLUZA	BALOXAVIR MARBOXIL	20 MG, 40 MG TABLET	New Entity
ANTIVENINS	ANAVIP	ANTIVENIN,CROTALIDA E (EQUINE)	VIAL	New Entity
TOPICAL ANTI-INFLAMMATORY STEROIDAL	LEXETTE	HALOBETASOL PROPIONATE	0.05% FOAM	New Dosage Form
PROTECTIVES	SCARCIN GEL	PROTECTIVES COMBINATION NO.6	GEL	New Dosage Form
ANTIMALARIAL DRUGS	ARAKODA	TAFENOQUINE SUCCINATE	100 MG TABLET	New Entity
MONOCLONAL ANTIBODIES TO IMMUNOGLOBULIN E (IGE)	XOLAIR	OMALIZUMAB	75 MG/0.5 ML, 150 MG/ML SYRINGE	New Dosage Form; claims will not adjudicate until pricing is effective 12/3/2018
SICKLE CELL ANEMIA AGENTS	SIKLOS	HYDROXYUREA	1000 MG TABLET	New strength; claims will not adjudicate until pricing is effective 11/15/2018
ANTICONVULSANT - BENZODIAZEPINE TYPE	SYMPAZAN	CLOBAZAM	5 MG, 10 MG, 20 MG FILM	New Dosage Form, New Strength
MIOTICS AND OTHER INTRAOCULAR PRESSURE REDUCERS	XELPROS	LATANOPROST	0.005% DROPS	New Dosage Form

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANDROGENIC AGENTS	XYOSTED	TESTOSTERONE ENANTHATE	50 MG/0.5 ML, 75 MG/0.5 ML, 100 MG/0.5 ML AUTO INJECTOR	New Dosage Form, New Strength; claims will not adjudicate until pricing is effective 12/1/2018
OPIOID ANALGESICS	MORPHINE SULFATE	MORPHINE SULFATE	0.4 MG/ML SYRINGE	New Strength; Compounded oral solution from outsource facility
LEUKOCYTE (WBC) STIMULANTS	GRANIX	TBO-FILGRASTIM	300 MCG/ML, 480 MCG/1.6 ML VIAL	New Dosage Form
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	LORBRENA	LORLATINIB	25 MG, 100 MG TABLET	New Entity
ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED	ABILIFY MYCITE	ARIPIRAZOLE	2 MG, 5 MG, 10 MG, 15 MG, 20 MG, 30 MG TABLET/SENSOR	New Combination, drug + device
METABOLIC DX ENZYME REPLACEMENT, SEV. COMB. IMMUNE DEF.	REVCIVI	ELAPEGADEMASE-LVLR	2.4 MG/1.5 ML VIAL	New Entity
TOPICAL ANTI-INFLAMMATORY STEROIDAL	BRYHALI	HALOBETASOL PROPIONATE	0.01% LOTION	New Strength
TOPICAL LOCAL ANESTHETICS	SUVICORT	LIDOCAINE HCL/ALOE/COLLAGEN	2%-1%-1% GEL	New strength; Medical Device

NEW INDICATIONS (EXISTING DRUGS)

Dupixent®

Oct. 19, 2018

Sanofi announced today that the U.S. Food and Drug Administration has approved Dupixent® (dupilumab) as an add-on maintenance therapy in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid-dependent asthma.

Dupixent inhibits the overactive signaling of interleukin-4 (IL-4) and interleukin-13 (IL-13), two key proteins that contribute to the Type 2 inflammation that may underlie moderate-to-severe asthma. This effect is associated with the reduction of inflammatory biomarkers including fractional exhaled nitric oxide (FeNO), immunoglobulin E (IgE) and eotaxin-3 (CCL26).

Source: Sanofi

EMPLICITI®

November 6, 2018

Bristol-Myers Squibb Company announced today that the U.S. Food and Drug Administration (FDA) approved Empliciti (elotuzumab) injection for intravenous use in combination with pomalidomide and dexamethasone (EPd) for the treatment of adult patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor.¹ In ELOQUENT-3, a randomized, open-label, Phase 2 trial, EPd demonstrated benefit in patients with relapsed or refractory multiple myeloma, doubling both median progression-free survival (PFS) and overall response rate (ORR) versus pomalidomide and dexamethasone (Pd).

Source: Bristol-Myers Squibb Company

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Implanted Pumps: Safety Communication - Use Caution When Selecting Pain Medicine for Intrathecal Administration

[Posted 11/14/18]

ISSUE: The FDA is aware that patients undergoing treatment or management of pain are commonly given pain medicines in the spinal fluid (intrathecal administration) that are not FDA approved for use with the implanted pump. While individual patients may experience some relief from using pain medicines not approved for intrathecal administration in their implanted pumps, such use may create additional risks including dosing errors, pump failures, and other safety concerns. The FDA wants to ensure that patients, caregivers, compounders, pharmacists, and health care providers are aware of these risks to make informed treatment decisions.

BACKGROUND: Implanted pumps are medical devices that are surgically implanted under the skin, typically in the abdomen. They are connected to an implanted catheter and are used to deliver prescription medicines and fluids within the body, including the intrathecal space (into the spinal fluid), to treat pain, muscle spasticity, and other diseases or conditions. Implanted pumps are periodically refilled with medicines or fluids by a health care provider.

They are often used to treat or manage pain after other treatments, such as oral medicines, physical therapy, or surgery, are unsuccessful.

The FDA-approved implanted pump labeling identifies which pain medicines are approved for use with each pump. Pain medicines approved by FDA for delivery into the spinal fluid must meet additional safety standards because the spinal cord and brain tissue are highly sensitive to preservatives or infectious organisms such as bacteria or viruses. The implanted pump's current labeling should be reviewed to determine which pain medicines are approved for use in each pump. The table below includes examples of medicines approved and not approved for intrathecal use with implanted pumps to treat or manage pain.

RECOMMENDATION: When considering a medicine for use in an implanted pump:

1. Review the implanted pump labeling to identify the medicines and medicine concentrations approved for use with that specific pump.
2. Be aware that the following medicines are NOT currently approved for use with implanted pumps for intrathecal infusion of pain medications:
 - a. Medicines not FDA approved for intrathecal administration or intrathecal implanted pump use (for example, hydromorphone, bupivacaine, fentanyl, clonidine)
 - b. Any mixture of two or more different kinds of medicines
 - c. Any compounded medicine (for example, to achieve higher concentration or different formulation of an FDA approved medicine)
3. Be aware that while individual patients may experience some relief from using medicines not approved for intrathecal administration in their implanted pumps for pain management, such use may pose additional risks including pump failures, dosing errors, and other potential safety issues.
4. Health care providers, patients, and caregivers are encouraged to consider and discuss both the benefits and risks of using implanted pumps for the intrathecal infusion of medications for pain management in order to make informed treatment decisions.

5. Report adverse events to the FDA if you suspect an implanted pump is having problems:
 - a. User facilities must comply with the applicable Medical Device Reporting (MDR) regulations.
 - b. Health care providers employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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

Sandoz Inc. Issues Voluntary Nationwide Recall of One Lot of Losartan Potassium and Hydrochlorothiazide Due to the Detection of Trace Amounts of NDEA (N-Nitrosodiethylamine) Impurity Found in the Active Pharmaceutical Ingredient (API)

[Posted 11/8/18]

Sandoz Inc. is voluntarily recalling one lot of Losartan Potassium Hydrochlorothiazide Tablets, USP 100mg/25mg to the consumer level. This product is being recalled due to the trace amount of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Losartan, USP manufactured by Zhejiang Huahai Pharmaceutical Co. Ltd. Sandoz Inc. Losartan Potassium Hydrochlorothiazide product is manufactured by Lek Pharmaceuticals dd, Ljubljana, Slovenia. This impurity, which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC).

To date, Sandoz Inc. has not received any reports of adverse events related to this lot.

Losartan Potassium Hydrochlorothiazide Tablets, USP are indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents. The product can be identified as Losartan Potassium Hydrochlorothiazide, 100 mg/25 mg tablets in 1000-count plastic bottles, NDC 0781-5207-10, Lot number JB8912; Exp. Date 06/2020. This product was distributed nationwide to distributors. The affected product was not distributed prior to October 8, 2018.

Sandoz Inc. is notifying its distributors by letter via overnight mail and patients by this public notification. Distributors and retailers that have product which is being recalled should immediately stop distribution of the identified lot above and quarantine any quantities remaining in your control and return the recalled product to the identified Reverse Distributor.

Patients with questions regarding this recall can contact Sandoz Inc. at 1-800-525-8747 Monday-Friday 8:30 AM – 5:00 PM (EST) or email usdrugsafety.operations@novartis.com. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on Losartan Potassium Hydrochlorothiazide should continue taking their medication, as the risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their physician or healthcare



provider if they have experienced any problems that may be related to taking or using Losartan Potassium Hydrochlorothiazide.

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.

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

Kadesh Incorporation Issues Voluntary Nationwide Recall of Puriton Eye Relief Drops Due to Non-Sterile Production Conditions

[Posted 11/7/18]

Kadesh, Inc. of Garden Grove, CA is voluntarily recalling all lots of Puriton Eye Relief Drops, 0.5 oz. (15ml) bottle, UPC 7 36972 1679 0, to the consumer level. During a recent FDA inspection, investigators observed that ophthalmic drugs, which are required to be sterile, are manufactured without necessary production controls and conditions to assure sterility.

Use of a non-sterile eye drop is potentially vision-threatening due to the risk of an eye infection. Additionally, the pH of the product is relatively high and can cause direct destruction of tissues in the cornea, anterior chamber and deeper structures of the eye which can lead to scarring, glaucoma or vision loss. To date, Kadesh, Inc. has not received any reports of adverse events related to this recall. This product is an over-the-counter homeopathic eye drop for the temporary relief of burning and irritation due to dryness of the eye and discomfort due to minor irritations of the eye or to exposure to wind or sun. It is packaged in a 15 ml plastic bottle, NDC 7079600115, UPC 7 36972 1679 0. Kadesh, Inc. is voluntarily recalling all lots of Puriton Eye Relief Drops within expiry. The product was distributed nationwide via the company's own online stores and retail distributors.

Kadesh, Inc. is notifying its distributors and customers by recall letter and is arranging for return of all recall products. Consumers and businesses that have the product, which is being recalled, are recommended to stop using and selling.

Consumers with questions regarding this recall can contact the Recall Department at contact@puriton.us, available Monday through Friday, from 9 am to 6 pm (Pacific Time). Product may be returned to Kadesh Inc., 4731 Lincoln Way, Garden Grove, CA 92841. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or 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.

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



Janssen Issues Voluntary Nationwide Recall for one lot of ORTHO-NOVUM 1/35 and two lots of ORTHO-NOVUM 7/7/7 Due to Incorrect Veridate Dispenser Instructions

[Posted 11/2/18]

The ORTHO-NOVUM® product itself remains safe and effective for use with the appropriate dispenser instructions

Janssen Pharmaceuticals, Inc. has initiated a voluntary recall of one lot of ORTHO-NOVUM® 1/35 (norethindrone/ethinyl estradiol) Tablets and two lots of ORTHO-NOVUM® 7/7/7 (norethindrone/ethinyl estradiol) Tablets to the pharmacy level. The patient information provided inside affected packages of ORTHO-NOVUM® does not include the appropriate instructions for the Veridate® dispenser.

The potential risk of taking ORTHO-NOVUM® without the appropriate instructions for correct use of the Veridate® dispenser pack is that the consumer could take the pills in the incorrect order (still receiving an effective dose) or could take an inactive "reminder" pill instead of an "active" pill which could lead to breakthrough bleeding or an unintended pregnancy.

ORTHO-NOVUM® 1/35 and ORTHO-NOVUM® 7/7/7 tablets are indicated for the prevention of pregnancy in women who elect to use this product as a method of contraception.

The ORTHO-NOVUM® product itself remains safe and effective for use with the appropriate dispenser instructions. Women should continue to take the 21 "active" pills (with hormones) (peach for ORTHO-NOVUM® 1/35; white, light-peach and peach for ORTHO-NOVUM® 7/7/7) for three weeks, followed by the one week of green "reminder" pills (without hormones).

This recall only affects the U.S., and no other ORTHO® contraceptive products beyond the three lots listed above are impacted by this recall action. ORTHO TRI-CYCLEN LO®, ORTHO TRI-CYCLEN®, ORTHO MICRONOR® and ORTHO CYCLEN® are not affected.

Products were distributed in the U.S. to wholesalers, distributors and pharmacies, and they have been notified by recall letter to return affected products.

Consumers with ORTHO-NOVUM® product from the affected lots can access the correct instructions for the Veridate® dispenser pack at <https://www.janssen.com/us/our-products> and talk to their prescribing medical professional if they have any concerns. Consumers should not stop taking the product and if they do miss a dose, they should follow the instructions included in the packet.

Consumers with questions regarding this recall can contact Janssen via phone on: 1-800-526-7736 (1-800-JANSSEN) Monday through Friday from 9:00 am to 8:00 pm ET. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this 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.

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

FDA alerts patients and health care professionals that some EpiPen auto-injectors may not readily slide out of carrier tube

[Posted 11/2/18]

FDA is alerting patients, caregivers and health care professionals that the labels attached to some EpiPen 0.3mg and EpiPen Jr 0.15mg auto-injectors, and the authorized generic versions, may block access to the auto-injector and prevent the ability to easily access the product.

In a letter to health care professionals from Pfizer, the manufacturer of the Mylan EpiPen, the label sticker on the auto-injector unit may have been improperly applied, causing resistance when removing it from the carrier tube. The carrier tube is the immediate package in which the auto-injector is contained. In some cases, the patient or caregiver may not be able to quickly remove the epinephrine auto-injector from the carrier tube.

The auto-injector device and the epinephrine it delivers are not affected by this issue and can be used as prescribed. It is vital for lifesaving products to work as designed in an emergency situation, and patients and caregivers should inspect their epinephrine auto-injector prior to needing it to ensure they can quickly access the product.

The letter also describes how to inspect potentially affected products and explains that patients should contact Mylan Customer Relations at 800-796-9526 if an auto-injector does not slide out easily from the carrier tube OR the label is not fully adhered to the auto-injector. Pharmacists should inspect the products before dispensing them to patients to ensure quick access to the auto-injector and should not dispense any product which does not easily slide out of its carrier tube.

FDA is not aware of any adverse event reports associated with improperly applied EpiPen or EpiPen Jr auto-injectors, or their authorized generics label. As stated on the product label, consumers should always seek emergency medical help right away after using their epinephrine auto-injector.

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

ScieGen Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Irbesartan Tablets, USP 75 Mg, 150 Mg, and 300 Mg Due to The Detection of Trace Amounts of NDEA (N-Nitrosodiethylamine) Impurity Found in The Active Pharmaceutical Ingredient (API)

[Posted 10/30/18]

ScieGen Pharmaceuticals, Inc. is voluntarily recalling listed lots, within expiry, of Irbesartan Tablets, USP 75 mg, 150 mg, and 300 mg dosage forms to the consumer level. These products are being recalled due to the presence of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Irbesartan, USP manufactured by Aurobindo Pharma Limited. This impurity, which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC)

To date, ScieGen Pharmaceuticals Inc has not received any reports of adverse events related to this product. Irbesartan tablets, USP are indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.



Irbesartan Tablets, USP 75 mg, 150 mg, and 300 mg were manufactured by ScieGen Pharmaceuticals Inc and are labeled as Westminster Pharmaceuticals and Golden State Medical Supply, Inc [GSMS].

Westminster is notifying its direct accounts by email and by phone to immediately discontinue distribution of the product being recalled and to notify their wholesale and retail accounts of this product recall and make arrangements for impacted product to be returned to Westminster. Instructions for returning recalled products are provided in the Recall Notice Letter and Recall Response Form. Patients should return the effected medication to their pharmacy. Pharmacies should return their effected stock to their wholesaler.

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

Promise Pharmacy Issues Voluntary Nationwide Recall of Prednisolone and Gatifloxacin Ophthalmic Solution 1%/0.5% Sterile Due to Small Particulate Floating in the Solution

[Posted 10/22/2018]

Promise Pharmacy is voluntarily recalling one lot of Prednisolone and Gatifloxacin Ophthalmic Solution 1%/0.5% sterile, 3ml vials, to the patient consumer level. The product has been found to have unidentified small particulate floating in the solution. To date Promise Pharmacy has not received any reports of adverse events related to this recall. Potential adverse health consequences could range from limited eye irritation, inflammation and visual impairment to permanent ocular damage with the use of this eye drop solution. The product is used as a post-surgical (cataract) ophthalmic treatment and was distributed Nationwide to individual patients.

Lot Number 09042018@2, Exp. 12/03/2018 is the only affected lot.

Promise Pharmacy is notifying its prescribers and patients by telephone and mail and is arranging for return/replacement/refund of all recalled product. Patients who have product that is being recalled should stop using it and return it to Promise Pharmacy. Patients will be sent packaging with a prepaid shipping label to facilitate prompt return of product to the pharmacy.

Prescribers and patients with questions regarding this recall can contact Promise Pharmacy at (727) 772-0500 x233 Monday through Friday between the hours of 9:00 am and 3:30 pm EST, or via email to mark@promisepharmacy.com. Patients should contact their prescribing physician if they have experienced any problems that may be related to using this product.

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

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



Aurobindo Pharma Limited Issues Voluntary Recall of Irbesartan Drug Substance due to the Detection of Trace Amounts of NDEA (NNitrosodiethylamine) Impurity Found in the Active Pharmaceutical Ingredient (API)

[Posted 10/26/2018]

Aurobindo Pharma Limited is voluntarily recalling 22 Batches of the drug substance Irbesartan due to the presence of an impurity, N-nitrosodiethylamine (NDEA). The impurity, which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC). These 22 batches of Irbesartan drug substance were supplied to ScieGen Pharmaceuticals Inc., U.S. for the manufacturing of finished Irbesartan drug product (see attached annexure).

Aurobindo Pharma Limited has notified ScieGen Pharmaceuticals, Inc. of the recall and is arranging for the return of all available Irbesartan drug substance. Aurobindo Pharma Limited has further advised ScieGen Pharmaceuticals, Inc. to contact its distributors and retailers to return Irbesartan drug product and finished Irbesartan tablets that has been identified by Aurobindo Pharma Limited.

Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on Irbesartan should continue taking their medication, as the risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using Irbesartan. 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.

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

STUDIES AND RECENT TOPICS

[Many U.S. drugstores fail to provide naloxone for opioid overdoses](#)

November 13, 2018

Despite state laws expanding access to the opioid-overdose antidote naloxone without a prescription, two U.S. studies suggest many pharmacies don't stock the drug or make it easily available to people who need it.

In California, where pharmacists have been able to dispense naloxone without a prescription since 2016, fewer than one in four drugstores in a survey gave the drug to people without a prescription, one of the studies found. When pharmacists were willing to give naloxone without a prescription, in theory, only about half of the drugstores had it in stock.

Source: reuters.com

[Drug with fish oil cuts risk of heart attack, stroke, study finds](#)

Nov. 10, 2018

A fish oil-derived medication may lessen the likelihood of a heart attack or stroke in patients who are at high risk despite taking statin therapy, a new study finds.

The medication, which contains high doses of the omega-3 fatty acid EPA, cut the risk of death due to cardiovascular causes, heart attack and stroke by 25 percent, the researchers found. And that was on top of the risk reduction brought about by cholesterol-lowering statins, according to the study, published Saturday in the New England Journal of Medicine.

Source: nbcnews.com

[Humira levels linked to biologic Crohn's remission](#)

November 8, 2018

Patients with optimized Humira drug levels were more likely to achieve biologic remission, according to research published in Inflammatory Bowel Diseases.

"It is increasingly recognized that clinical symptom activity indices correlate poorly with the degree of underlying intestinal inflammation," Nikolas Plevris, MRCP, of the Edinburgh IBD Unit at Western General Hospital in Edinburgh, Scotland, and colleagues wrote. "In the era of treating beyond symptoms, data are emerging that even higher serum drug levels are required to achieve objective end points like mucosal healing."

Source: healio.com

[Dupilimab Granted Priority Review for Moderate-to-Severe Atopic Dermatitis in Adolescents](#)

November 6, 2018

The US Food and Drug Administration (FDA) has accepted Sanofi's supplemental biologics license application (sBLA) for priority review of dupilumab (Dupixent) in patients aged 12 to 17 years with moderate-to-severe atopic dermatitis. Indications for the adolescent patient population also include those whose disease has not been fully controlled with topical therapies or for whom topical treatment was not medically advised.

Source: mdmag.com

Naloxone could be used past expiration date, new study finds

November 6, 2018

Extended shelf life would be welcome amid opioid epidemic
Researchers have discovered that two widely used naloxone products could be chemically stable well past their expiration dates.

Source: pharmacist.com

FDA releases real-world data collection app

November 6, 2018

FDA released on Tuesday an open source code app that can be used to collect real-world data directly from patients, including from mobile devices.

The MyStudies app is a digital platform that users can adapt to collect data from a “variety of sources, such as electronic health records, claims and billing activities, product and disease registries, as well as patient-generated data including in home-use settings, as well as data gathered from other sources, such as mobile devices,” according to an FDA announcement. The app can be customized and used to administer questionnaires assessing patient-reported outcomes, symptom scales or patient reports of medication use.

Source: biocentury.com

Galcanezumab Effective at Decreasing Monthly Headache Days in Migraine

November 02, 2018

Galcanezumab has demonstrated efficacy in treating episodic migraine, with 40% of users achieving a 100% response rate for at least 1 month, according to a study recently published in Headache. This study included 1739 individuals with episodic migraine, 436 of whom were randomly assigned galcanezumab 120 mg, 428 of whom were randomly assigned galcanezumab 240 mg, and 875 of whom were randomly assigned placebo. Those given galcanezumab 240 mg showed the highest mean monthly 100% response rate (14.3%; odds ratio 2.6; P <.001), followed by galcanezumab 120 mg (13.5%; odds ratio 2.5; P <.001) and placebo (5.9%).

Source: neurologyadvisor.com

Ofev Benefits Less for Severe IPF Patients Than Mild-to-moderate Patients

November 2, 2018

Treatment with Ofev (nintedanib) offers less clinical benefit to patients with severe idiopathic pulmonary fibrosis (IPF), compared to those with mild-to-moderate disease, a new study shows. The study, “Utility of nintedanib for severe idiopathic pulmonary fibrosis: a single-center retrospective study,” was published in the journal Drug Design, Development and Therapy.

Source: pulmonaryfibrosisnews.com

FDA panel recommends Sage's postpartum depression treatment

November 2, 2018

An advisory panel to the U.S. Food and Drug Administration on Friday recommended Sage Therapeutics Inc's experimental treatment for postpartum depression, saying the benefits of the drug outweighed risks.

The panel voted 17-1 in favor of the injectable treatment, Zulresso, which aims to treat major episodes of depression during pregnancy or within four weeks of delivery.

Source: reuters.com

FDA grants Sanofi Pasteur's dengue vaccine priority review

October 31, 2018

Sanofi Pasteur said its controversial dengue vaccine, known in other countries as Dengvaxia, has been granted priority review by the FDA. A decision on approval is expected by May 1, 2019.

If approved, it would be the first vaccine against dengue available in the United States, including Puerto Rico and the U.S. Virgin Islands, where the disease is endemic.

Source: healio.com

FDA approves pembrolizumab in combination with chemotherapy for first-line treatment of metastatic squamous NSCLC

October 30, 2018

The Food and Drug Administration approved pembrolizumab (KEYTRUDA, Merck & Co. Inc.) in combination with carboplatin and either paclitaxel or nab-paclitaxel as first-line treatment of metastatic squamous non-small cell lung cancer (NSCLC).

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

Mortality Rates in Parkinson Disease Psychosis With Pimavanserin, Quetiapine

October 30, 2018

The rate of mortality was 7.1% in the pimavanserin group, 11.5% in the quetiapine group. For patients with Parkinson disease (PD) psychosis, treatment with pimavanserin has a lower risk for mortality compared with quetiapine or combination therapy, according to results published in Neurology.

Source: neurologyadvisor.com

Abortion pills now available by mail in US -- but FDA is investigating

October 25, 2018

Signaling a new chapter in the battle over abortion access in the United States, a European organization has stepped into the fray, providing Americans a way to get doctor-prescribed pills by mail to medically induce abortions at home.

Source: cnn.com

NSAID, aspirin use increases microscopic colitis risk

October 18, 2018

Use of nonsteroidal anti-inflammatory drugs and aspirin — but not acetaminophen — correlated with an increased risk for microscopic colitis, according to a presentation at the American College of Gastroenterology Annual Meeting.

“The influence of other common analgesics typically used for the same clinical indications [as NSAIDs], such as aspirin and acetaminophen, has not been extensively studied,” Kristin E. Burke, MD, MPH, from the Massachusetts General Hospital, said during her presentation. “Our goal was to examine the associations between these three and the risk of microscopic colitis in two large prospective cohorts of U.S. women.”

Source: healio.com

RECALLS

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drug	Sinus Relief (oxymetazoline HCl) Nasal decongestant, 0.05%, 0.5 FL OZ	Class I	Lot: 173089J Exp. 09/19	Microbial Contamination of Non-Sterile Products: Failed microbiological testing for Pseudomonas aeruginosa.	Product Quest Manufacturing LLC
Drugs	Native Remedies VertiFree Oral Spray, 2 fl oz (59 mL) per bottle, Distributed by: Silver Star Brands, Oshkosh, WI 54906. NDC 68703-253-02	Class I	Lot K061417B	Microbial Contamination of Non-Sterile Products	Silver Star Brands
Drugs	Native Remedies HypoSlim Oral Spray, 2 fl oz (59 mL) per bottle, Distributed by: Silver Star Brands, Oshkosh, WI 54906. NDC 68703-275-02	Class I	Lot K051818A	Microbial Contamination of Non-Sterile Products	Silver Star Brands
Drugs	Native Remedies VaricoGo Oral Spray, 2 fl oz (59 mL) per bottle, Distributed by: Silver Star Brands, Oshkosh, WI 54906. NDC 68703-105-59	Class I	Lot K111717A	Microbial Contamination of Non-Sterile Products	Silver Star Brands
Drugs	Native Remedies EyeClear Pro Oral Spray, 2 fl oz (59 mL) per bottle, Distributed by: Silver Star Brands, Oshkosh, WI 54906. NDC 68703-151-59	Class I	Lot K022317A and K022317B	Microbial Contamination of Non-Sterile Products	Silver Star Brands
Drug	DERMATONE (titanium oxide 6% and zinc oxide 4.7%) No-Touch Sunscreen Stick, SPF 50, Net Wt. 0.49 oz. (13.9g) stick, Distributed by: Beaumont Products, Inc. Kennesaw, GA 30144, UPC 0 20908 05100 3.	Class II	Lot: 172428G	Microbial Contamination of Non-Sterile Products: sample tested positive for Staphylococcus aureus.	Product Quest Manufacturing LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drug	Thyroid, USP (Porcine) Levothyroxine 36.3 mcg/grain Liothyronine 9.7 mcg/grain Active Pharmaceutical Ingredient Rx Only 1000 grams NDC 0395-8077-43 Packaged by: Humco Texarkana, TX 75501	Class II	Lots: A24542 Exp. 02/2019; A25528 Exp. 04/2019; A27119 Exp. 05/2019; A27810 Exp. 06/2019	CGMP Deviations: Recall notice received from supplier that Thyroid Powder has inconsistent levels of the active ingredients levothyroxine and liothyronine.	Humco Holding Group, Inc
Drug	Clonazepam Orally Disintegrating Tablets USP, 2 mg., 60-count carton. RX only. Teva Pharmaceuticals USA, INC. North Wales, PA 19454. NDC 0555-0098-96	Class II	Lot # 34033752A, EXP 1/2020	Failed Stability Specifications: Out-of-specification test result for water content obtained during routine stability testing.	Teva Pharmaceuticals USA
Drug	Thyroid, USP (Porcine) Levothyroxine 36.3 mcg/grain Liothyronine 9.7 mcg/grain Active Pharmaceutical Ingredient Rx Only 100 grams NDC 0395-8077-62 Packaged by: Humco Texarkana, TX 75501 USA	Class II	Lots: A24543 Exp. 02/2019; A25724 Exp. 01/2019; A25529 Exp. 04/2019; A25723 Exp. 04/2019; A27120 Exp. 05/2019; A27811 Exp. 06/2019; A28626 Exp. 06/2019; A29171 Exp. 06/2019; A29221 Exp. 06/2019	CGMP Deviations: Recall notice received from supplier that Thyroid Powder has inconsistent levels of the active ingredients levothyroxine and liothyronine.	Humco Holding Group, Inc
Drugs	Thyroid, USP (Full Strength) Levothyroxine 112.1 mcg/grain Liothyronine 29.2 mcg/grain Active Pharmaceutical Ingredient Rx Only 1000 grams NDC 0395-6580-43 Packaged by: Humco Texarkana, TX 75501 USA	Class II	Lot: A26450 Exp. 05/2019	CGMP Deviations: Recall notice received from supplier that Thyroid Powder has inconsistent levels of the active	Humco Holding Group, Inc

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
				ingredients levothyroxine and liothyronine.	
Drugs	Rhinall (phenylephrine hydrochloride) Nasal Decongestant Nose Drops, 0.25%, 1 FL OZ (30 mL) bottle,	Class II	All lots remaining within expiry.	CGMP Deviations: products manufactured under conditions that could impact its product quality.	Product Quest Manufacturing LLC
Drugs	CareOne, Saline Nasal Gel With Soothing Aloe, Net Wt. 0.5 OZ (14.1 g) tube; CVS Health, Sterile Saline Nasal Mist (sodium chloride) Saline Nasal Moisturizer, 0.9%; CVS Health, Saline Nasal Spray, Nasal Moisturizing Spray; CVS Health, Sterile Saline Nasal Mist (sodium chloride) Allergy & Sinus Relief, 3.0%, 4.25 OZ (126 g) can; CVS Health, Baby Nasal Spray/Drops, Non-Medicated, 0.5 FL OZ (15 mL) bottle; CVS Health, Saline Nasal Gel with Soothing Aloe; CVS Health, Saline Nasal Spray, 1.5 FL OZ bottle; Discount Drug Mart, Food Fair, Saline Nasal Spray (sodium chloride) 0.65%, packaged as a) 3 FL OZ; DG health, No Drip, Nasal Pump Mist (oxymetazoline hydrochloride), 0.05%; FAMILY wellness, Sterile Saline, Nasal Mist, Saline Nasal Relief; Harmon Face Values, Saline Nasal Gel with Soothing Aloe, 0.5 oz. (14.1	Class II	All lots remaining within expiry.	CGMP Deviations: products manufactured under conditions that could impact its product quality.	Product Quest Manufacturing

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	<p>g) tube; Harmon Face Values, Saline Nasal Spray (sodium chloride); Meijer, Saline Nasal Spray, Nasal Moisturizing Spray; Meijer, Sterile Saline Nasal Mist (0.9% Sodium Chloride Solution); HuMist Saline Nasal Mist 1.5 FL OZ (45 mL) bottle; Premier Value Nasal Decongestant Extra Moisturizing Nasal Spray; Premier Value, Nasal Decongestant, No Drip Nasal Spray; Premier Value, Sterile Saline Nasal Mist, Saline Nasal Moisturizer; Premier Value, Saline Nasal Spray, Sodium Chloride 0.65%, packaged as a) 3 FL OZ; QC Quality Choice, Saline Nasal Gel with Soothing Aloe, 0.5 OZ (14.1 g) tube; QC Quality Choice, Saline Nasal Relief, Moisturizing Nasal Spray, Sodium Chloride 0.65%; Rite Aid Pharmacy, nasal relief NO DRIP PUMP SPRAY nasal spray, (oxymetazoline hydrochloride 0.05%), 12 Hour; Thayers Natural Remedies, Saline Nasal Mist, TopCare, Saline Nasal Gel with Soothing Aloe, 0.5 OZ; OCEAN Saline Nasal Spray, packaged in a) 3.5 Fl. Oz., Best Choice, 12 Hour Extra Moisturizing, Nasal Spray; Best Choice, 12 Hour No-Drip Nasal Spray; Best Choice, SALINE Nasal Spray; Walgreens, Nasal Spray; Walgreens, NO DRIP Anefrin Nasal Spray; Well at Walgreens, ULTRA FINE Sinus Relief Mist;</p>				

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Walgreens, NO DRIP Severe Anefrin Nasal Spray; Rhinall Nasal Decongestant Nasal Spray (phenylephrine HCl), 0.25%, 1 1/3 Fl Oz.; Rexall, Sinus Nasal Pump Mist; Rexall, Extra Moisturizing No Drip Nasal Spray; Rexall, Extra Moisturizing No Drip Nasal Spray; Family Dollar Saline Nasal Spray 4.25 oz. can, 24 pk, SKU 0900562				
Drugs	dr. brandt, BB cream with signature FLEXITONE, SPF 30, 1 oz./30 g tube, Distributed by: Cosmetic Dermatology, Inc., Miami, FL 33172, UPC 6 63963 00828 7	Class II	Lot: 161223D, Exp. 4/16/2019	Failed Stability Specifications: separation of product and failure for actives.	Product Quest Manufacturing
Drugs	FREEZE IT (camphor 0.2% and menthol 3.5%) spray, 118.29 mL (4 fl. oz.) can, Distributed by: Expedite Products, Inc	Class II	Lot: 170498B, Exp. 02/23/2020	Superpotent Drug: high out of specification assay results for the camphor ingredient.	Product Quest Manufacturing LLC
Drugs	Rite Aid Pharmacy, First Aid Antibiotic Ointment, (neomycin sulfate 3.5 mg, polymyxin B sulfate 5,000 units, bacitracin zinc 400 units per gram), 2 OZ (56 g) tube	Class II	Lot: 170591E, Exp. 11/17/18	Subpotent Drug: low out of specification assay results for the bacitracin zinc ingredient.	Product Quest Manufacturing LLC
Drugs	Premier Value, Fast Relief, Muscle Rub, (menthol 10% and methyl salicylate 15%) 4 OZ (113 g) tube	Class II	Lot. 172598G, Exp. 7/4/2019	Superpotent Drug: high out of specification assay results for the menthol ingredient.	Product Quest Manufacturing LLC
Drugs	CVS Health, Original Strength, Triple Antibiotic Ointment Spray (bacitracin zinc 400 units, neomycin sulfate 3.5 mg, polymyxin B sulfate 5,000 units per gram), 2 OZ	Class II	Lot: 170591E, Exp. 11/17/18	Subpotent Drug: low out of specification assay results for the bacitracin zinc ingredient.	Product Quest Manufacturing LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Finafta Baby, Oral Gel (benzocaine 7.5%), 7.1 Grams (0.25 Oz.) tube	Class II	All lots remaining within expiry.	CGMP Deviations: products manufactured under conditions that could impact its product quality.	Product Quest Manufacturing LLC
Drugs	Paliperidone Extended Release Tablets 3 mg, packaged in a) 30-count bottle(NDC 0591-3693-30), b) 90-count bottle (NDC-0591-3693-19), Rx only	Class II	Lot #: a) 1220221A, Exp 03/2019; 1269627A, Exp 09/2019; 1274295A, Exp 10/2019; b) 1220222A, Exp 03/2019; 1270501A, Exp 09/2019; 1274296A, Exp 10/2019; 1288766A, Exp 01/2020	Defective Delivery System: There is a potential for some tablets to be missing the laser drilling which might affect drug release.	Teva Pharmaceuticals
Drugs	Paliperidone Extended Release Tablets 9 mg, packaged in a) 30-count bottle(NDC 0591-3695-30) , b) 90-count bottle (NDC 0591-3695-19), Rx only	Class II	Lot #: a) 1291192A, Exp 01/2020; b) 1291193A, Exp 01/2020	Defective Delivery System: There is a potential for some tablets to be missing the laser drilling which might affect drug release.	Teva Pharmaceuticals
Drugs	Fortamet (metformin HCl) extended release tablets, 1000 mg, 60-count bottle, Rx only, Manufactured by: Actavis Laboratories FL, In	Class II	Lot #: 1237868A, 1248900A, Exp 5/2020	Defective Delivery System: There is a potential for some tablets to be missing the laser drilling which might affect drug release.	Teva Pharmaceuticals

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Metformin Hydrochloride Extended Release Tablets, 500 mg, 100-count bottle, Rx only, Manufactured by: Actavis Laboratories, FL Inc	Class II	Lot #: 1210888A, Exp 03/2019	Defective Delivery System: There is a potential for some tablets to be missing the laser drilling which might affect drug release.	Teva Pharmaceuticals USA
Drugs	Metformin Hydrochloride Extended Release Tablets 1000 mg, 60-count bottle, Rx only, Manufactured by: Actavis Laboratories FL, Inc.	Class II	Lot #: 1139500A, Exp 04/2019; 1240343A, 1248901M, 1256614M, Exp 05/2020	Defective Delivery System: There is a potential for some tablets to be missing the laser drilling which might affect drug release.	Teva Pharmaceuticals USA
Drugs	Alprostadil 500 mcg/mL Injectable, Vials, Westlab Pharmacy, Inc., Gainesville, FL	Class II	Lot: 03192018@42 Discard after 9/15/2018	Incorrect Product Formulation	Westlab Pharmacy, Inc
Drugs	ADAA Cataract Drops, (Lido 1.47%, Phenyleph 0.294% Cyclopentolate 0.147%, Tropicamide 0.0735%, Moxiflox 0.0294%, Ketorolac 0.0147%) 1x 1cc syringe, Westlab Pharmacy, Inc.	Class II	Lot: 06182018@30 Exp. 08/28/2018	Lack of Process Controls	Westlab Pharmacy, Inc.
Drugs	Cyclosporine 1% Human Eye Drops, Westlab Pharmacy, Inc.	Class II	Lot: 07262018@7 Exp. 08/25/2018	Lack of Process Controls	Westlab Pharmacy, Inc.
Drugs	Cortaid Intensive Therapy Cooling Spray (1% hydrocortisone), 2 FL OZ (59 mL) spray bottle, OTC	Class II	Lot #: 171205E, 171951E, Exp 5/19; 173365K, Exp 10/19	CGMP deviations: Notice received from supplier of a voluntary recall of all their nasal products and baby oral gels due to the possibility of	Valeant Pharmaceuticals

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
				microbial contamination. No positive results for the firm's products were obtained. After the firm review, cGMP deviations were evident	
Drugs	Fluocinolone Acetonide Topical Solution, USP 0.01%, 60ml Bottle, Manufactured for: Lupin Pharmaceutical, Inc.	Class II	Lot# M16666, EXP 12/2018	Failed Impurities/Degradation Specifications: Out of specification result noticed for total impurities observed during stability analysis	LUPIN SOMERSET
Drugs	HydroXYZine HYDROCHLORIDE SYRUP (HydroXYZine Hydrochloride Oral Solution, USP), 10 mg per 5 mL, Rx only	Class II	Lot #: 1097, Exp 10/18	CGMP Deviations: cleaning procedures during manufacturing caused out of specification results for unknown impurities.	Lannett Company, Inc
Drugs	Cidofovir injection 375 mg/mL (75 mg/mL) vial Injection, 5 mL vials, Rx Only, Mfg. By Emcure Pharmaceutical	Class II	Lot #: VCIA083, Exp. JUN2020	Lack of Assurance of Sterility: complaints received about dried powder on the outside of the bottle	Heritage Pharmaceuticals, Inc.
Drugs	Meropenem for Injection, USA (I.V.), 1 gram/vial, 25 vials per carton, Sterile, Rx Only	Class II	Lot: 609G047, EXP 10/2018	Lack of assurance of sterility: loss of container integrity.	Pfizer Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Lidocaine 1% + Epinephrine 1:100,000 (MDV) INJ SOL, 50 mL per glass vial, Rx only	Class II	Lot# 04042018:58, Exp 10/17/18	Subpotent drug: During testing of the retention sample, the firm discovered that the product was sub-potent.	RXQ Compounding LLC
Drugs	Metoprolol Succinate Extended Release Tablets, USP 50 mg, 100-count bottle, Rx only, Manufactured by: Actavis Laboratories FL	Class II	Lot # 1220211M, Exp 02/2019	Failed dissolution specifications: Out-of-Specification dissolution test result obtained during routine stability testing.	Teva Pharmaceuticals USA
Drugs	Cortaid Maximum Strength Cream (1% hydrocortisone), 1 OZ (28 g) tube, OTC	Class II	Lot #: 170843B, Exp 2/19; 171484D, Exp 4/19; 171791E, 171848E, Exp 5/19; 172359J, 172360J, 173184J, Exp 9/19; 173512P, Exp 12/19; 180180B, Exp 2/20; 181098C, Exp 3/20	CGMP deviations: Notice received from supplier of a voluntary recall of all their nasal products and baby oral gels due to the possibility of microbial contamination. No positive results for the firm's products were obtained. After the firm review, cGMP deviations were evident	Valeant Pharmaceuticals
Drugs	Cortaid 12-Hour Advanced Anti-itch Cream (1% hydrocortisone), NET WT 1.5 oz. (42 g) tube, OTC	Class II	Lot #: 172185F, Exp 6/19	CGMP deviations: Notice received from supplier of a voluntary recall of all their nasal products and baby oral gels due to the	Valeant Pharmaceuticals

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
				possibility of microbial contamination. No positive results for the firm's products were obtained. After the firm review, cGMP deviations were evident	
Drugs	Amlodipine/Valsartan HCTZ 10 mg/320 mg/25 mg tablets, HDPE 90 cc bottles in cardboard trays Original NDC 13668-0325-30 Repackaged NDC 70518-1220-00	Class II	Lot # B0438903-052118 70518-1220-00	CGMP deviations: Notice received from supplier of a voluntary recall of all their nasal products and baby oral gels due to the possibility of microbial contamination. No positive results for the firm's products were obtained. After the firm review, cGMP deviations were evident.	RemedyR epack Inc.
Drugs	Metformin Hydrochloride Extended Release Tablets 1000 mg, 90-count bottle, Rx only, Manufactured by: Actavis Laboratories FL, Inc.	Class II	Lot # B0438903-052118 70518-1220-00	Defective Delivery System: There is a potential for some tablets to be missing the laser drilling which might affect drug release.	Teva Pharmaceuticals USA

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	PIO&METFORMIN 15/1000 mg Tab 1 (Pioglitazone and Metformin XT) tablets, Takeda Brand Name: Actoplus Met XR (Pioglitazone and metformin HCl extended -release) tablets, 15 mg/1000 mg, packaged in a fiber drum	Class II	Bulk Lot no 1250668, 15 mg/1000 mg Bulk product No # 1274150, no NDC Codes, bulk exp. date 05/2020 & 10/2020	Defective Delivery System: There is a potential for some tablets to be missing the laser drilling which might affect drug release.	Teva Pharmaceuticals USA
Drugs	Acetylcysteine Injection 10 mg/5 mL (2 mg/mL), Pharm D Solutions, Houston, Texas ---- NDC 69699-1424-10	Class II	Lots: 07032018:93 Discard by: 01/03/2019; 07032018:27 Discard by: 01/03/2019; 07032018:97 Discard by: 01/03/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Arginine Injections 100 mcg/mL, Pharm D Solutions, Houston, Texas NDC 69699-1414-20	Class II	Lots: 04112018:83 Discard by: 10/8/2018; 03202018:48 Discard by: 9/16/2018; 04302018:91 Discard by: 10/27/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Ascorbic Acid 500 mg/mL Solution Pharm D Solutions, Houston, Texas --- NDC 69699-1502-50	Class II	Lot: 04252018:91 Discard by: 10/21/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Beta-complex B-1, B-6, B-3, B-12, B-5 100, 2.54 Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1611-30	Class II	Lot: 06182018:55 Discard by: 12/25/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Bacteriostatic Water for Injection 10 mL, Pharm D Solutions, Houston, Texas --- NDC 69699-1417-10	Class II	Lots: 07182018:12 Discard by: 1/14/2019; 04042018:68 Discard by: 9/30/2018; 05152018:57	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			Discard by: 11/10/2018; 06202018:17 Discard by: 12/17/2018		
Drugs	Bi-Mix Injection (Alprostadil 150 mcg/Lidocaine 2 mg/mL), Pharm D Solutions, Houston, Texas --- NDC 69699-1323-05	Class II	Lots: a)04032018:49 Discard by: 9/30/2018; 05242018:72 Discard by: 11/20/2018; b) 06192018:08 Discard by: 12/16/2018; 06132018:29 Discard by: 12/10/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Caffeine and Sodium Benzoate Injection 125 mg/125 mg/mL Injectable Pharm D Solutions, Houston, Texas ---- NDC 69699-1428-02	Class II	Lots: 07192018:88 Discard by: 10/16/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Calcium Gluconate 1% Eyewash Oph. Soln, 10 mg/mL, 1000 mL bottles, Pharm D Solutions, Houston, Texas ---- NDC 69699-0907-10	Class II	Lots: 07192018:88 Discard by: 10/16/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Calcium Gluconate1% Eyewash 10 mg/mL, 125 mL bottles, Pharm D Solutions, Houston, Texas ---- NDC 69699-0906-12	Class II	Lots: 05072018:27 Discard by: 5/2/2019; 07122018:11 Discard by 7/7/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Calcium Gluconate1% Eyewash 10 mg/mL, 125 mL bottles, Pharm D Solutions, Houston, Texas ---- NDC 69699-0906-12	Class II	Lots: 07312018:46 Discard by: 1/27/2019; 07262018:97 Discard by: 1/21/2019; 07122018:40 Discard by: 1/8/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Dexpanthenol Injection, 250 mg/mL Pharm D Solutions, Houston, Texas --- NDC 69699-1610-30	Class II	Lot: 08292018:08 Discard by: 2/23/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Epi-Shugarcaine Kit Solution Pharm D Solutions, Houston, Texas --- NDC 69699-1409-60	Class II	08272018:79 Discard by: 10/1/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Epinephrine 1 mg/1 mL 3 mL Injectable Pharm D Solutions, Houston, Texas --- - NDC 69699-0109-03	Class II	Lots: 07272018:17 Discard by: 9/25/2018; 08292018:74 Discard by: 10/28/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Glutamine 10 mg/mL Solution, Pharm D Solutions, Houston, Texas ---- NDC 69699-1439-59	Class II	Lots: 01402018:93 Discard by: 10/10/2018; 07122018:16 Discard by: 9/10/2018; 08302018:65 Discard by:	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Glutathione 200 mg/mL Solution, Pharm D Solutions, Houston, Texas --- NDC 69699-1504-30	Class II	Lot: 08012018:94 Discard by: 1/27/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Glycerin 72% (Lidocaine/Epi 2:1) Injectable, Pharm D Solutions, Houston, Texas --- - NDC 69699-1401-30	Class II	Lot: 07312018:13 Discard by: 9/28/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	HCG Lyophilized 5000 IU Injectable Pharm D Solutions, Houston, Texas --- - NDC 69699-1707-10	Class II	Lot: 04252018:33 Discard by: 10/21/2018; 05082018:39 Discard by: 11/4/2018; 06262018:00 Discard by: 12/23/2018; 07192018:13	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			Discard by: 1/15/2019; 08012018:46 Discard by: 1/28/2019; 08212018:69 Discard by: 11/30/2018		
Drugs	HCG Lyophilized 1200 IU Injectable, Pharm D Solutions, Houston, Texas --- - NDC 69699-1743-12	Class II	Lot: 04092018:58 Discard by: 10/6/2018; 06072018:03 Discard by: 12/4/2018; 05292018:86 Discard by: 11/25/2018; 07192018:64 Discard by: 1/15/2019; 08302018:30 Discard by: 2/26/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	HCG 3000 Unit Powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1738- 10	Class II	Lot: 03262018:79 Discard by: 9/22/2018; 08212018:75 Discard by: 2/17/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	HCG 4000 Unit Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1704- 01	Class II	Lot: 03142018:73 Discard by: 3/9/2019; 04122018:64 Discard by: 4/7/2019; 07162018:84 Discard by: 7/11/2019; 06192018:36 Discard by: 6/12/2019; 08062018:28 Discard by: 8/1/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	HCG 50,000 unit/0.3 gm Mannitol Lyophilized Powder Pharm D Solutions, Houston, Texas --- NDC 69699-1736-50	Class II	Lot: 04092018:36 Discard by: 10/6/2018; 05292018:93 Discard by: 11/25/2018; 08062018:96 Discard by: 2/2/2019; 07022018:64 Discard by: 7/6/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	HCG 6000 unit/0.3 gm Mannitol Lyophilized 6000 IU/vial injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1739-06	Class II	Lot: 04092018:14 Discard by: 10/6/2018; 06042018:54 Discard by: 12/1/2018; 05292018:81 Discard by: 11/25/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Levocarnitine 170 mg/mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1617-10	Class II	Lot: 04232018:63 Discard by: 10/20/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Lipo MIC-12 Compound Injectable a) NDC 69699-1603-10; b) 30 mL Stock Solution Compound Injectable NDC 69699-1603-30, Pharm D Solutions, Houston, Texas	Class II	Lot: a) 09042018:66/A Discard by: 3/3/2019; 07302018:65 Discard by: 1/26/2019; b) 08132018:75/A Discard by: 2/1/2019; 04172018:16 Discard by: 9/30/2018; 03212018:27 Discard by: 9/17/2018; 04242018:82 Discard by: 10/20/2018;	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			05142018:72 Discard by: 11/10/2018; 06192018:67 Discard by: 12/18/2018; 08142018:00 Discard by: 2/1/2019; 07302018:64 Discard by: 1/26/2019		
Drugs	Magnesium 40 gm/ns 1000 mL IV, Pharm D Solutions, Houston, Texas --- NDC 69699-0904-10	Class II	Lot: 05242018:04 Discard by: 8/22/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Methylcobalamin 1 mg/mL a) 10 mL Injectable NDC 69699-1501-10; b) 30 mL Injectable NDC 69699-1501-30, Pharm D Solutions, Houston, Texas	Class II	Lot: a) 04242018:27 Discard by: 9/15/2018; 04302018:55 Discard by: 10/27/2018; b) 03192018:33 Discard by: 9/15/2018; 05222018:28 Discard by: 11/18/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Oxytocin 30 unit in LR 500 mL 0.06 units/mL IV, Pharm D Solutions, Houston, Texas --- NDC 69699-1203-50	Class II	Lot: 03152018:12 Discard by: 6/13/2018; 04182018:08 Discard by: 7/17/2018; 04302018:94 Discard by: 7/29/2018; 03292018:44 Discard by: 6/26/2018; 05212018:95 Discard by: 8/19/2018; 06142018:46	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			Discard by: 9/12/2018; 05312018:37 Discard by: 8/29/2018; 06282018:80 Discard by: 9/26/2018; 07312018:12 Discard by: 10/29/2018; 07102018:53 Discard by: 10/8/2018; 08222018:18 Discard by: 11/20/2018		
Drugs	Phenol 5% and Glycerin Aqueous Solution 10 mL Injection, Pharm D Solutions, Houston, Texas --- NDC 69699-1431-10	Class II	Lot: 05082018:59 Discard by: 11/4/2018; 08082018:57 Discard by: 2/4/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Phenol 7% and Glycerin Aqueous Solution 10 mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1432-10	Class II	Lot: 08082018:86 Discard by: 2/4/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Phosphate Buffer Solution 0.05 m Aqueous Solution, Pharm D Solutions, Houston, Texas --- NDC 69699-0912-20	Class II	Lot: 06252018:63 Discard by: 12/22/2018; 07312018:35 Discard by: 1/26/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Prostaglandin E1 150 mcg/mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1623-05	Class II	Lot: 04262018:18 Discard by: 10/22/2018; 03292018:66 Discard by: 9/24/2018; 05312018:19 Discard by: 11/27/2018; 07022018:55 Discard by:	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			12/29/2018; 06122018:51 Discard by: 12/9/2018; 07242018:71 Discard by: 1/20/2019; 08302018:90 Discard by: 2/23/2019		
Drugs	Prostaglandin E1 40 mcg/mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1347-05	Class II	Lot: 04262018:95 Discard by: 10/22/2018; 03292018:59 Discard by: 9/24/2018; 05312018:66 Discard by: 11/27/2018; 06122018:07 Discard by: 12/9/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Prostaglandin E1 80 mcg/mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1337-05	Class II	Lot: 04252018:84 Discard by: 10/22/2018; 03292018:62 Discard by: 9/24/2018; 05312018:52 Discard by: 11/27/2018; 07022018:82 Discard by: 11/17/2018; 06122018:96 Discard by: 12/9/2018; 07242018:22 Discard by: 1/20/2019; 08302018:71 Discard by: 2/23/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Pyridoxine 100 mg/mL, 30 mL MDV Injectable, Pharm D Solutions, Houston, TX --- NDC 69699-1614-30	Class II	Lot: 03132018:47 Discard by: 9/9/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	QM-4A Quadmix 5 mL 30 PA-2PH-150A-Atropine 0.4 mg Aqueous Solution, Pharm D Solutions, Houston, TX --- NDC 69699-1342-05	Class II	Lot: 07242018:90 Discard by: 1/20/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Reck Injection, Pharm D Solutions, Houston, Texas --- NDC 69699-1459-50	Class II	Lot: 03262018:11 Discard by: 4/25/2018; 04102018:38 Discard by: 5/10/2018; 05312018:63 Discard by: 6/30/2018; 05032018:97 Discard by: 6/2/2018; 06082018:24 Discard by: 7/8/2018; 05212018:80 Discard by: 6/20/2018; 07102018:60 Discard by: 8/9/2018; 06202018:44 Discard by: 7/19/2018; 07232018:08 Discard by: 8/22/2018; 07022018:62 Discard by: 8/1/2018; 08292018:95 Discard by: 9/28/2018; 08202018:61 Discard by: 9/19/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Sermorelin/Ipamorelin 18 mg/15 mg Powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1759-18	Class II	Lot: 07272018:31 Discard by: 1/23/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Sermorelin/GHRP-2 6 mg/6 mg Powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1727-10	Class II	Lot: 05012018:48 Discard by: 10/28/2018; 05242018:32 Discard by: 11/20/2018; 06112018:53 Discard by: 12/8/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Sermorelin/GHRP-2 18 mg/6 mg powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1748-10	Class II	Lot: 04232018:89 Discard by: 10/15/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Sermorelin/GHRP-2 9 mg-6 mg Powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1728-10	Class II	Lot: 03202018:06 Discard by: 9/16/2018; 06112018:49 Discard by: 12/8/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Sermorelin/GHRP-2/GHRP-6 Mannitol 9 mg/9 mg/9 mg/300 mg Powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1726-10	Class II	Lot: 04232018:46 Discard by: 10/13/2018; 06252018:30 Discard by: 12/22/2018; 07232018:10 Discard by: 1/19/2019; 08302018:07 Discard by: 2/25/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Sermorelin/GHRP-2/Theanine/Mannitol 15 mg/6 mg/75 mg/300 mg Powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1731-10	Class II	Lot: 07062018:05 Discard by: 1/2/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Slenderella Compound Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1617-30	Class II	Lot: 04202018:59 Discard by: 10/17/2018; 08282018:46 Discard by: 2/1/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	0.9% Sodium Chloride for Injection, 50 mL bags, Pharm D Solutions, Houston, Texas --- NDC 69699-1426-10	Class II	Lot: 04192018:13 Discard by: 10/16/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Sterile Water 50 mL Aqueous Solution, Pharm D Solutions, Houston, Texas --- NDC 69699-1421-50	Class II	Lot: 08092018:38 Discard by: 2/5/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Tilarginine Acetate 50 mg/mL, 10 mL, Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1461-10	Class II	Lot: 06212018:28 Discard by: 12/11/2019; 06152018:24 Discard by: 12/12/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Tri-Mix XL 150 mg/10 mg/100 mcg a) Injectable NDC 69699-1353-10; b) (LYO) Powder NDC 69699-1353-10, Pharm D Solutions, Houston, Texas	Class II	Lot: a) 04132018:97 Discard by: 10/10/2018; 04032018:25 Discard by: 9/30/2018; b) 04162018:29 Discard by: 10/11/2018; 03282018:80 Discard by: 9/24/2018; 06122018:06 Discard by: 12/9/2018; 08132018:55 Discard by: 2/9/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Tri-Mix Papaverine/Phentolamine/A Iprostadil 150 mg/5 mg/50 mcg a) Injectable NDC 69699-1332-05 b) (LYO) Powder NDC 69699-1332-05, Pharm D Solutions,	Class II	Lot: a) 09062018:87 Discard by: 1/14/2019 b) 04042018:44 Discard by: 10/29/2018; 09022018:04	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Houston, Texas		Discard by: 3/1/2019; 05212018:44 Discard by: 11/17/2018; 06122018:83 Discard by: 12/9/2018; 08132018:86 Discard by: 2/9/2019		
Drugs	Trimix BM3 Papaverine 60 mg/Phentolamine 4 mg Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1310-03	Class II	Lot: 07262018:58 Discard by: 1/21/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Trimix QM10 Papaverine 30 mg/Phentolamine 4 mg/Atropine 1 mg/PGE 150 mcg/mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1352-05	Class II	Lot: 04262018:09 Discard by: 10/22/2018; 07022018:48 Discard by: 12/29/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Trimix T 101 Alprostadil/Papverine/Phentolamine 5.9 mcg/17.65 mg/0.59 mcg per mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1336-05	Class II	Lot: 05312018:22 Discard by: 6/30/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Trimix 30-1-30 Papavarin 30 mg/Phentolamine 1 mg/Alprostadil 30 mg/mL Aqueous Solution, Pharm D Solutions, Houston, Texas --- NDC 69699-1319-10	Class II	Lot: 06192018:98 Discard by: 12/16/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Trimix Alprostadil/Phentolamine/Papavarin 40 mcg/1 mg/30 mg 10 mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1330-05	Class II	Lot: 08062018:52 Discard by: 10/5/2018; 08012018:08 Discard by: 9/30/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Trimix AT-6 Papa 30 mg/Phent 4 mg/Atrop. 0.3 mg Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1343-05	Class II	Lot: 04262018:90 Discard by: 10/22/2018; 05312018:92 Discard by: 11/27/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Trimix Papaverine/Phentolamine/A Iprostadil 30 mg/1 mg/10 mcg Powder Pharm D Solutions, Houston, Texas --- NDC 69699-1365-10	Class II	Lot: 03292018:02 Discard by: 9/24/2018; 05302018:54 Discard by: 11/26/2018; 06062018:79 Discard by: 12/3/2018; 06122018:31 Discard by: 11/17/2018; 07252018:44 Discard by: 1/21/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Trimix Papaverine/Phentolamine/A Iprostadil 30 mg/1 mg/20 mcg Powder Pharm D Solutions, Houston, Texas --- NDC 69699-1366-02	Class II	Lot: 03292018:70 Discard by: 9/25/2018; 05302018:94 Discard by: 11/26/2018; 06072018:67 Discard by: 12/4/2018; 06122018:72 Discard by: 12/9/2018; 07252018:72 Discard by: 1/21/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Trimix Papaverine/Phentolamine/A Iprostadil 30 mg/1 mg/60 mcg Powder Pharm D Solutions, Houston, Texas --- NDC 69699-1367-02	Class II	Lot: 06132018:87 Discard by: 12/10/2018; 05302018:66 Discard by: 11/25/2018; 06122018:54 Discard by: 11/17/2018;	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			07252018:88 Discard by: 1/21/2019		
Drugs	Trimix Papaverine/Phentolamine/A lprostadil/Lidocaine 30 mg/1 mg/175 mcg/1 mg Powder Pharm D Solutions, Houston, Texas --- NDC 69699-1369- 02	Class II	Lot: 05302018:59 Discard by: 11/26/2018; 06132018:44 Discard by: 12/10/2018; 06062018:64 Discard by: 12/3/2018; 07262018:97 Discard by: 11/1/2018; 07052018:23 Discard by: 1/1/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Trimix ST-1 30PA-1.5PH-50A Aqueous Solution Pharm D Solutions, Houston, Texas --- NDC 69699-1388-05	Class II	Lot: 05312018:12 Discard by: 11/27/2018; 07242018:04 Discard by: 1/20/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Trimix ST-9B 30 PA-2PH- 100A Aqueous Solution Pharm D Solutions, Houston, Texas --- NDC 69699-1344- 05	Class II	Lot: 04262018:54 Discard by: 10/23/2018; 03292018:91 Discard by: 9/24/2018; 05312018:10 Discard by: 11/27/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Phentolamine 1 mg/Papaverine 15 mg/Alprostadil 150 mcg Aqueous Solution Pharm D Solutions, Houston, Texas --- NDC 69699-1308-03	Class II	Lot: 04102018:07 Discard by: 10/7/2018; 05102018:18 Discard by: 11/6/2018; 05222018:64 Discard by: 8/1/2018; 07022018:46 Discard by: 12/29/2018;	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			08012018:81 Discard by: 1/28/2019; 06202018:97 Discard by: 9/17/2018		
Drugs	Trimix ST9D 30PA-2PH-150A Aqueous Solution Pharm D Solutions, Houston, Texas --- NDC 69699-1311-03	Class II	Lot: 04102018:12 Discard by: 10/7/2018; 05102018:06 Discard by: 11/6/2018; 05222018:76 Discard by: 11/18/2018; 07022018:35 Discard by: 12/29/2018; 08272018:00 Discard by: 1/14/2019; 08082018:14 Discard by: 2/4/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Trimix T-101 Alprostadil/Phapaverine/Ph entolamine 5.9 mcg/17.65 mg/Phentolamine 0.59 mcg per mL Pharm D Solutions, Houston, Texas --- NDC 69699-1366-05	Class II	Lot: 07242018:35 Discard by: 8/23/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Trimix T-106 30PA-1PH-25A Aqueous Solution Pharm D Solutions, Houston, Texas --- NDC 69699-1339-05	Class II	Lot: 03292018:66 Discard by: 9/24/2018; 05312018:81 Discard by: 11/27/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Trimix T105 PGE/Phentolamine/Papaveri ne 10 mcg/30 mg/1 mg Injectable Pharm D Solutions, Houston, Texas --- NDC 69699-1351-05	Class II	Lot: 04262018:08 Discard by: 10/22/2018; 07242018:81 Discard by: 1/20/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Vigamox Oph. Solution Pharm D Solutions, Houston, Texas --- NDC 69699-0304- 05	Class II	Lot: 04192018:22 Discard by: 5/17/2018; 04022018:47 Discard by: 4/23/2018; 05102018:77 Discard by: 6/7/2018; 08022018:63 Discard by: 8/30/2018; 08272018:66 Discard by: 9/24/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Zinc Sulfate 1 mg/mL MDV Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1418-10	Class II	Lot: 06072018:60 Discard by: 12/4/2018	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Testosterone in Grapeseed Oil 200 mg/mL, a) 4 mL, b) 5 mL, c) 10 mL and d) 30 mL Injectable, Pharm D Solutions, Houston, Texas NDC 69699-1702-05	Class II	Lot: a) Lot: 01302018:77/A Discard by: 1/25/2019; 09042017:74/B Discard by: 8/30/2018; 04042018:51/A Discard by: 3/31/2019; 05152018:94/A Discard by: 5/9/2019; 07022018:04/A Discard by: 6/27/2019; 07162018:80/B Discard by: 7/11/2019; 08272018:15/B Discard by: 8/22/2019; b) 12052017:13/B, Discard by: 11/30/2018; 09042017:74/A	Lack of Assurance of Sterility	Pharm D Solutions, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			Discard by: 8/30/2018; 03212018:39/B Discard by: 3/17/2019; 01302018:77/B		
Drugs	Testosterone Cypionate/Propionate 200 mg/10 mg/1 mL 30 mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1745-30	Class II	Lot: 02272018:63/A Discard by: 2/22/2019; 08162018:63/A Discard by: 4/30/2019; 10092017:30 Discard by: 10/1/2018; 02272018:63 Discard by: 2/22/2019; 08162018:63 Discard by: 4/30/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Catapres .2 (clonidine hydrochloride, USP) 0.2mg, 100-count bottles, Rx only, Dist. by: Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877 USA. Made in Germany. NDC 0597-0007-01	Class II	Lot: 757739, EXP 9/2020	Failed Dissolution Specifications: OOS results during routine stability testing	Boehring er Ingelhei m Pharmac euticals, Inc.
Drugs	Morphine (1 mg/mL) in NS 100 mL Bag, Rx only, Advanced Pharma, Inc. d/b/a Avella of Houston, and Avella of Deer Valley, Inc. #38	Class II	Lot # 7/10/18 0415 24110P, Exp 11/07/2018; 7/25/18 0247 24110P, Exp 11/22/2018	Lack of assurance of sterility	Avella of Deer Valley, Inc.
Drugs	Fentanyl (10 mcg/mL) in NS 1 mL (in 3mL BD Syringe), Rx only, Advanced Pharma, Inc. d/b/a Avella of Houston, and Avella of Deer Valley, Inc. #38	Class II	Lot # 8/8/18 0200 15-21070S, Exp 11/06/2018	Lack of assurance of sterility	Avella of Deer Valley, Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Hydromorphone (0.2 mg/mL) in NS 100 mL Bag, Rx only, Advanced Pharma, Inc. d/b/a Avella of Houston, and Avella of Deer Valley, Inc. #38	Class II	Lot # 8/27/18 0215 22110P, Exp 12/10/2018	Lack of assurance of sterility	Avella of Deer Valley, Inc.
Drugs	Phenylephrine 25 mg added to NS 250 mL Bag, Rx only, Advanced Pharma, Inc. d/b/a Avella of Houston, and Avella of Deer Valley, Inc. #38	Class II	Lot# 138-20182308@88, Exp 11/06/2018	Lack of assurance of sterility	Avella of Deer Valley, Inc.
Drugs	Phenylephrine 30 mg added to NS 250 mL Bag, Rx only, Advanced Pharma, Inc. d/b/a Avella of Houston, and Avella of Deer Valley, Inc. #38	Class II	Lot# 138-20180409@55, Exp 11/18/2018	Lack of assurance of sterility	Avella of Deer Valley, Inc.
Drugs	5% Dextrose Injection, USP, Rx Only, a) 25 mL NDC 0409-7923-20; b) 250 mL NDC 0409-7922-02, Hospira, Inc. Lake Forest, IL 60045	Class II	Lots: a) 84-017-JT Exp. December 01, 2019; b) 84-012-JT Exp. June 01, 2019	Lack of Assurance of Sterility; bags have the potential to leak	ICU Medical Inc
Drugs	0.9% Sodium Chloride Injection, USP Rx Only a) 250 mL NDC 0409-7983-02; b) 150 mL NDC 0409-7983-61; c) 50 mL NDC 0409-7984-36; d) 100 mL NDC 0409-7984-37, Hospira, Inc. Lake Forest, IL 60045	Class II	Lots: a) 84-011-JT Exp. December 01, 2019 and 85-014-JT Exp. January 01, 2020; b) 84-015-JT Exp. December 01, 2019; c) 84-016-JT Exp. June 01, 2019; d) 84-005-JT Exp. December 01, 2019 and 84-014-JT Exp. December 01, 2019	Lack of Assurance of Sterility; bags have the potential to leak	ICU Medical Inc
Drugs	Healthful Naturals DizziFree Oral Spray, 2 fl oz (59 mL) per bottle, Distributed by: Silver Star Brands, Oshkosh, WI 54906. NDC 68703-204-02	Class II	Lot K022616D	CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible	Silver Star Brands

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
				microbial contamination.	
Drugs	Healthful Naturals Leg Cramp Support Oral Spray, 2 fl oz (59 mL) per bottle, Distributed by: Silver Star Brands, Oshkosh, WI 54906 NDC 68703-206-02	Class II	Lot K022216C	CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.	Silver Star Brands
Drugs	Ortho-Novum 1/35 (norethindrone/ethinyl estradiol) Tablets, 1 mg/0.035 mg, 28-Day Regimen per pouch (NDC 50458-176-28), 6 Veridate Tablet Dispensers and 6 refills per carton (NDC 50458-176-06), Rx only, Manufactured by: Janssen Ortho, LLC, Manati, Puerto Rico 00674;	Class II	Lot # 18BM114, Exp. 03/2020	Labeling: Incorrect Instructions; Instructions included for use with the Veridate dispenser contained instructions for the Dialpak dispenser.	Janssen Pharmaceuticals, Inc.
Drugs	Tesamorelin, 1mg/vial, 6mL vial, Lyophilized Powder for Reconstitution and Subcutaneous Injection, Rx Only, Tailor Made Compounding, Nicholasville, KY 40356	Class II	Lot, exp: 7101804, 7111807, 7131807, 7151801, 7161804, 7181805, 7191801, 7201803, 7211801, 7221801, 7231805, 7241803, 7251803, 7261802, 7271801, 7281801, 7301805, 7311805, exp 7/19; 8021801, 8031801, 8041801, 8081802, 8091804, 8101803, 8111810, 8121801, 8141801, 8161803, 8171803, 8201801, 8251801, exp 8/19	Labeling: Incorrect or Missing Lot and/or Expiration Date; vial indicates a 1 year expiration date instead of a 6 month expiration date	Tailor Made Compounding

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Estradiol 10mg pellet, 1 count (NDC 69761-010-01), 6 count (NDC 69761-010-06), 12 count (NDC 69761-010-12), and 30 count (NDC 69761-010-30) vials, Rx Only, Qualgen, LLC, Edmond, OK 73013	Class II	Lots; C262 BUD: 12/20/2018; D067 BUD: 03/21/2019; D072 BUD: 03/28/2019	Lack of Assurance of Sterility	Qualgen, LLC
Drugs	Estradiol 12.5mg pellet, 1 count (NDC 69761-012-01), 6 count (NDC 69761-012-06), 12 count (NDC 69761-012-12), and 30 count (NDC 69761-012-30) vials, Rx Only, Qualgen, LLC, Edmond, OK 73013	Class II	Lots: C236 BUD: 11/13/2018	Lack of Assurance of Sterility	Qualgen, LLC
Drugs	Estradiol 15mg pellet, 1 count (NDC 69761-015-01), 6 count (NDC 69761-015-06), 12 count (NDC 69761-015-12), and 30 count (NDC 69761-015-30) vials, Rx Only, Qualgen, LLC, Edmond, OK 73013	Class II	Lots: C253 BUD: 12/12/2018; D016 BUD: 1/18/2019	Lack of Assurance of Sterility	Qualgen, LLC
Drugs	Estradiol 18mg pellet, 1 count (NDC 69761-018-01), 6 count (NDC 69761-018-06), 12 count (NDC 69761-018-12), and 30 count (NDC 69761-018-30) vials, Rx Only, Qualgen, LLC, Edmond, OK 73013	Class II	Lots: C255 BUD: 12/13/2018	Lack of Assurance of Sterility	Qualgen, LLC
Drugs	Estradiol 25mg pellet, 1 count (NDC 69761-025-01), 6 count (NDC 69761-025-06), 12 count (NDC 69761-025-12), and 30 count (NDC 69761-025-30) vials, Rx Only, Qualgen, LLC, Edmond, OK 73013	Class II	Lots: C238 BUD: 11/14/2018	Lack of Assurance of Sterility	Qualgen, LLC
Drugs	Estradiol 6 mg pellet, 1 count (NDC 69761-006-01), 6 count (NDC 69761-006-06), 12 count (NDC 69761-006-12), and 30 count (NDC	Class II	Lots: D007 BUD: 01/09/2019; D060 BUD: 3/14/2019	Lack of Assurance of Sterility	Qualgen, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	69761-006-30) vials, Rx Only Qualgen, LLC, Edmond, OK 73013				
Drugs	Testosterone 100mg pellet, 1 count (NDC 69761-110-01), 6 count (NDC 69761-110-06), 12 count (NDC 69761-110-12), and 30 count (NDC 69761-110-30) vials, Rx Only Qualgen, LLC, Edmond, OK 73013	Class II	Lots: C232 BUD: 11/3/2018; C239 BUD: 11/14/2018; C246 BUD: 11/29/2018; C260 BUD: 12/19/2018; D004 BUD: 1/4/2019; D017 BUD: 1/18/2019; D023 BUD: 1/26/2019; D053 BUD: 3/6/2019	Lack of Assurance of Sterility	Qualgen, LLC
Drugs	Testosterone 12.5mg pellet, 1 count (NDC 69761-112-01), 6 count (NDC 69761-112-06), 12 count (NDC 69761-112-12), and 30 count (NDC 69761-112-30) vials, Rx Only Qualgen, LLC, Edmond, OK 73013	Class II	Lots: C261 BUD: 12/20/2018	Lack of Assurance of Sterility	Qualgen, LLC
Drugs	Testosterone 200mg pellet, 1 count (NDC 69761-120-01), 6 count (NDC 69761-120-06), 12 count (NDC 69761-120-12), and 30 count (NDC 69761-120-30) vials, Rx Only Qualgen, LLC, Edmond, OK 73013	Class II	Lots: C230 BUD: 11/1/2018; C233 BUD: 11/3/2018; C234 BUD: 11/9/2018; C237 BUD: 11/13/2018; C240 BUD: 11/15/2018; C242 BUD: 11/20/2018; C244 BUD: 11/27/2018; C248 BUD: 12/4/2018; C250 BUD: 12/6/2018; C252 BUD: 12/12/2018; C256 BUD: 12/14/2018; C258 BUD: 12/18/2018; C264 BUD: 12/27/2018; D006 BUD: 1/8/2019; D009 BUD:	Lack of Assurance of Sterility	Qualgen, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			1/10/2019; D013 BUD: 1/15/2019		
Drugs	Testosterone 25 mg pellet, 1 count (NDC: 69761-125-01) and 30 count vials (NDC: 69761-125-30), Rx Only Qualgen, LLC, Edmond, OK 73013	Class II	Lots: C235 BUD: 11/10/2018; C241 BUD: 11/17/2018; C251 BUD: 12/8/2018; C265 BUD: 12/28/2018; D008 BUD: 1/9/2019; D018 BUD: 1/19/2019; D022 BUD: 1/25/2019; D032 BUD: 2/7/2019; D037 BUD: 2/13/2019; D057 BUD: 3/8/2019; D061 BUD: 3/14/2019; D069 BUD: 3/23/2019	Lack of Assurance of Sterility	Qualgen, LLC
Drugs	Testosterone 37.5 mg pellet, 1 count (NDC 69761-137-01), 6 count (NDC 69761-137-06), 12 count (NDC 69761-137-12) and 30 count (NDC 69761-137-30) vials, Rx Only, Qualgen, LLC, Edmond, OK 73013	Class II	Lots: C245 BUD: 11/28/2018; D005 BUD: 1/5/2019; D027 BUD: 1/31/2019; D035 BUD: 2/9/2019; D058 BUD: 3/9/2019	Lack of Assurance of Sterility	Qualgen, LLC
Drugs	Testosterone 50mg pellet, 1 count (NDC 69761-150-01), 6 count (NDC 69761-150-06), 12 count (NDC 69761-150-12), and 30 count (NDC 69761-150-30) vials, Rx Only Qualgen, LLC, Edmond, OK 73013	Class II	Lots: C247 BUD: 11/30/2018; C249 BUD: 12/5/2018; C266 BUD: 12/29/2018; D012 BUD: 1/12/2019; D029 BUD: 2/2/2019	Lack of Assurance of Sterility	Qualgen, LLC
Drugs	Testosterone 87.5mg pellet, 1 count (NDC 69761-187-01), 6 count (NDC 69761-187-06), 12 count (NDC 69761-187-12), and 30 count (NDC 69761-187-30) vials, Rx Only Qualgen, LLC, Edmond, OK 73013	Class II	Lots: C243 BUD: 11/21/2018; D010 BUD: 1/11/2019; D025 BUD: 1/30/2019	Lack of Assurance of Sterility	Qualgen, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Testosterone 200 mg/Anastrozole 20 mg pellet, 1 count (NDC 69761-222-01), 6 count (NDC 69761-222-06), 12 count (NDC 69761-222-12), and 30 count (NDC 69761-222-30) vials, Rx Only, Qualgen, Edmond, OK 73013	Class II	Lot: C254 BUD: 12/13/2018	Lack of Assurance of Sterility	Qualgen, LLC
Drugs	SparkleFresh Fluoride Toothpaste, Sodium Monofluorophosphate 0.76%, a) 17 g tube (NDC 53329-083-92, product number NONTP6I), b) 24 g tube (NDC 53329-083-93, product number NONTP85I), c) 42.5 g (NDC 53329-083-21, product number NONTP15I), d) 24 g tube (NDC 53329-081-93, product number DGN1000), Made in Malaysia for Medline Industries, Inc.,	Class II	a) Lot 102920C, exp 10/29/2020 and 111220C, exp 11/11/2020; b) 111620D, exp 11/16/2020; c) 111420D, exp 11/14/2020; d) 111720C, exp 11/17/2020	Microbial Contamination of Non-Sterile Product	Medline Industries Inc
Drugs	deb stoko, Refresh AntiBac FOAM (benzalkonium chloride), 0.13%, 1 L (33.8 fl. oz.) cartridge packaged in 8 cartridges per case, Made in the USA, Deb USA, Inc., Charlotte, NC 28217, NDC 11084-010-27.	Class II	Lot 9131	CGMP Deviations: Product was released to market prior to microbiological testing.	S.C. Johnson Professional
Drugs	Alcohol Free Foaming Hand Sanitizer (benzalkonium chloride), 0.13%, 1 L (33.8 fl. oz.) cartridge packaged in 8 cartridges per case, Safe-T-Fresh Inc., USA, 2530 Xenium Lane North, Minneapolis, MN 55441.	Class II	Lot 9085	CGMP Deviations: Product was released to market prior to microbiological testing.	S.C. Johnson Professional
Drugs	BEVACIZUMAB 2.5 MG/0.1ML, pre-filled syringe (deliverable dose of 1.25MG in normject syringe) Repackaged by Avella	Class II	Lot # 138-20182408@58 BUD 12/22/2018	Lack of Assurance of Sterility	Avella of Deer Valley, Inc

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Specialty Pharmacy, 24416 N 19th Avenue, Phoenix, AZ 85085. NDC 42852-001-24				
Drugs	Ortho-Novum 7/7/7 (norethindrone/ethinyl/estradiol) Tablets, 0.5 mg/0.035 mg, 0.75 mg/0.035 mg, 1 mg/0.035, 28-Day Regimen per pouch, packaged in a) 6 Veridate Tablet Dispensers and 6 Refill pouches (NDC 504-58-178-28) per carton (NDC 50458-178-06); and b) 12 Veridate Tablet Dispenser Refills (NDC 50458-178-12) per carton (NDC 50458-178-12)	Class II	Lot #: a) 18CM120, Exp 03/2020; b) 18BM110, Exp. 03/2020	Labeling: Incorrect Instructions; Instructions included for use with the Veridate dispenser contained instructions for the Dialpak dispenser.	Janssen Pharmaceuticals, Inc.
Drugs	Metoprolol Tartrate Injection, USP, 5 mg/ 5 mL (1 mg/mL), 5 mL per sterile single use glass vial, Rx Only, Manufactured for: Claris Lifesciences, Inc., North Brunswick, NJ 08902. By: Claris Injectables Ltd., Gujarat, India. NDC: 36000-033-10	Class III	Lot #S: A061267, A061273, EXP 10/2018; A061392, A061395, A061398, A061403, A061407, EXP 11/2018; A0A0070, A0A0073, A0A0079, A0A0081, A0A0083, EXP 12/2018; A0A0119, A0A0124, A0A0125, A0A0133, A0A0141, A0A0145, A0A0152, EXP 1/2019; A0A0247, A0A0252, A0A0253, A0A0292, A0A0293, EXP 2/2019; A0A0361, A0A0367, A0A0390, EXP 3/2019; A0A0438, A0A0445, A0A0453, A0A0459, EXP 4/2019; A0A0547, A0A0551, A0A0554, A0A0630, A0A0631, A0A0637, A0A0638, EXP 5/2019;	Failed pH Specifications: Upward shift in the pH of the solution within the shelf life of the impacted lots.	Baxter Healthcare Corporation

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			A0A0777, EXP 7/2019; A0A0915, A0A0919, A0A0924, A0A0930, EXP 8/2019; A0A1094, A0A1097, A0A1110, EXP 11/2019		
Drugs	Contrave (naltrexone HCl and bupropion HCl). Extended-Release Tablets, 8mg/90 mg, 120-count bottles, Rx only, Distributed by Orexigen therapeutics, Inc., La Jolla, CA 92037, NDC 51267-890-99	Class III	Lot #: ZYCY, Exp. 04/11/2021	Container packaging defect.	Orexigen Therapeutics, Inc.
Drugs	Calcium Gluconate 2.5% a) 250 mL 25 mg/mL NDC 69699-0908-25; b) Nasal Spray 2.5 Inhal Soln. NDC 69699-0908-10; c) Nebulization Solution 2.5% Inhal. Soln NDC 69699-0908-10; d) Nebulization 250 mL 2.5% Inhal Soln NDC 69699-0908-25; e) Oral Spray 2.5% 2.5% Oral Soln NDC 69699-0917-60, Pharm D Solutions, Houston, Texas	Class III	Lots: a) 05072018:40 Discard by: 5/2/2019; b) 07262018:44 Discard by: 1/22/2019; c) 07122018:83 Discard by: 7/12/2019; d) 07262018:93 Discard by: 1/22/2019; e) 07262018:81 Discard by: 1/21/2019	Lack of Assurance of Sterility	Pharm D Solutions, LLC
Drugs	Testosterone Topical Solution, 30mg/1.5mL, 110mL bottles, Rx only, Manufactured for: Lupin Pharmaceuticals Inc. Baltimore, Maryland 21202 United States, Manufactured by: Lupin Limited Pithampur (M.P.) 454 775 INDIA, NDC 68180-943-11	Class III	Lot #: K700085, K700087, Exp. November 2019	Defective Container: Repetitive complaints received indicating pump not working.	Lupin Pharmaceuticals Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Prednisolone and Gatifloxacin Ophthalmic Solution, 1%/0.5%, 3 mL dropper bottle, Rx Only, 31818 US Hwy 19N, Palm Harbor, FL 34684	Class III	Lot#: 04092018@2, Exp 12/03/2018	Presence of precipitate	Promise Pharmacy LLC
Drugs	Well at Walgreens, Scar Cream with SPF 30, (Avobenzene 3%, Octocrylene 10%, Oxybenzone 6%), 0.7 OZ (19.8 g) tube, Distributed By: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015, UPC 3 11917 18281 0.	Class III	Lot: 163241K, Exp. October 2018	Subpotent Drug: low out of specification assay results for the octocrylene and avobenzene ingredients.	Product Quest Manufacturing LLC
Drugs	Cicatricure, Scar Cream + Sunscreen SPF 30 (avobenzene 3%, octocrylene 10%, oxybenzone 6%), 0.7 oz. (19.8 g) tube, Distributed by: Genomma Lab USA Inc., Houston, TX 77027, UPC 6 50067 00018 7	Class III	Lot: 163241K, Exp. October 2018	Subpotent Drug: low out of specification assay results for the octocrylene and avobenzene ingredients.	Product Quest Manufacturing LLC
Drugs	Temozolomide capsules, 20 mg, packaged in a) 5-count bottle(NCD 43975-253-05), b) 14-count bottle (NDC 43975-253-14), Rx only, Mfd. by: Stason Pharmaceuticals, Inc., Irvine, CA 92618, Dist. By: Amerigen Pharmaceuticals, Lyndhurst, NJ 07071	Class III	Lot #: a) 17F058A, Exp 6/19; b) 17F058B, Exp 6/19	Failed dissolution specifications: Out-of-Specification dissolution results obtained during stability testing.	Amerigen Pharmaceuticals Inc.
Drugs	Levonorgestrel and Ethinyl Estradiol Tablets, USP 0.15 mg/0.03 mg, Rx Only, 3 extended-cycle blister packs containing 91 tablets each, Made in India, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A., NDC 0378-7281-53.	Class III	Lot # 8508F004A; Exp. 02/20	Labeling: Not Elsewhere Classified-Incorrect NDC and product name identified on blister packs.	Mylan Pharmaceuticals Inc.

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

CURRENT DRUG SHORTAGES

Alcohol Dehydrated Injection (Ethanol)

November 14, 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 back order and the company estimates a release date in mid-December 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=274>

Butorphanol Tartrate Injection

November 14, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has butorphanol 1 mg/mL 1 mL vials and 2 mg/mL 2 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=414>

Calcitriol Injection

November 14, 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>

Carbidopa and Levodopa Extended-Release Tablets

November 14, 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 late-December 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-November 2018.

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

Ciprofloxacin Injection

November 14, 2018

Reason for the Shortage

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

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

Hepatitis A Virus Vaccine Inactivated

November 14, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- GlaxoSmithKline has Havrix adult prefilled syringes on back order and the company estimates a release date in late-December 2018.
- 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>

Hepatitis B Vaccine (Recombinant)

November 14, 2018

Reason for the Shortage

- Merck has Recombivax HB on shortage due to increase in global demand.
- GlaxoSmithKline did not provide a reason for the shortage.
- GlaxoSmithKline discontinued Engerix B pediatric vials in October 2017.

Estimated Resupply Dates

- GlaxoSmithKline has Enderix B adult syringes on back order and the company estimates a release date in mid-November 2018.
- 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>

Indomethacin Capsules

November 14, 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 capsules on back order and the company estimates a release date of mid- to late-December 2018. The 50 mg capsules are on allocation.
- Glenmark has indomethacin 50 mg capsules in 100 count and 500 count on back order and the company estimates a release date of late-November 2018 for the 100 count size and mid-November 2018 for the 500 count size. The 25 mg capsules in 100 count and 1000 count are on back order and the company estimates a release date of mid-November 2018..

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=235>

Ketamine Injection

November 14, 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

- Hikma has ketamine 100 mg/mL 5 mL vials on back order and the company estimates a release date of December 2018 to January 2019.
- Mylan Institutional has ketamine 10 mg/mL 20 mL on back order and the company estimates a release date of late-November 2018. The 50 mg/mL 10 mL vials are on back order and the

company estimates a release date of early-January 2019. The 100 mg/mL 10 mL vials are on back order and the company estimates a release date of mid-March 2019.

- Pfizer has ketamine 50 mg/mL 10 mL vials on back order and the company estimates a release date of 1st quarter 2020. The 100 mg/mL 5 mL vials are on back order and the company estimates a release date of 4th quarter 2019.
- Par has Ketalar 10 mg/mL 20 mL vials, 50 mg/mL 10 mL vials, and 100 mg/mL 5 mL vials on intermittent back order with monthly releases.

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

Labetalol Injection

November 14, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Akorn has labetalol 5 mg/mL 20 mL and 40 mL vials on back order and the company cannot estimate a release date.
- Alvogen has labetalol 5 mg/mL 20 mL and 40 mL vials on back order and the company estimates a release date of early- to mid-December. There are short-dated 40 mL vials available.
- Hikma has labetalol 5 mg/mL 40 mL vials available with an expiration date of May 2019. The 20 mL vials are on allocation.
- Pfizer has labetalol 5 mg/mL 20 mL and 40 mL vials on back order and the company estimates a release date of 3rd quarter 2019 for the 20 mL vials and December 2018 for the 40 mL vials. The 5 mg/mL 4 mL Carpuject syringes are on back order and the company estimates a release date of 1st quarter 2019.

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

Methylphenidate Extended-Release Oral Suspension and Chewable Tablets

November 14, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Tris Pharma 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.

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

Multiple Vitamins for Infusion

November 14, 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 December 2018. The M.V.I. Adult 2 X 50 mL vials and Pediatric 5 mL vials are on back order and the company estimates a release date of 4th quarter 2019. There is limited short-dated product available for all 3 presentations.

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

Penicillin G Procaine Injection

November 14, 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 January 2019.

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

Tobramycin Sulfate Injection

November 14, 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.
- Fresenius Kabi has tobramycin 40 mg/mL 2 mL vials on back order and the company estimates a release date of mid- to late-November 2018. The 10 mg/mL 2 mL vials are on back order and the company estimates a release date of early-December 2018. The tobramycin 1.2 gram preservative-free 50 mL vials are on back order and the company estimates a release date of mid- to late-November 2018. There are short-dated 40 mg/mL 30 mL vials with an expiration date of <2 months.
- Mylan Institutional has tobramycin 40 mg/mL 2 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 January 2019.
- Teva has temporarily discontinued tobramycin 40 mg/mL 2 mL vials.

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

Vancomycin Hydrochloride Injection

November 14, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has vancomycin 1 gram, 5 gram, and 10 gram vials on back order and the company estimates a release date of mid-November 2018 for the 1 gram vials, mid- to late-November 2018 for the 5 gram vials, and early-December 2018 for the 10 gram vials.
- Pfizer has vancomycin 500 mg ADD-Vantage vials, 750 mg vials, 750 mg ADD-Vantage vials, 1 gram vials, and 5 gram vials available in limited supply. The 1 gram ADD-Vantage vials are on back order and the company estimates a release date of December 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 a release date of November 2018.

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

0.9% Sodium Chloride Large Volume Bags

November 13, 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.
- BBraun did not provide a reason for the shortage.
- ICU Medical cited increased demand as the reason for the shortage.
- Fresenius Kabi is no longer importing product.
- Baxter has received FDA approval for 0.9% sodium chloride in Viaflo containers manufactured in an FDA-approved facility in Spain.

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.

- ICU Medical has all 0.9% sodium chloride bags available to current customers.
<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=76>

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

November 13, 2018

Reason for the Shortage

- Baxter has 0.9% sodium chloride small volume bags available.
- BBraun has 0.9% sodium chloride small volume bags available.
- ICU Medical has 0.9% sodium chloride small volume bags on shortage due to increased demand.
- Pfizer did not provide a reason for the shortage.

Estimated Resupply Dates

- ICU Medical has all 0.9% sodium chloride bags available to current customers.
- 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 2nd quarter 2019.

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

5% Dextrose Injection

November 13, 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 was 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

- ICU Medical has 5% dextrose bags available to current customers.

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

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

November 13, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- BBraun has 5% dextrose 250 mL PVC/DEHP-free bags on allocation to current customers.
- ICU Medical has 5% dextrose PVC/DEHP-free bags available to current customers.

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

Alpha-1 Proteinase Inhibitor

November 13, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- CLS Behring has Zemaira 1 mg vials on intermittent back order and the company cannot provide an estimate of the next release date.

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

Belatacept Injection

November 13, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Bristol-Myers Squibb has Nulojix 250 mg vials available. Nulojix is distributed by McKesson Plasma Biologics.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=299>

Sterile Water for Injection Large Volume Bags

November 12, 2018

Reason for the Shortage

- Baxter had sterile water for injection on shortage due to manufacturing delays.
- BBraun did not provide a reason for the shortage.
- ICU Medical has sterile water for injection on shortage due to increased demand.

Estimated Resupply Dates

- BBraun has sterile water for injection 250 mL and 500 mL bags on allocation to current customers.
- ICU Medical has sterile water for injection 1000 mL and 2000 mL bags available to current customers.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=368>

Ampicillin Sodium and Sulbactam Sodium Injection

November 12, 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, 3 gram, and 15 gram vials on back order and the company estimates a release date of mid- to late-November 2018 for the 1.5 gram and 3 gram vials and late-November to early-December 2018 for the 15 gram vials.
- Mylan Institutional has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on back order and the company estimates a release date of early-April 2019 for the 1.5 gram vials, late-January to early-February 2019 for the 3 gram vials, and late-January 2019 for the 15 gram vials.
- Pfizer has ampicillin sulbactam 3 gram ADD-Vantage vials available in limited supply. Unasyn 1.5 gram vials, 3 gram vials, and 15 gram bulk vials are on back order and the company estimates a release date of November 2018 for the 1.5 gram and 3 gram vials and December 2018 for the 15 gram vials.
- 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 January 2019.
- WG Critical Care has ampicillin sulbactam 1.5 gram vials on back order and the company cannot estimate a release date.

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

Bumetanide Injection

November 12, 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 2nd quarter 2019 for the 4 mL vials and 2019 for the 10 mL vials.

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

Dexamethasone Sodium Phosphate Injection

November 12, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- AuroMedics has dexamethasone sodium phosphate 4 mg/mL 1 mL, 5 mL, 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 1st quarter 2019. The 10 mg/mL 1 mL preservative-free vials are on back order and the company estimates a release date of early-December 2018. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of mid-November 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 late-November to early-December 2018.

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

Famotidine Injection

November 12, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has famotidine 20 mL vials on back order and the company estimates a release date of early-December 2018. Check wholesalers for inventory.
- Mylan Institutional has famotidine 4 mL and 20 mL vials on back order and the company estimates a release date of late-December 2018 for the 4 mL vials and late-November 2018 for the 20 mL vials.

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

Fluphenazine Tablets

November 12, 2018

Reason for the Shortage

- Lannett did not provide a reason for the shortage.
- Mylan did not provide a reason for the shortage.

Estimated Resupply Dates

- Mylan has fluphenazine 1 mg tablets in 100 count and 500 count, 2.5 mg tablets in 100 count and 500 count, 5 mg tablets in 100 count and 500 count, and 10 mg in 100 count bottles on back order and the company estimates a release date of mid-March 2019. The 1 mg tablets in 100 count unit-dose packs are on back order and the company estimates a release date of late-April to early-May 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=478>

Hydralazine injection

November 12, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Akorn has hydralazine 20 mg/mL 1 mL vials on back order and the company 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-November 2018. Check wholesalers for inventory.
- X-Gen has hydralazine 20 mg/mL 1 mL vials on intermittent back order with regular releases.

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

Leucovorin Calcium Injection

November 12, 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 and 500 mg vials on back order and the company estimates a release date of mid-November 2018.
- Hikma has leucovorin 100 mg vials on back order and the company estimates a release date of late-November to early-December 2018.
- Sagent has leucovorin 350 mg and 500 mg 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=35>

Methyldopa Tablets

November 12, 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-February 2019 for the 250 mg tablets and early-March 2019 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>

Mycophenolate Mofetil Capsules and Tablets

November 12, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Accord has all mycophenolate mofetil presentations on allocation.
- Ascend has all mycophenolate mofetil presentations on intermittent back order and the company is releasing product as it becomes available.
- Hikma has all mycophenolate mofetil presentations on allocation.
- Mylan has mycophenolate mofetil 500 mg tablets in 100 count and 500 count on back order and the company estimates a release date of mid- to late-November 2018. The 500 mg capsules in 100 count unit-dose presentations are on back order and the company estimates a release date of early-January 2019.
- Sandoz has mycophenolate mofetil 500 mg tablets in 100 count and 500 count on back order and the company estimates a release date of late-November 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=448>

Olanzapine Intramuscular Injection

November 12, 2018

Reason for the Shortage

- Zyprexa intramuscular injection, Lilly USA, LLC, 10 mg, vial, 1 count, NDC 00002-7597-01

Estimated Resupply Dates

- American Regent has olanzapine 10 mg vials for intramuscular injection available in limited supply.
- Sandoz has olanzapine 10 mg vials for intramuscular injection on back order and the company estimates a release date of mid-November 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=492>

Penicillamine

November 12, 2018

Reason for the Shortage

- Mylan did not provide a reason for the shortage.
- Bausch Health did not provide a reason for the shortage.

Estimated Resupply Dates

- Mylan has Depen tablets on back order and the company estimates a release date of mid-March 2019.

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

Remifentanil Injection

November 12, 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 late-November 2018 for the 1 mg and 2 mg vials, and early-January 2019 for the 5 mg vials.
- Fresenius Kabi has remifentanil 1 mg and 5 mg 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=371>

Rocuronium Injection

November 12, 2018

Reason for the Shortage

- Fresenius Kabi has rocuronium available.
- Pfizer had 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 back order and the company cannot estimate a release date.
- X-Gen has rocuronium 10 mg/mL 10 mL vials on back order and the company estimates a release date of mid-November 2018.

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

Sincalide Injection

November 12, 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>

Spironolactone Tablets

November 12, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Accord has spironolactone 100 mg tablets in 500 count on back order with an estimated release date of mid-November 2018.
- Amneal has all spironolactone presentations on back order and the company cannot estimate a release date.
- Cadista has temporarily discontinued spironolactone tablets.
- Mylan has spironolactone 100 mg tablets in 100 count unit dose blister packs on back order and the company estimates a release date of mid-November 2018. The 25 mg tablets in 100 count and 500 count, 50 mg tablets in 100 count, and 100 mg tablets in 100 count are on back order and the company estimates a release date of mid-December 2018. The 50 mg tablets in 500 count are on back order and the company estimates a release date of late-December 2018.
- Par has most presentations on back order and the company cannot estimate a release date.
- Pfizer has Aldactone 50 mg tablets in 100 count on back order and the company estimates a release date of mid-November 2018.
- Sun Pharma has all spironolactone presentations on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=447>

Theophylline Extended-Release Tablets

November 12, 2018

Reason for the Shortage

- Major has discontinued theophylline extended-release tablets.
- Teva cannot provide a reason for the shortage.

Estimated Resupply Dates

- Teva has theophylline extended-release tablets temporarily unavailable and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=205>

Trifluoperazine Tablets

November 12, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Mylan has trifluoperazine 1 mg, 2 mg, 5 mg, and 10 mg tablets in 100 count bottles on back order and the company estimates a release date of late-January to early-February 2019 for the 1 mg tablets, early- to mid-December 2018 for the 2 mg tablets, early-December 2018 for the 5 mg tablets, and late-November 2018 for the 10 mg tablets. The 1 mg, 2 mg, 5 mg, and 10 mg tablets in 100 count unit-dose packs are on back order and the company estimates a release date of late-January to early-February 2019 for the 1 mg tablets and early- to mid-January 2019 for the 2 mg, 5 mg, and 10 mg tablets.
- Upsher-Smith has trifluoperazine 1 mg, 2 mg, 5 mg, and 10 mg tablets in 100 count bottles on long-term back order and the company cannot estimate a release date.

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

Bupivacaine Injection

November 11, 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 early-January 2019. The 0.25% 30 mL preservative-free vials are on back order and the company estimates a release date of late-November 2018. The 0.25% 50 mL vials are on back order and the company estimates a release date of mid-November 2018. The 0.5% Sensorcaine 10 mL preservative-free vials are on back order and the company estimates release dates of late-November 2018. The 0.5% Sensorcaine 30 mL preservative-free vials are on back order and the company estimates release dates of mid-December 2018. The 0.5% Sensorcaine 50 mL vials are on back order and the company estimates a release date of mid- to late-November 2018. The 0.75% 30 mL preservative-free vials are on back order and the company estimates a release date of early-January 2019. The 0.25% and 0.5% Sensorcaine 30 mL preservative-free vials in sterile packs are on back order and the company cannot estimate release dates.

- Pfizer has 0.25% bupivacaine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of December 2018. The 0.25% bupivacaine 50 mL vials are on back order and the company estimates release dates of December 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. The 0.5% bupivacaine 50 mL vials are on back order and the company estimates a release date of 1st quarter 2019. The 0.75% bupivacaine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of January 2019 for the 10 mL vials and November 2018 for the 30 mL vials.
- Pfizer has all Marcaine vials on back order and the company estimates a release date of 1st quarter 2020.

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

Bupivacaine with Epinephrine Injection

November 11, 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-November 2018. The 0.25% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of mid-November 2018. The 0.25% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of mid-November 2018. The 0.5% Sensorcaine-MPF with epinephrine 10 mL vials are on back order and the company estimates a release date of late-December 2018. The 0.5% Sensorcaine-MPF with epinephrine 30 mL sterile packs are on back order and the company cannot estimate a release date. The 0.5% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of mid-November 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 3rd quarter 2019. The 0.25% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 3rd quarter 2019. The 0.5% bupivacaine with epinephrine 10 mL preservative-free vials are on back order and the company estimates a release date of 3rd quarter 2019. The 0.5% bupivacaine with epinephrine 30 mL preservative-free vials are on back order and the company estimates a release date of December 2018. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 3rd quarter 2019.
- Pfizer has 0.25% Marcaine with epinephrine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of 3rd quarter 2019. The 0.25% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 3rd quarter 2019. The 0.5% Marcaine with epinephrine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of 1st quarter 2020. The 0.5% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 3rd quarter 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=261>

Hydromorphone Hydrochloride Injection

November 11, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Akorn has hydromorphone 10 mg/mL 50 mL vials on allocation.
- Fresenius Kabi has Dilaudid 1 mg/mL 0.5 mL syringes on back order and the company estimates a release date of mid-November 2018. The 1 mg/mL 1 mL syringes are on back order and the company estimates a release date of mid-November 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 are on back order and the company estimates a release date of mid-November 2018. The hydromorphone 4 mg/mL 1 mL vials are on back order and the company cannot estimate a release date. The hydromorphone 10 mg/mL 1 mL vials and 5 mL vials are on back order and the company cannot estimate a release date.
- Pfizer has 10 mg/mL 5 mL vials on back order and the company estimates a release date of early-December 2018. The 1 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of December 2018. The 10 mg/mL 50 mL vials are on back order and the company estimates a release date of 2nd quarter 2019. The 0.5 mg/0.5 mL 0.5 mL iSecure syringes are on back order and the company estimates a release date of 1st quarter 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 estimates a release date of 2nd quarter 2019. The 1 mg/mL 1 mL iSecure syringes and 2 mg/mL 1 mL iSecure syringes are on back order and the company estimates a release date of 2nd quarter 2019. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 4th quarter 2019.
- Teva has hydromorphone 10 mg/mL 5 mL and 50 mL vials on intermittent back order and the company is allocating product upon release.

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

Lidocaine with Epinephrine Injection

November 11, 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 late-November 2018. The 1% Xylocaine with epinephrine (1:200,000) 10 mL vials are on back order and the company estimates a release date of late-November 2018. The 1% Xylocaine with epinephrine (1:200,000) 20 mL vials are on back order and the company estimates release dates of mid-November 2018. The 1% Xylocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates release dates of early-December 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-November 2018. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company cannot estimate a release date. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company cannot estimate a release date. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 10 mL regular vials are on back order and the company estimates a release date of early-December 2018. The 2% Xylocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates a release date of late-November 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 mid- to late-November 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 December 2018. The 1% lidocaine with epinephrine (1:100,000) 20 mL vials are on back order and the company estimates a release date of November 2018. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are on back order and the company estimates a release date of December 2018. The 1% lidocaine with epinephrine (1:100,000) 50 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) 30 mL vials are on back order and the company estimates a release date of 1st quarter 2019. The 1.5% lidocaine with epinephrine (1:200,000) 5 mL ampules are on back order and the company estimates a release date of January 2019. The 2% lidocaine with epinephrine (1:100,000) 20 mL vials are on back order and the company estimates a release date of 1st quarter 2019. The 2% lidocaine with epinephrine (1:100,000) 30 mL and 50 mL vials are on back order and the company estimates a release date of 1st quarter 2019 for the 30 mL vials and 2nd quarter 2019 for the 50 mL vials. The 2% lidocaine with epinephrine (1:200,000) 20 mL vials are 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=98>

Magnesium Sulfate Injection

November 11, 2018

Reason for the Shortage

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

- WG Critical Care had magnesium sulfate injection on shortage due to increased demand for the product.

Estimated Resupply Dates

- Fresenius Kabi has magnesium sulfate 500 mg/mL 2 mL, 10 mL, and 50 mL vials on back order and the company estimates a release date of mid-November 2018 for the 2 mL vials, early-December 2018 for the 10 mL vials, and late-November 2018 for the 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-November 2018 for the 50 mL and 100 mL premixed bags and early-December 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-December 2018. Check wholesalers for inventory.
- Pfizer has magnesium sulfate 500 mg/mL 20 mL vials on back order and the company estimates a release date of 2019. The 500 mg/mL 10 mL syringes are on back order and the company estimates a release date of November 2018. The magnesium sulfate 10 mg/mL 100 mL bags are available in limited supply. The magnesium sulfate 40 mg/mL 50 mL and 1000 mL bags are on back order and the company estimates a release date of November 2018. The 40 mg/mL 100 mL bags are available in limited supply. The 80 mg/mL 50 mL bags are on back order and the company estimates a release date of December 2018.

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

Mepivacaine Injection

November 11, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has 1.5% Polocaine-MPF 30 mL vials on back order and the company estimates a release date of early-January 2019. The 2% Polocaine-MPF 20 mL vials are on back order and the company estimates a release date of early-January 2019. The 1% Polocaine 50 mL vials are on back order and the company estimates a release date of mid-November 2018. Check wholesalers for inventory.
- Pfizer has 2% Carbocaine 20 mL preservative-free vials, 2% Carbocaine 50 mL multiple-dose vials, 1% Carbocaine 30 mL preservative-free vials, 1% Carbocaine 50 mL multiple-dose vials, and 1.5% Carbocaine 30 mL preservative-free vials on back order and the company estimates a release date of 1st quarter 2020.

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

Morphine Injection

November 11, 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.

- Astramorph injection has been unavailable since 2012. Fresenius Kabi changed manufacturing sites and cannot estimate if Astramorph will return.
- Pfizer states the shortage is due to manufacturing delays. Pfizer discontinued morphine ADD-Vantage vials in January 2017.
- 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.
- 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.

Estimated Resupply Dates

- Fresenius Kabi has morphine 2 mg/mL 1 mL syringes on back order and the company estimates a release date of mid-November 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 late-November 2018. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of mid- to late-November 2018. The 5 mg/mL 1 mL vials are on back order and the company estimates a release date of early-December 2018. The 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 estimates a release date of mid- to late-November 2018. Check wholesalers for inventory.
- Pfizer has morphine 2 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of December 2018. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of January 2019. The 1 mg/mL 10 mL preservative-free vials are available in limited supply. 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 2nd quarter 2019. The 50 mg/mL 20 mL vials are available in limited supply. The 50 mg/mL 50 mL vials are on back order and the company estimates a release date of December 2018.
- Hikma has morphine 4 mg/mL 1 mL vials on back order and the company estimates a release date of November 2018. The 8 mg/mL 1 mL vials are on back order and the company estimates a release date of late-November to early-December 2018. Infumorph 10 mg/mL 20 mL ampules and 25 mg/mL 20 mL ampules are on back order and the company estimates a release date of late-November to early-December 2018.

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

Procainamide Hydrochloride Injection

November 11, 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 procainamide 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>

Ropivacaine Injection

November 11, 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 early-December 2018. The 5 mg/mL 30 mL Steripak ampules are on back order and the company estimates a release date of early-January 2019. The 5 mg/mL 100 mL bottles are on back order and the company estimates a release date of mid-November 2018. Check wholesalers for inventory.

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

Sodium Phosphate Injection

November 11, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has sodium phosphate 3 mmol/mL 5 mL and 15 mL vials on back order and the company estimates a release date of late-November 2018 for the 5 mL vials and mid-November 2018 for the 15 mL vials.
- Pfizer has sodium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of 3rd quarter 2019.

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

Dexrazoxane Injection

November 9, 2018

Reason for the Shortage

- Cumberland Pharmaceuticals relaunched Totect in late-July 2017.
- Hikma did not provide a reason for the shortage.

- Mylan Institutional has dexrazoxane available.
- Pfizer states manufacturing delay as the reason for the shortage.

Estimated Resupply Dates

- Pfizer has Zinecard 500 mg vials 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=107>

Diphenhydramine Injection

November 9, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has diphenhydramine 50 mg/mL 1 mL vials on back order and the company estimates a release date of mid-November 2018. The 50 mg/mL 1 mL syringes are on back order and the company estimates a release date of 1st quarter 2019. Check wholesalers for inventory.
- Hikma has diphenhydramine 50 mg/mL 1 mL vials on back order and the company estimates a release date of mid- to late-November 2018.
- Mylan Institutional has diphenhydramine 50 mg/mL 10 mL vials on back order and the company estimates a release date of mid-January 2019.
- Pfizer has diphenhydramine 50 mg/mL 1 mL vials on back order and the company estimates a release date of 1st quarter 2020.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=456>

Iron Dextran Injection

November 9, 2018

Reason for the Shortage

- Allergan had INFeD on shortage due to manufacturing delays.
- American Regent discontinued Dexferrum injection in 2014.

Estimated Resupply Dates

- Allergan has INFeD 50 mg/mL 2 mL vials on back order and the company estimates a release date of late-November 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=408>

Pentostatin Injection

November 4, 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 early-December 2018. The 1% lidocaine 2 mL and 10 mL vials are on back order and the company estimates a release date of mid- to late-November 2018 for the 2 mL vials and early-January 2019 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 mid- to late-November 2018 for the 20 mL vials and early-December 2018 for the 50 mL vials. 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-November 2018 for the 2 mL vials, early-December 2018 for the 5 mL vials, and late-December 2018 for the 30 mL vials. The 1% Xylocaine-MPF 10 mL ampule sterile packs are on back order and the company estimates a release date of mid-January 2019. The 1% Xylocaine-MPF 30 mL vial sterile packs are on back order and the company cannot estimate a release date. The 1.5% Xylocaine-MPF 20 mL ampules are on back order and the company 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-November 2018 for the 10 mL vials and mid- to late-November 2018 for the 20 mL and 50 mL vials. The 2% Xylocaine-MPF 2 mL vials are on back order and the company estimates a release date of mid-November 2018. The 2% Xylocaine-MPF 10 mL ampules are on back order and the company estimates a release date of mid-January 2019. The 2% lidocaine 2 mL and 5 mL vials are on back order and the company estimates a release date of mid-January 2019 for the 2 mL vials and mid- to late-November 2018 for the 5 mL vials. 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 1st quarter 2019. The 1% lidocaine 2 mL preservative-free ampules on back order and the company estimates a release date of November 2018. The 1% lidocaine 5 mL preservative-free ampules are on back order and the company estimates a release date of 1st quarter 2020. The 1% lidocaine 20 mL vials and 30 mL preservative-free vials are on back order and the company estimates a release date of November 2018 for the 20 mL vials and December 2018 for the 30 mL vials. The 1% lidocaine 50 mL vials are on back order and the company estimates a release date of November 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 Ansyng syringes are on back order and the company estimates a release date of November 2018. The 1.5% lidocaine 20 mL preservative-free ampules are on back order and the company estimates a release date of 3rd quarter 2019. The 2% lidocaine 2 mL preservative-free ampules are on back order and the company estimates a release date of 1st quarter 2019. The 2% lidocaine 10 mL ampules are on back order and the company cannot estimate a release date. The 2% lidocaine 5 mL vials are on back order and the company estimates a release date of 3rd quarter 2019. The 2% lidocaine 20 mL and 50 mL vials are on back order and the company

estimates a release date of January 2019 for the 20 mL vials and November 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 1st quarter 2019. The 2% lidocaine 5 mL Ansyf syringes are on back order and the company estimates a release date of November 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 and 50 mL vials on back order and the company estimates a release date of mid- to late-November 2018 for the 5 mL vials and early- to mid-November 2018 for the 50 mL vials. The 2% lidocaine 5 mL and 50 mL vials are on back order and the company estimates a release date of late-November to early-December 2018 for the 5 mL vials and early- to mid-November 2018 for the 50 mL vials.

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

Lidocaine Injection

November 9, 2018

Reason for the Shortage

- Pfizer has Nipent on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Nipent 10 mg vials on back order and the company estimates a release date of March 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=474>

Octreotide Injection

November 9, 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 500 mcg/mL 1 mL vials on back order and the company estimates a release date of mid-November 2018.
- Hikma has octreotide 50 mcg/mL 1 mL vials and 1000 mcg/mL 5 mL vials on back order and the company estimates a release date of late-November to early-December 2018. There are short-dated 100 mcg/mL 1 mL vials, 500 mcg/mL 1 mL vials, and 200 mcg/mL 5 mL vials available but with an expiration date of March 2019.
- Sagent has 500 mcg/mL 1 mL vials on back order and the company estimates a release date of November 2018.
- Sun Pharma has all octreotide presentations on back order and the company cannot estimate a release date.

- Novartis has short-dated Sandostatin 50 mcg/mL 1 mL ampules available with an expiration date of September 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=229>

23.4% Sodium Chloride Injection

November 8, 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, and 200 mL vials on back order and the company estimates a release date of early-December 2018 for the 30 mL vials, mid-January 2019 for the 100 mL vials, and mid-December 2018 for the 200 mL vials. Check wholesalers for inventory.
- Pfizer has 23.4% sodium chloride 200 mL vials on back order and the company estimates a release date of 3rd quarter 2019.

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

5% Lidocaine and 7.5% Dextrose Injection

November 8, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has 5% lidocaine and 7.5% dextrose 2 mL ampules on long-term back order and the company estimates a release date of 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=253>

Calcium Chloride Injection

November 8, 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

- Pfizer has calcium chloride 100 mg/mL 10 mL Ansyr syringes and 100 mg/mL 10 mL LifeShield syringes available in limited supply.

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

Dexmedetomidine Hydrochloride 100 mcg/mL Vials for Injection

November 8, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Accord has 100 mcg/mL 2 mL vials on back order with an estimated release date of early-November 2018.
- Hikma has 100 mcg/mL 2 mL vials on back order with an estimated release date of mid- to late-November 2018.
- Mylan has short dated 100 mcg/mL 2 mL vials available with an expiration date of September 2019.
- Sandoz has short dated 100 mcg/mL 2 mL vials available with an expiration date of July 2019.
- Sun Pharma has 100 mcg/mL 2 mL vials on back order with an estimated release date of early-December 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=491>

Dexmedetomidine Hydrochloride 4 mcg/mL Premix for Injection

November 8, 2018

Reason for the Shortage

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

Estimated Resupply Dates

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

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

Hydroxocobalamin Injection

November 8, 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 is releasing supplies as they become available

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

Levetiracetam Injection

November 8, 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 did not provide a reason for the shortage.
- 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.
- Fresenius Kabi has levetiracetam 100 mg/mL 5 mL vials on back order and the company estimates a release date in early-December 2018.
- 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>

Lorazepam Tablets

November 8, 2018

Reason for the Shortage

- Aurobindo did not provide a reason for the shortage.
- Leading has lorazepam tablets on shortage due to increased demand.

- Major did not provide a reason for the shortage.
- Mylan has discontinued all bottled presentations.
- Mylan Institutional did not provide a reason for the shortage for the unit-dose blister packs.
- Sandoz discontinued all lorazepam presentations.
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates

- Aurobindo has lorazepam 0.5 mg tablets in 500 count, 1 mg tablets in 500 count, and 2 mg tablets in 100 count on back order and the company cannot estimate a release date.
- Leading has all lorazepam tablets on allocation.
- Major has lorazepam 0.5 mg tablets in 100 count bottles on back order and the company cannot estimate a release date. The 1 mg tablets in 100 count bottles are on back order and the company estimates a release date of late-November 2018.
- Mylan Institutional has lorazepam 0.5 mg, 1 mg, and 2 mg tablets in 100 count unit-dose packs on back order and the company estimates a release date of early-December 2018.
- Teva has lorazepam 0.5 mg tablets in 100 count and 1000 count on back order and the company estimates a release date of late-November 2018. The 1 mg tablets in 100 count and 1000 count are on back order and the company estimates a release date of late-November 2018. The 1 mg tablets in 500 count are on back order and the company estimates a release date of mid-November 2018. The 2 mg tablets in 100 count and 500 count are on back order and the company estimates a release date of mid-November 2018 for the 100 count presentations and early-November 2018 for the 500 count presentations. There are short-dated 2 mg tablets in 100 count available with an expiration date of June 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=480>

Norepinephrine Bitartrate Injection

November 8, 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 1st quarter 2020.
- 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>

Polyvinyl Alcohol (Artificial Tears) Ophthalmic Solution

November 8, 2018

Reason for the Shortage

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

- Rugby did not provide a reason for the shortage.

Estimated Resupply Dates

- Major has Liquitears ophthalmic drops on back order and the company cannot estimate a release date.
- Akorn has Artificial Tears Solution ophthalmic drops on back order and the company cannot estimate a release date.
- 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>

Sterile Water for Injection - Small Volume Vials

November 8, 2018

Reason for the Shortage

- American Regent has sterile water for injection available.
- 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

- Fresenius Kabi has sterile water for injection 50 mL vials on back order and the company estimates a release date of mid-December 2018. 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 and 50 mL vials on back order and the company estimates a release date of November 2018. The 100 mL vials are available in limited supply.

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

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

November 7, 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 and 20 mL vials on back order and the company estimates a release date of mid-December 2018 for the 10 mL vials and late-December 2018 for the 20 mL vials.
- Pfizer has 0.9% sodium chloride preservative free 50 mL vials on back order and the company estimates a release date of 2nd quarter 2019.

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

Bacteriostatic 0.9% Sodium Chloride Vials

November 7, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has bacteriostatic 0.9% sodium chloride 10 mL and 30 mL vials available in limited supply.
- Fresenius Kabi has bacteriostatic 0.9% sodium chloride 10 mL vials on back order and the company cannot estimate a release date. The 30 mL vials are on back order and the company estimates a release date of late-December 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=441>

Chlorprocaine Hydrochloride Injection

November 7, 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

- All marketed presentations are available.

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

Cidofovir Injection

November 7, 2018

Reason for the Shortage

- Heritage did not provide a reason for the shortage.
- Mylan Institutional did not provide a reason for the shortage.

Estimated Resupply Dates

- Heritage has cidofovir 75 mg/mL 5 mL vials on back order and the company estimates a release date of mid-November 2018.
- Mylan Institutional has cidofovir 75 mg/mL 5 mL vials on back order and the company estimates a release date of mid-December 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=486>

Etoposide Solution for Injection

November 7, 2018

Reason for the Shortage

- Accord had etoposide injection on shortage due to increased demand.
- Fresenius Kabi had etoposide on back order due to manufacturing delays.
- Teva had Toposar on allocation due to increased demand.
- Hikma had etoposide on shortage due to increased demand.

- Etoposide phosphate powder for injection (Etopophos) is unaffected by this shortage.

Estimated Resupply Dates

- Fresenius Kabi has etoposide 20 mg/mL 50 mL vials on back order and the company estimates a release date of early-December 2018.

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

Fluorouracil Injection

November 7, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has fluorouracil 50 mg/mL 100 mL vials on back order and the company estimates a release date of mid-November 2018.

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

Meropenem Injection

November 7, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Amneal has meropenem 1 gram vials available in limited supply. The available vials are short-dated (May 2019).
- AuroMedics has meropenem 500 mg and 1 gram vials on intermittent back order and the company is releasing product as it becomes available.
- Pfizer has Merrem 500 mg vials (NDC 00310-0325-20) and 1 gram vials (NDC 00310-0321-30) on back order and the company cannot estimate a release date. Pfizer has generic meropenem 500 mg and 1 gram vials on back order and the company estimates a release date of 2019.
- Sagent has meropenem 500 mg vials and 1 gram vials on back order and the company cannot estimate a release date.

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

Protamine Injection

November 7, 2018

Reason for the Shortage

- Fresenius Kabi had 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 available. Check wholesalers for inventory.

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

Sodium Bicarbonate Injection

November 6, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has 8.4% sodium bicarbonate 50 mL vials on back order and the company estimates a release date of mid-November 2018.
- 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 date of November 2018. The 8.4% 50 mL vials are available in limited supply.
- Pfizer has Neut 4% 5 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=293>

50% Dextrose Injection

November 6, 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 2nd quarter 2019. The 50% dextrose 50 mL Ansyf syringes are on back order and the company estimates a release date of December 2018. The 50% dextrose 50 mL vials are on back order and the company estimates a release date of December 2018.

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

Aminophylline Injection

November 6, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has aminophylline 25 mg/mL 10 mL and 20 mL vials are on back order and the company estimates a release date of January 2019.

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

Calcium Gluconate Injection

November 6, 2018

Reason for the Shortage

- American Regent is not currently marketing calcium gluconate.
- Fresenius Kabi has calcium gluconate available.

Estimated Resupply Dates

- Fresenius Kabi has calcium gluconate 100 mg/mL 100 mL vials on back order and the company estimates a release date of late-November 2018. Check wholesalers for inventory.

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

Fentanyl Citrate Injection

November 6, 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. They are not currently marketing fentanyl ampules, just vials.
- Pfizer has fentanyl injection on shortage due to manufacturing delays. The 20 mL ampules were discontinued in September 2017.

Estimated Resupply Dates

- Akorn has Sublimaze 50 mcg/mL 2 mL ampules in 10 count and 25 count, and 5 mL ampules in 10 count and 25 count on allocation.
- Pfizer has fentanyl 50 mcg/mL 2 mL ampules on back order and the company estimates a release date of November 2018. The 2 mL Carpuject syringes are on back order and the company estimates a release date of 3rd quarter 2019. The 2 mL and 50 mL vials are available in limited supply.

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

Flumazenil Injection

November 6, 2018

Reason for the Shortage

- Baxter did not provide a reason for the shortage.

- Hikma did not provide a reason for the shortage.
- Mylan Institutional did not provide a reason for the shortage.

Estimated Resupply Dates

- Baxter has flumazenil 0.1 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of late-November 2018.
- Hikma has flumazenil 0.1 mg/mL 10 mL vials on back order and the company cannot estimate a release date.
- Mylan Institutional has flumazenil 0.1 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of mid- to late-December 2018 for the 5 mL vials and early- to mid-January 2019 for the 10 mL vials.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=490>

Ketorolac Injection

November 6, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Alvogen has 15 mg/mL 1 mL vials and 30 mg/mL 1 mL vials on on allocation. The 30 mg/mL 2 mL vials are on back order with an estimated release date of late-November 2018.
- Amphastar has ketorolac 30 mg/mL 1 mL vials on back order and the company cannot estimate a release date.
- Athenex has ketorolac 15 mg/mL 1 mL vials on back order and the company estimates a release date of October 2018.
- Fresenius Kabi has ketorolac 15 mg/mL 1 mL and 30 mg/mL 1 mL prefilled syringes on back order with an estimated release date of the first quarter of 2019. There are limited quantities of ketorolac 15 mg/mL 1 mL prefilled syringes available with short expiration dating of < 8 months. The 30 mg/mL 1 mL prefilled syringes are also available in limited quantities with short expiration dating of < 6 months. The 30 mg/mL 2 mL syringes for intramuscular use are available with an expiration date of < 9 months. The 15 mg/mL 1 mL vials are on back order and the company estimates a release date of mid- to late-November 2018.
- Pfizer has ketorolac 30 mg/mL 1 mL Carpuject syringes, 30 mg/mL 2 mL Carpuject syringes for intramuscular injection, and 30 mg/mL 1 mL iSecure syringes on back order and the company estimates a release date of 1st quarter 2020.

- Sagent has ketorolac 15 mg/mL 1 mL vials on back order and the company cannot estimate a release date. The 30 mg/mL 1 mL vials, and 30 mg/mL 2 mL vials for intramuscular injection are on back order and the company estimates a release date of December 2018.

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

Potassium Chloride Injection

November 6, 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 ringer's and 5% dextrose on back order and the company cannot estimate a release date.
- Fresenius Kabi has potassium chloride 10 mEq/5 mL vials on back order and the company estimates a release date of late-November 2018.
- 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 20 mEq/10 mL vials available in limited supply. The 40 mEq/20 mL vials are on back order and the company estimates a release date of December 2018.

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

Proparacaine Hydrochloride Ophthalmic Solution

November 6, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Akorn has proparacaine 0.5% ophthalmic drops on allocation.
- Sandoz has proparacaine 0.5% ophthalmic drops on back order and the company estimates a release date in early-November 2018..

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

Valsartan and Hydrochlorothiazide Tablets

November 6, 2018

Reason for the Shortage

- Several drug products containing valsartan were recalled due to an unexpected impurity found in the active pharmaceutical ingredient manufactured by a third party. The impurity is N-nitrosodimethylamine (NDMA) and is classified as a probably human carcinogen.
- Solco and Teva valsartan/hydrochlorothiazide tablets were affected by the recall.
- Solco and Teva discontinued valsartan/hydrochlorothiazide tablets in July 2018.
- Alembic, Aurobindo, Lupin, Mylan, Macleods, and Novartis are not affected by this recall.
- Repackagers may have some presentations affected depending on the source supplier.
- Mylan is discontinuing valsartan/hydrochlorothiazide 160 mg/12.5 mg in 500 count bottles.

Estimated Resupply Dates

- Mylan has valsartan/hydrochlorothiazide 80 mg/12.5 mg tablets in 90 count, 160 mg/25 mg tablets in 90 count, and 320 mg/25 mg tablets in 90 count and 500 count bottles 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=445>

Valsartan Tablets

November 6, 2018

Reason for the Shortage

- Several drug products containing valsartan were recalled due to an unexpected impurity found in the active pharmaceutical ingredient manufactured by a third party. The impurity is N-nitrosodimethylamine (NDMA) and is classified as a probably human carcinogen.
- Camber, Major, Solco, and Teva valsartan tablets were affected by the recall.
- Major, Solco, and Teva discontinued valsartan tablets in July 2018.
- Alembic, Aurobindo, Cadista, Lupin, Mylan, Macleods, and Novartis are not affected by this recall.
- Repackagers may have some presentations affected depending on the source supplier.

Estimated Resupply Dates

- Camber has valsartan 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=444>

Epinephrine Injection

November 5, 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.
- Pfizer stopped distributing epinephrine 1 mg/mL presentations on May 10, 2017.
- BPI has epinephrine 1 mg/mL 2 mL ampules available.
- Par has Adrenalin 1 mg/mL 1 mL and 30 mL vials available.

Estimated Resupply Dates

- Amphastar has epinephrine 0.1 mg/mL 10 mL syringes on allocation.
- Pfizer has epinephrine 0.1 mg/mL 10 mL syringes on back order and the company estimates a release date of November 2018.
- 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>

Erythromycin Lactobionate Injection

November 5, 2018

Reason for the Shortage

- Pfizer has Erythrocin on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Erythrocin 500 mg vials and 500 mg ADD-Vantage vials on back order and the company estimates a release date of 4th quarter 2019 for the regular vials and 2019 for the ADD-Vantage vials.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=247>

Furosemide Tablets

November 5, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Hikma has furosemide 40 mg tablets in 100 count bottles on allocation. There are short-dated 20 mg tablets in 100 count unit dose packs available with an expiration date of October 2019.

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

Phenytoin Sodium Injection

November 5, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Hikma has phenytoin sodium 50 mg/mL 2 mL and 5 mL vials available.

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

Potassium Phosphate Injection

November 5, 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 available in limited supply.
- Fresenius Kabi has potassium phosphate 3 mmol/mL 5 mL, 15 mL, and 50 mL vials on back order and the company estimates a release date of mid-November 2018.

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

Sodium Acetate Injection

November 4, 2018

Reason for the Shortage

- American Regent is not currently marketing sodium acetate injection.
- Fresenius Kabi had sodium acetate on shortage due to increased demand.
- Pfizer had sodium acetate on shortage due to manufacturing delays.

Estimated Resupply Dates

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

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

Isocarboxazid Tablets

November 4, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Validus has Marplan 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=411>

Pentostatin Injection

November 2, 2018

Reason for the Shortage

- Pfizer has Nipent on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Nipent 10 mg vials on back order and the company estimates a release date of March 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=474>

Metoprolol Injection

November 1, 2018

Reason for the Shortage

- Alvogon has metoprolol injection available.
- American Regent is not currently marketing metoprolol injection.
- Athenex has metoprolol injection available.
- Baxter did not provide a reason for the shortage.
- Fresenius Kabi has metoprolol injection on shortage due to increased demand.
- Mylan Institutional acquired metoprolol injection from Sagent. They discontinued metoprolol injection in March 2018.
- Pfizer has metoprolol injection on shortage due to manufacturing delays.
- Hikma did not provide a reason for the shortage.

Estimated Resupply Dates

- Baxter (formerly Claris) has metoprolol 1 mg/mL 5 mL vials on back order and the company cannot estimate a release date.
- Pfizer has metoprolol 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 ampules are on back order and the company estimates a release date of 1st quarter 2020. The 1 mg/mL 5 mL vials are available in limited supply.
- Hikma has metoprolol 1 mg/mL 10 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=363>

Abciximab Injection

November 1, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Janssen has Reopro on long-term back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=413>

Albuterol Inhalation Solution

November 1, 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>

Amiodarone Injection

November 1, 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

- Auromedics has amiodarone 50 mg/mL 9 mL vials on back order and the company estimates a release date of late-December 2018.
- Sagent has amiodarone 50 mg/mL 3 mL vials available with short expiration dating of February 2019.

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

Clindamycin Phosphate Injection

November 1, 2018

Reason for the Shortage

- Alvogen refuses to provide availability information.
- Akorn did not provide a reason for the shortage.
- Baxter has clindamycin injection available.
- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer did not provide a reason for the shortages. Pfizer discontinued Cleocin 900 mg/50 mL in 5% dextrose and 600 mg/50 mL in 5% dextrose premixed bags in October 2018.
- Sagent had clindamycin on shortage due to manufacturing delays.
- Sandoz has clindamycin injection available.

Estimated Resupply Dates

- Akorn has clindamycin 900 mg/50 mL in 5% dextrose premixes on back order and the company cannot estimate a release date. The 300 mg/50 mL and 600 mg/50 mL in 5% dextrose are available in limited supply.
- Pfizer has Cleocin 150 mg/mL 2 mL, 4 mL, and 6 mL ADD-Vantage vials on back order and the company estimates a release date of 2019.
- Fresenius Kabi has clindamycin 150 mg/mL 60 mL vials available with an expiration date of <4 months.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=97>

Enoxaparin Sodium Injection

November 1, 2018

Reason for the Shortage

- Actavis has enoxaparin available.

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

Estimated Resupply Dates

- Amphastar has enoxaparin 40 mg/0.4 mL and 60 mg/0.6 mL prefilled syringes on intermittent back order and is shipping the product when available.
- Fresenius Kabi has enoxaparin 80 mg/0.8 mL, 120 mg/0.8 mL, and 150 mg/1 mL prefilled syringes on back order and the company estimates release dates of late-November 2018. Enoxaparin 100 mg/mL 1 mL and 150 mg/mL 1 mL prefilled syringes are available with short expiration dating (< 4 months for the 150 mg/mL 1 mL syringes and < 7 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 Lovenox 120 mg/0.8 mL prefilled syringes on back order and the company cannot estimate a release date.

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

Hydroxyethyl Starch in Sodium Chloride Injection

November 1, 2018

Reason for the Shortage

- BBraun has Hespan available now.
- 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

- 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 November 2018.

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

Indocyanine Green

November 1, 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 back order and the company cannot estimate a release date. Check wholesalers for inventory.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=324>

Liotrix (Levothyroxine/Liothyronine T4/T3)

November 1, 2018

Reason for the Shortage

- Thyrolar tablets from Actavis (formerly Forest) are on shortage due to manufacturing changes.

Estimated Resupply Dates

- Actavis (formerly Forest) has all Thyrolar presentations 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=131>

Mineral Oil and Petrolatum Ophthalmic Ointment

November 1, 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.
- Alcon states the shortage is due to manufacturing issues.
- 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.
- Rugby has Artificial Tears 3.5 gram tubes available in limited supply.
- Alcon has Systane Lubricating Night ointment on intermittent back order and the company is releasing supplies as they become available.
- Perrigo has Puralube ointment in 3.5 gram and 1 gram tubes on back order and the company estimates release dates in January 2019 for the 3.5 gram tubes and December 2018 for the 1 gram tubes.

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

Sodium Polystyrene Sulfonate Oral or Rectal Suspension

November 1, 2018

Reason for the Shortage

- CMP Pharma reports that increased demand has led to a shortage of raw material required to manufacture the products.
- Perrigo has temporarily discontinued their Kionex suspension and sodium polystyrene sulfonate (sorbitol-free) suspension. They cannot estimate when these products will be manufactured again.
- Hikma did not provide a reason for the shortage.

Estimated Resupply Dates

- Hikma is not currently marketing sodium polystyrene sulfonate suspension in 60 mL and 120 mL bottles. The 500 mL bottles are on allocation.
- CMP Pharma has SPS Suspension on intermittent back order and the company is releasing supplies as they becomes available. They anticipate more product becoming available in January 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=430>

Enalaprilat Injection

October 31, 2018

Reason for the Shortage

- Hikma did not provide a reason for the shortage.
- Pfizer has enalaprilat injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Hikma has enalaprilat 1.25 mg/mL 1 mL vials on back order and the company cannot estimate a release date.
- Pfizer has enalaprilat 1.25 mg/mL 1 mL and 2 mL vials on back order and the company estimates a release date of 1st quarter 2020.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=488>

Potassium Acetate Injection

October 31, 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 20 mL vials available in limited supply. The 50 mL vials are on back order and the company estimates a release date of December 2018.

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

Dalbavancin Injection

October 30, 2018

Reason for the Shortage

- Allergan did not provide a reason for the shortage. Allergan is the sole supplier of dalbavancin.

Estimated Resupply Dates

- Allergan has Dalvance available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=477>

Heparin Injection

October 30, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has heparin 10,000 unit/mL 0.5 mL preservative-free vials on back order and the company estimates a release date in mid- to late-December 2018. The 10,000 unit/mL 4 mL vials are available as short-dated product (<5 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 early- to mid-November 2018.
- Pfizer has 5,000 unit/mL 1 mL Carpuject syringes on back order and the company estimates a release date of 4th quarter 2019. The 1,000 unit/mL 10 mL and 30 mL vials, 5,000 unit/mL 10 mL 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 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>

Letermovir Injection

October 30, 2018

Reason for the Shortage

- Merck has Prevmis on shortage due to a supply disruption.

Estimated Resupply Dates

- Merck has Prevmis 20 mg/mL 24 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=487>

Leuprolide Acetate 14-Day Kit

October 30, 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>

Methocarbamol Tablets

October 30, 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 methocarbamol 500 mg and 750 mg tablets in 100 count and 500 count bottles on intermittent back order and the company is releasing product as it becomes available.
- Hikma has methocarbamol 500 mg tablets in 100 count available with short expiration dating of
- 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 cannot estimate a release date.
- Endo has Robaxin 500 mg and 750 mg tablets in 100 count on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=423>

Scopolamine Transdermal System

October 30, 2018

Reason for the Shortage

- GlaxoSmithKline states the shortage is due to increased demand.
- 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.
- GlaxoSmithKline has Transderm Scop 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>

Atropine Sulfate Injection

October 29, 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 available in limited supply. The 0.1 mg/mL 10 mL Ansyr syringes are on back order and the company estimates a release date of

December 2018. The 0.1 mg/mL 5 mL LifeShield syringes are on back order and the company estimates release dates of 1st quarter 2019. The 0.05 mg/mL 5 mL Ansyf syringes are available with an expiration date of February 2019.

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

Ceftazidime Injection

October 29, 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, 1 gram TwistVials, and 2 gram TwistVials 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>

Cefuroxime Sodium Injection

October 29, 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 750 mg vials and 7.5 gram vials on back order and the company estimates a release date of November 2018. The 1.5 gram vials are on back order and the company cannot estimate a release date.

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

Pyridoxine Hydrochloride Injection

October 29, 2018

Reason for the Shortage

- Baxter has heparin on shortage due to manufacturing delays.
- BBraun did not provide a reason for the shortage.
- Fresenius Kabi has heparin premixes on shortage due to increased demand.

- Pfizer has heparin on shortage due to manufacturing delays.

Estimated Resupply Dates

- Baxter has heparin 2000 units/1000 mL premixed bags on back order and the company cannot estimate a release date.
- BBraun has all heparin premixed bags on allocation.
- Fresenius Kabi has heparin 25,000 units/500 mL 0.45% sodium chloride premixed bags on back order and the company estimates a release date of mid-December 2018. The 25,000 units/250 mL 5% dextrose premixed bags are on back order and the company estimates a release date of mid-December 2018.
- Pfizer has heparin 2000 units/1000 mL 0.9% sodium chloride premixed bags and 1000 units/500 mL 0.9% sodium chloride premixed bags on back order and the company estimates a release date of November 2018. The 25,000 units/250 mL 5% dextrose premixed bags are on back order and the company estimates a release date of December 2018.

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

Heparin Sodium Premixed Bags

October 29, 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 early-December 2018. Check wholesaler for inventory.

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

Metronidazole Hydrochloride Injection

October 29, 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 available in limited supply.

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

Nalbuphine Injection

October 29, 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 early-December 2018. Check wholesaler for inventory.

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

Pyridoxine Hydrochloride Injection

October 29, 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 early-December 2018. Check wholesaler for inventory.

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

Etomidate Injection

October 26, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Mylan Institutional has etomidate 2 mg/mL 10 mL and 20 mL vials on back order and the company estimates a release date of late-January 2019.
- Pfizer has Amidate 2 mg/mL 20 mL LifeShield syringes on back order and the company cannot estimate a release date. The 2 mg/mL 20 mL vials 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=147>

Rosuvastatin Calcium Tablets

October 26, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Accord has rosuvastatin 10 mg tablets in 90 and 1,000 count bottles, 20 mg tablets in 1,000 count bottles, and 40 mg tablets in 30 count bottles on back order and the company estimates release dates of late-October 2018. The 40 mg tablets in 1,000 count bottles are on back order and the company estimates a release date of early-November 2018.
- Biocon has rosuvastatin tablets in limited supply.
- Glenmark has rosuvastatin 5 mg, 10 mg, and 20 mg tablets in 90 count bottles on back order and the company estimates release dates of early-November 2018. The 40 mg tablets in 90 count bottles are on back order and the company estimates a release date in early- to mid-November 2018.
- Mylan has rosuvastatin 5 mg tablets in 100 count unit-dose packaging available with short expiration dating of May 2019. The 10 mg tablets in 100 count unit-dose packaging are on back order and the company cannot estimate a release date.
- Rising has rosuvastatin 5 mg tablets in 500 count bottles, 10 mg in 90 count bottles, and 20 mg tablets in 90 count bottles on allocation. The 40 mg tablets in 90 count bottles are on back order and the company cannot estimate a release date.
- Sandoz has rosuvastatin 10 mg tablets in 90 count bottles on back order and the company estimates a release date of early-November 2018.
- Sun Pharma will be discontinuing production of rosuvastatin 5 mg, 10 mg, 20 mg, and 40 mg tablets in 90 count bottles.

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

Atenolol and Chlorthalidone Tablets

October 25, 2018

Reason for the Shortage

- Almatica Pharma has Tenoretic available.
- Mylan has discontinued the production of atenolol/chlorthalidone tablets.
- Teva has atenolol/chlorthalidone tablets available.

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

Betamethasone Acetate/Betamethasone Sodium Phosphate Suspension for Injection

October 25, 2018

Reason for the Shortage

- American Regent has betamethasone acetate/betamethasone sodium phosphate on shortage due to minor shipping delays.
- Merck has Celestone Soluspan available.

Estimated Resupply Dates

- American Regent has betamethasone acetate/betamethasone sodium phosphate 6 mg/mL 5 mL vials available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=485>

Cefoxitin Sodium Injection

October 25, 2018

Reason for the Shortage

- Apotex did not provide a reason for the shortage.
- BBraun has cefoxitin on allocation due to increased demand.
- Fresenius Kabi not provide a reason for the shortage.
- Hikma did not provide a reason for the shortage. Hikma is not currently marketing the 2 gram and 10 gram vials.
- Sagent has cefoxitin on shortage due to increased demand.
- WG Critical Care did not provide a reason for the shortage.

Estimated Resupply Dates

- Apotex has temporarily discontinued cefoxitin 1 gram, 2 gram, and 10 gram vials and the company cannot estimate when product will be available again.
- BBraun has cefoxitin 1 gram and 2 gram vials on allocation.
- Fresenius Kabi has cefoxitin 2 gram vials on back order and the company estimates a release date of early- to mid-January 2019
- Hikma has cefoxitin 1 gram vials on back order and the company estimates a release date of November 2018.
- Sagent has cefoxitin 2 gram vials on back order and the company estimates a release date of January 2019.
- WG Critical Care has cefoxitin 10 gram 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=271>

Doxorubicin Injection

October 25, 2018

Reason for the Shortage

- Hikma did not provide a reason for the shortage of Adriamycin.
- Teva has doxorubicin solution for injection on shortage due to increased demand.
- Fresenius Kabi has doxorubicin solution for injection available.
- Caraco has discontinued doxorubicin solution for injection 25 mL and 100 mL vials.
- Pfizer has doxorubicin on shortage due to manufacturing delays.
- Sagent discontinued doxorubicin solution for injection in late-2017.
- Mylan Institutional did not provide a reason for the shortage of doxorubicin lyophilized powder for injection.[8]
- Athenex has doxorubicin available.
- FDA was allowing temporary importation of doxorubicin lyophilized powder for injection 50 mg vials. These vials were manufactured for Hospira UK Limited. The labeling as well as bar coding for the imported product is different from the US version. FDA has the Dear Healthcare

Professional Letter linked on their website. The letter includes a link to both the US and United Kingdom package inserts to help explain the differences in labeling and packaging. The link to the letter is <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM507498.pdf>. Ordering can be done directly with Hospira Customer Care at 877-946-7747

Estimated Resupply Dates

- Athenex has doxorubicin 2 mg/mL 25 mL vials available with short expiration dating of March 2019. The 100 mL vials also have short expiration dating of April 2019.
- Hikma has Adriamycin 2 mg/mL 5 mL on back order with an expiration date of November or December 2018. The 10 mL vials are available with short expiration dating of June 2019. Hikma has 100 mL vials available with normal expiration dating and 100 mL vials available with short expiration dating of July 2019.
- Mylan Institutional has doxorubicin lyophilized powder 10 mg vials on back order and the company cannot estimate a release date. The 50 mg vials are on back order and the company estimates a release date of late-November 2018.
- Pfizer has doxorubicin 2 mg/mL 10 mL vials available with short expiration dating of December 2018.6
- Sagent has doxorubicin 2 mg/mL 5 mL, 10 mL, and 25 mL vials on back order and the company cannot estimate a release date.
- Teva has doxorubicin 2 mg/mL 10 mL (NDC 45963-0733-57) and 100 mL vials (NDC 45963-0733-60) on back order and the company will allocate these as they become available. The 5 mL vials (NDC 00703-5043-03) are available with short expiration dating

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

Eflornithine Hydrochloride Cream

October 25, 2018

Reason for the Shortage

- Allergan did not provide a reason for the shortage.

Estimated Resupply Dates

- Allergan has Vaniqa cream on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=438>

Ethiodized Oil

October 25, 2018

Reason for the Shortage

- Guerbet states their Lipiodol product is in short supply due to manufacturing problems at Jubilant HollisterStier, the manufacturing site in Canada that supplies Lipiodol for Guerbet. The company estimates the shortage will last at least one year

Estimated Resupply Dates

- Guerbet is shipping supplies of Lipiodol Ultra-Fluide. Lipiodol Ultra-Fluide is not FDA approved. In order to prevent a drug shortage, FDA is allowing Guerbet to import Lipiodol Ultra-Fluide, a product manufactured for Guerbet in France by Delpharm Tours.

- Customers must order Lipiodol Ultra-Fluide directly from Guerbet by calling 1-877-729-6679. Lipiodol Ultra-Fluide is non-refundable and may not be resold.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=39>

Fludrocortisone Acetate Tablets

October 25, 2018

Reason for the Shortage

- Teva did not provide a reason for the shortage.

Estimated Resupply Dates

- Teva has fludrocortisone acetate 0.1 mg tablets temporarily unavailable and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=484>

Hypromellose Ophthalmic Solution

October 25, 2018

Reason for the Shortage

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

Estimated Resupply Dates

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

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

Lactated Ringer's Injection

October 25, 2018

Reason for the Shortage

- Baxter did not provide a reason for the shortage.
- BBraun states the reason for the shortage is increased demand.
- ICU Medical states the reason for the shortage is increased demand.

Estimated Resupply Dates

- Baxter has lactated ringer's 1000 mL bags on allocation.
- BBraun has lactated ringer's with 5% dextrose injection solution on allocation to current customers.
- ICU Medical has lactated ringer's with 5% dextrose 1000 mL bags 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=361>

Nelarabine Injection

October 25, 2018

Reason for the Shortage

- Novartis did not provide a reason for the shortage.

Estimated Resupply Dates

- Novartis has Arranon 5 mg/mL 50 mL vials in 1 count and 6 count on back order with an expected release date of mid-November 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=458>

Thrombin Topical Solution (Bovine)

October 25, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has Thrombin-JMI 20,000 unit vials on back order and the company estimates a release date of November 2018. The 5000 unit vials, 5000 unit epistaxis kit, 5000 unit spray kit, 20,000 unit pump spray kit, and 20,000 unit syringe spray kit are available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=479>

Yellow Fever Vaccine

October 25, 2018

Reason for the Shortage

- Sanofi Pasteur states the shortage is due to production delays. [1]
- There are no other suppliers of yellow fever vaccine.

Estimated Resupply Dates

- Sanofi Pasteur has YF-Vax multi-dose vials and single dose vials on back order and the company estimates a release date in mid-2019.[1]
- FDA accepted an investigational new drug application in October 2016. This is for the importation of another yellow fever vaccine from France. The trade name of the imported product is Stamaril

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=197>

Daptomycin Injection

October 23, 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>

Deferoxamine Injection

October 23, 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 vials on back order and the company estimates a release date of 2019. The 2 gram vials are available in limited supply
- Novartis has short-dated Desferal 500 mg vials available with an expiration date of August 2019.

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

Mupirocin Calcium 2% Cream

October 23, 2018

Reason for the Shortage

- GlaxoSmithKline is looking for an alternative supply source.
- Prasco discontinued mupirocin calcium 2% cream in February 2016.

Estimated Resupply Dates

- GlaxoSmithKline has Bactroban 2% cream in 15 gram and 30 gram sizes 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=162>

Mupirocin Calcium 2% Nasal Ointment

October 23, 2018

Reason for the Shortage

- GlaxoSmithKline states the shortage is due to manufacturing issues. GlaxoSmithKline is looking for an alternative supply source

Estimated Resupply Dates

- GlaxoSmithKline has Bactroban Nasal 2% Ointment in 1 gram tubes 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=148>

Oxacillin Sodium Injection

October 23, 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

- Wockhardt has oxacillin 2 gram and 10 gram vials on back order and the company estimates a release date of early-November 2018.

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

Dorzolamide 2% and Timolol 0.5% Ophthalmic Solution

October 19, 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 mid- to late-November 2018.
- Sandoz has dorzolamide 2% and timolol 0.5% ophthalmic solution in 10 mL bottles on back order and the company estimates a release date of mid- to late-November 2018.

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

Mannitol Injection

October 19, 2018

Reason for the Shortage

- American Regent is not currently marketing mannitol.
- 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

- Pfizer has mannitol 250 mg/mL 50 mL vials on back order and the company estimates a release date of 1st quarter 2019.
- 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>

Recombinant Zoster Vaccine (Shingrix)

October 19, 2018

Reason for the Shortage

- GlaxoSmithKline has Shingrix on shortage due to high demand for the product.

Estimated Resupply Dates

- GlaxoSmithKline has Shingrix kits in 1 count and 10 count on intermittent back order with regular releases.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=427>

*Please refer to ASHP website for more information at: <https://www.ashp.org/Drug-Shortages/Current-Shortages>