TABLE OF CONTENTS

NEWLY AVAILABLE GENERICS ................................................................. 2
NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS ............................................. 3
NEW INDICATIONS (EXISTING DRUGS) .............................................................. 4
FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS ........................................ 5
STUDIES AND RECENT TOPICS ........................................................................ 7
RECALLS ........................................................................................................ 11
CURRENT DRUG SHORTAGES ................................................................ ........ 63
# NEWLY AVAILABLE GENERICS

<table>
<thead>
<tr>
<th>GENERIC DRUG NAME</th>
<th>STRENGTH &amp; DOSAGE FORM</th>
<th>GENERIC MANUFACTURER</th>
<th>BRAND NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERYTHROMYCIN ETHYL SUCCINATE</td>
<td>400 MG/5 ML ORAL SUSPENSION</td>
<td>ANI PHARMACEUTICALS</td>
<td>ERYPED 400</td>
</tr>
<tr>
<td>PENTAMIDINE ISETHIONATE</td>
<td>300 MG POWDER FOR RECONSTITUTION, INJECTION</td>
<td>SETON PHARMACEUTICALS</td>
<td>PENTAM 300</td>
</tr>
<tr>
<td>DEFERASIROX</td>
<td>125 MG, 250 MG, 500 MG TABLET, SOLUBLE</td>
<td>ACTAVIS</td>
<td>EXJADE</td>
</tr>
<tr>
<td>CHLORZOXAZONE</td>
<td>375 MG, 750 MG TABLET</td>
<td>TRIGEN LABORATORYIEX</td>
<td>LORZONE</td>
</tr>
<tr>
<td>FENOFIBRATE NANOCRYSTALLIZED</td>
<td>160 MG TABLET</td>
<td>BASIEM</td>
<td>TRIGLIDE</td>
</tr>
<tr>
<td>THEOPHYLLINE ANHYDROUS</td>
<td>80 MG/15 ML ORAL ELIXIR</td>
<td>PHARMACEUTICAL ASSOCIATES</td>
<td>ELIXOPHYLLIN</td>
</tr>
<tr>
<td>COLLAGEN, TYPE 1/SILVER OXIDE</td>
<td>1% GEL</td>
<td>EMERALD THERAPEUTICS</td>
<td>PROTYL AG</td>
</tr>
<tr>
<td>AMBRISSENTAN</td>
<td>5 MG, 10 MG TABLET</td>
<td>PAR, SUN, ZYDUS</td>
<td>LETAIRIS</td>
</tr>
<tr>
<td>PROTECTIVES COMBINATION NO. 6</td>
<td>GEL</td>
<td>NATIONAL BIO GREEN SCIENCES</td>
<td>SCARCIN</td>
</tr>
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</table>
# NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>BRAND NAME</th>
<th>GENERIC NAME</th>
<th>STRENGTH</th>
<th>NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTIMIGRAINE PREPARATIONS</td>
<td>AIMOVIG</td>
<td>ERENUMBA-AOOE</td>
<td>140 MG/ML AUTO INJCT</td>
<td>NEW STRENGTH</td>
</tr>
<tr>
<td>GLUCOCORTICOIDS</td>
<td>DXEVO</td>
<td>DEXAMETHASONE</td>
<td>1.5 MG (39 TABLETS) DOSE PACK</td>
<td>NEW PACKAGE SIZE</td>
</tr>
<tr>
<td>AGENTS TO TREAT MULTIPLE SCLEROSIS</td>
<td>MAYZENT</td>
<td>SIPONIMOD</td>
<td>0.25 MG, 2 MG TABLET; 0.25 MG TABLET STARTER PACK</td>
<td>NEW ENTITY</td>
</tr>
<tr>
<td>TOPICAL AGENTS, MISCELLANEOUS</td>
<td>PROTYL AG</td>
<td>COLLAGEN, TYPE 1/SILVER OXIDE</td>
<td>1% GEL</td>
<td>NEW ENTITY</td>
</tr>
<tr>
<td>MIOTICS AND OTHER INTRAOCULAR PRESSURE REDUCERS</td>
<td>ROCKLATAN</td>
<td>NETARSUDIL MESYLATE/ LATANOPROST</td>
<td>0.02%/0.005% OPHTHALMIC DROPS</td>
<td>NEW COMBINATION</td>
</tr>
<tr>
<td>EYE ANTI-INFLAMMATORY AGENTS</td>
<td>DEXTENZA</td>
<td>DEXAMETHASONE</td>
<td>0.4 MG INTRACANALICULAR INSERT</td>
<td>NEW DOSAGE FORM, STRENGTH</td>
</tr>
<tr>
<td>PRENATAL VITAMINS WITH LOW OR NO IRON</td>
<td>AZESCO</td>
<td>PRENATAL 147/IRON/FOLIC ACID</td>
<td>13 MG/1 MG TABLET</td>
<td>RX DIETARY SUPPLEMENT</td>
</tr>
<tr>
<td>AGENTS TO TREAT MULTIPLE SCLEROSIS</td>
<td>MAVENCLAD</td>
<td>CLADRIBINE</td>
<td>10 MG TABLET (4-, 5-, 6-, 7-, 8-, 9-, 10-TABLET PACK)</td>
<td>NEW DOSAGE FORM</td>
</tr>
<tr>
<td>ANTICONVULSANTS</td>
<td>DIACOMIT</td>
<td>STIRIPENTOL</td>
<td>250 MG, 500 MG CAPSULE</td>
<td>NEW ENTITY</td>
</tr>
<tr>
<td>ANTICONVULSANTS</td>
<td>DIACOMIT</td>
<td>STIRIPENTOL</td>
<td>250 MG, 500 MG POWDER PACKET</td>
<td>NEW ENTITY</td>
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<tr>
<td>ANTINEOPLASTIC EGF RECEPTOR BLOCKER MONOCLONAL ANTIBODY</td>
<td>HERCEPTIN HYLECTA</td>
<td>TRASTUZUMAB HYALURONIDASE-OYSK</td>
<td>600 MG/10,000 U SOLUTION VIAL</td>
<td>NEW COMBINATION</td>
</tr>
<tr>
<td>ANTIRETROVIRAL-INTEGRASE INHIBITOR AND NRTI COMBINATION</td>
<td>DOVATO</td>
<td>DOLUTEGRAVIR SODIUM/LAMIVUDINE</td>
<td>50 MG/300 MG TABLET</td>
<td>NEW COMBINATION</td>
</tr>
<tr>
<td>BONE FORMATION AGENTS - SCLEROSTIN INHIBITOR, MONOCLONAL ANTIBODY</td>
<td>EVENITY</td>
<td>ROMOSOZUMAB-AQQG</td>
<td>210 MG/2.34 ML, 105 MG/1.17 ML SOLUTION SYRINGE</td>
<td>NEW ENTITY</td>
</tr>
<tr>
<td>ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS</td>
<td>BALVERSA</td>
<td>ERDAFITINIB</td>
<td>3 MG, 4 MG, 5 MG TABLET</td>
<td>NEW ENTITY</td>
</tr>
</tbody>
</table>
NEW INDICATIONS (EXISTING DRUGS)

**CIMZIA®**

March 29, 2019

UCB, a global biopharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has approved extending the label for CIMZIA® (certolizumab pegol) to include a new indication for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. The approval makes CIMZIA the first and only FDA-approved treatment for nr-axSpA.

Source: UMB, Inc.

**ZELNORM™**

April 1, 2019

US WorldMeds has announced that Sloan Pharma, S.a.r.l., a subsidiary of US WorldMeds Holdings, LLC, has received approval from the U.S. FDA for the reintroduction of Zelnorm™ (tegaserod), a twice-daily oral treatment for Irritable Bowel Syndrome with Constipation (IBS-C) in women under 65.

Source: PRNewswire

**KEYTRUDA®**

April 16, 2019

Tessa Therapeutics, a clinical-stage immunotherapy company focused on autologous and off-the-shelf, allogeneic therapies targeting solid tumors, today announced that it has entered into an agreement with MSD (tradename of Merck & Co., Inc., Kenilworth, N.J., USA), through a subsidiary, to evaluate Tessa's armored human papillomavirus-specific T cell (HPVST) therapy, or TT12, in combination with KEYTRUDA® (pembrolizumab), MSD’s anti-PD-1 (programmed death receptor-1) therapy, in patients with recurrent or metastatic HPV 16 and 18-positive cervical cancer.

Source: Tessa Therapeutics
FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Opioid Pain Medicines: Drug Safety Communication - Harm to Patient Reported From Sudden Discontinuation of Opioid Pain Medicine

[Posted 4/9/2019]

The U.S. FDA has received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased. These include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.

While we continue to track this safety concern as part of our ongoing monitoring of risks associated with opioid pain medicines, we are requiring changes to the prescribing information for these medicines that are intended for use in the outpatient setting. These changes will provide expanded guidance to health care professionals on how to safely decrease the dose in patients who are physically dependent on opioid pain medicines when the dose is to be decreased or the medicine is to be discontinued.

Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse. Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances.

Opioids are a class of powerful prescription medicines that are used to manage pain when other treatments and medicines cannot be taken or are not able to provide enough pain relief. They have serious risks, including abuse, addiction, overdose, and death. Examples of common opioids include codeine, fentanyl, hydrocodone, hydromorphone, morphine, oxycodone, and oxymorphone.

Health care professionals should not abruptly discontinue opioids in a patient who is physically dependent. When you and your patient have agreed to taper the dose of opioid analgesic, consider a variety of factors, including the dose of the drug, the duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient. No standard opioid tapering schedule exists that is suitable for all patients. Create a patient-specific plan to gradually taper the dose of the opioid and ensure ongoing monitoring and support, as needed, to avoid serious withdrawal symptoms, worsening of the patient’s pain, or psychological distress (For tapering and additional recommendations, see Additional Information for Health Care Professionals).

Patients taking opioid pain medicines long-term should not suddenly stop taking your medicine without first discussing with your health care professional a plan for how to slowly decrease the dose of the opioid and continue to manage your pain. Even when the opioid dose is decreased gradually, you may experience symptoms of withdrawal (See Additional Information for Patients). Contact your health care professional if you experience increased pain, withdrawal symptoms, changes in your mood, or thoughts of suicide.
We are continuing to monitor this safety concern and will update the public if we have new information. Because we are constantly monitoring the safety of opioid pain medicines, we are also including new prescribing information on other side effects including central sleep apnea and drug interactions. We are also updating information on proper storage and disposal of these medicines that is currently available on our Disposal of Unused Medicines webpage.

- To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving opioids or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page. If you are taking opioid pain medicines long-term, do not suddenly stop taking your medicine without first discussing with your health care professional a plan for gradually getting off the medicine. Stopping opioids abruptly or reducing the dose too quickly can result in serious problems, including withdrawal symptoms, uncontrolled pain, and thoughts of suicide.
- Even when the opioid dose is decreased gradually, you may experience symptoms of withdrawal such as:
  o Restlessness
  o Eye tearing
  o Runny nose
  o Yawning
  o Sweating
  o Chills
  o Muscle aches
- Other symptoms also may develop, including:
  o Irritability
  o Anxiety
  o Difficulty sleeping
  o Backache
  o Joint pain
  o Weakness
  o Abdominal cramps
  o Loss of appetite
  o Nausea
  o Vomiting
  o Diarrhea
- Contact your health care professional if you experience increased pain, withdrawal symptoms, changes in your mood, or thoughts of suicide. Also contact them if you have any questions or concerns.

Source: U.S. FDA
STUDIES AND RECENT TOPICS

New Recombinant Zoster Vaccine to Prevent Shingles Deemed Cost-Effective

March 28, 2019

The new recombinant zoster vaccine (RZV) is more cost-effective than the live attenuated vaccine according to a new study that supports U.S. Advisory Committee on Immunization Practices recommendations for preferred use of the newer vaccine.

Source: uspharmacist.com

FDA warns homeopathic firms for putting patients at risk with significant violations of manufacturing quality standards

April 1, 2019

The U.S. FDA today posted warning letters to four companies who produce homeopathic drug products for significant violations of current good manufacturing practice (CGMP) regulations, including a letter to King Bio Inc. of Asheville, N.C. The FDA previously warned the public about the agency’s serious concerns with the quality of drug products produced by King Bio.

Source: U.S. FDA

Benefits of landmark HIV drug outweigh risks of birth defects, study shows

April 2, 2019

The benefits of a landmark treatment for HIV outweigh the risks, despite the fact it has been linked to birth defects in babies born to mothers taking the drug, researchers have said.

The antiretroviral drug dolutegravir, taken in conjunction with other drugs to suppress an HIV patient’s viral load and to stop them passing the virus to others, is considered one of the best HIV drugs available and has become the cornerstone of treatment in many richer countries since it was first introduced in the United States in 2013.

Source: telegraph.co.uk
Websites Offering Sale of Opioids are Targets of FDA Warning Letters

April 2, 2019

Officials with the FDA announced today the issuance of 2 warning letters, to operators of websites that illegally market potentially dangerous, unapproved and misbranded opioid medications, including tramadol. The warning letters issued to azmedicinalshop.com and thedonrx.net request that these enterprises immediately cease offering violative drugs for sale to consumers in the United States.

Source: pharmacytimes.com

Hypertension Control Program May Go Nationwide

April 3, 2019

The CDC is currently conducting investigations into a Michigan-based comprehensive hypertension control program to determine whether the setup has the potential for nationwide implementation.

According to the CDC, 1,332 patients with hypertension were served by Michigan Medicine clinic pharmacists in 2017, while an additional 514 were served in community pharmacies in three Meijer stores. Overall, the CDC reports that hypertension management control rates increased to 77% in 2017, up 5% from the previous recording in 2016.

Source: drugtopics.com

Melatonin: An Unlikely Antioxidant with Growth Receptors in the Skin

April 3, 2019

We all know melatonin as a sleeping pill because it is released by the pineal gland in the brain, and helps us fall asleep at night when it is dark. Melatonin is very connected with our circadian rhythm and the environment.

Source: pharmacytimes.com

Approach Respiratory Illnesses Rationally

April 3, 2019

When patients present with respiratory illnesses, pharmacists must assess factors such as comorbidities, symptoms and symptom control, medication history, and adverse effects. The first question they should ask is, “Does this patient have a known respiratory diagnosis?” While investigating accessible health records, including the patient’s pharmacy profile, in search of a diagnosis, it is important to keep an eye out for comorbidities that can affect treatment choice.
Blood pressure patients can take tainted pills during valsartan shortage, FDA says CNN Digital Expansion 2016

April 4, 2019

Due to a shortage of certain commonly used blood pressure drugs, the U.S. FDA took the unusual step Thursday of reminding patients that they have access to available -- if tainted -- medicines while a fresh supply of uncontaminated pills is manufactured.

Source: cnn.com

Drugs Are Keeping Seniors Healthy, and Hurting Them

April 8, 2019

We are living in the age of prescription drugs. They can turn once-fatal diseases into manageable, chronic conditions. But especially for older adults, many of whom take five or more medications each day, they can cause illness or even death.

Source: forbes.com

Alkermes says long-acting drugs could help schizophrenics stay on medication longer

April 9, 2019

Alkermes Plc said on Tuesday its long-acting injectable therapy for schizophrenia has helped reduce symptoms and can become an effective option for ensuring patients stay on medication even after being discharged from hospital.

Source: reuters.com

U.S. FDA loosens alcohol restrictions for female libido pill

April 11, 2019

The U.S. FDA said on Thursday women taking Sprout Pharmaceuticals Inc’s female libido pill, Addyi, need not completely avoid alcohol.

The FDA ordered Sprout to make changes to the drug’s label to reflect that patients should stop drinking two hours before taking Addyi at bedtime or to skip the dose that evening.

Source: reuters.com
The FDA Just Approved a New Prescription Weight-Management Device. Here’s How It Works

April 15, 2019

In a rare move, the FDA has approved a novel prescription device meant to help with weight management.

The product, called Plenity and developed by Gelesis, has been cleared for overweight or obese adults with a body mass index of at least 25, even if they do not have other health problems. It should be used in conjunction with diet and exercise, the FDA says, and can also be taken alongside other weight-loss medications.

Source: time.com

Are your antibiotics not working anymore? Arsenic could be a lifesaver, research says

April 16, 2019

For the generations of high school students whose English class assignments included reading Joseph Kesselring’s play, “Arsenic and Old Lace,” the idea of arsenic as an aid to health seems either amusing or frightening.

Source: sacbee.com

Diabetes drug has heart and kidney benefits, researchers find

April 16, 2019

A common diabetes drug has been found to lower the risk of kidney failure in a new study. The finding has raised some eyebrows since diabetes is a major cause of kidney failure worldwide.

The risk of kidney failure and cardiovascular-related problems was lowered in patients with type 2 diabetes and kidney disease who took a daily dose of the drug canagliflozin as part of the study published in The New England Journal of Medicine on Sunday.

Source: cnn.com
## RECALLS

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Product Description</th>
<th>Classification</th>
<th>Code Info</th>
<th>Reason for Recall</th>
<th>Recalling Firm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs</td>
<td>8.4% Sodium Bicarbonate Injection, USP 50 mEq (1 mEq/mL) 4.2 grams (84 mg/mL) 50 mL Single-dose flip top vial, 25 vials per carton, Rx only Hospira, Inc. Lake Forest, IL 60045 USA ---- NDC 0409-6625-02</td>
<td>Class I</td>
<td>Lots: 79-238-EV Exp. 1 July 2019; 79-240-EV Exp. 1 July 2019; 80-088-EV Exp. 1 August 2019</td>
<td>Presence of Particulate Matter; glass particulates</td>
<td>Pfizer Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>8.4% Sodium Bicarbonate Injection, USP 50 mEq (1 mEq/mL) 4.2 grams (84 mg/mL) 50 mL Single-dose flip top vial, 25 vials per carton, Rx only Hospira, Inc. Lake Forest, IL 60045 USA ---- NDC 0409-6625-02</td>
<td>Class I</td>
<td>Lots: 79-238-EV Exp. 1 July 2019; 79-240-EV Exp. 1 July 2019; 80-088-EV Exp. 1 August 2019</td>
<td>Presence of Particulate Matter; glass particulates</td>
<td>Pfizer Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>LEOPARD Miracle Honey packaged in a wooden box, UPC 8 699415 910534, containing 12 sachets 180Gr / 6.36 Oz, each 1 Sachet 15 gr / 0.53 Oz is labeled as LEOPARD Miracle of Honey, UPC 8 699415 912859, Manufactured in Turkey, <a href="http://www.leopardhoneytr.com">www.leopardhoneytr.com</a>.</td>
<td>Class I</td>
<td>All lots</td>
<td>Marketed Without An Approved NDA/ANDA: product tainted with undeclared sildenafil, an FDA approved drug for the treatment of male erectile dysfunction. The presence of sildenafil in Leopard Miracle Honey renders it an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.</td>
<td>USA LESS Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Kopi Jantan Tradisional</td>
<td>Class I</td>
<td>All Lots labeled</td>
<td>Marketed</td>
<td>Brian P.</td>
</tr>
<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
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<tr>
<td>Natural Herbs Coffee, 13g individual packages, Manufactured By: Fikrysz (M) Sdn. Bhd., Kedah, Malaysia, UPC 9 557205 060083.</td>
<td></td>
<td></td>
<td></td>
<td>Without An Approved NDA/ANDA: FDA analysis found this product to be tainted with undeclared sildenafil and tadalafil, two FDA approved drugs for the treatment of male erectile dysfunction, making this an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.</td>
<td>Richardson</td>
</tr>
<tr>
<td>Docusate Sodium, 100mg softgels, packaged in 10 x 10 unit dose blister cards, For institutional use only, Mfg by: Aenova Holding GmBh, Miami, Fl 33186, NDC 63739-0478-10</td>
<td>Class II</td>
<td>Lot # 0119397, Exp 02/2020</td>
<td>Labeling: Label mix-up: Secondary carton may be labeled as Gabapentin 300mg instead of Docusate Sodium 100mg softgel caps.</td>
<td>Rx Pak Division of McKesson Corporation</td>
<td></td>
</tr>
<tr>
<td>Alprazolam Tablets, USP, 0.25 mg, 10x10 per carton, Rx Only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 51079-788-20</td>
<td>Class II</td>
<td>Lots: 3095198, 3096266, 3098776, EXP 05-2019</td>
<td>Failed Impurities/Degradation Specifications: Elevated levels of a known impurity detected during 6-month RT stability interval.</td>
<td>Mylan Institutional, Inc. (d.b.a. UDL Laboratories)</td>
<td></td>
</tr>
<tr>
<td>Valsartan Tablets USP 320 mg, 90 count bottles, Rx only, Distributed by:</td>
<td>Class II</td>
<td>Lot Numbers: 473180004A, 473180005A, exp.</td>
<td>GCMP Deviations: FDA analysis</td>
<td>Aurobindo Pharma USA Inc.</td>
<td></td>
</tr>
<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
<td>Recalling Firm</td>
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<tr>
<td>Drugs</td>
<td>Amlodipine and Valsartan Tablets USP 10mg/160mg, 30 count bottles, Manufactured for:</td>
<td>Class II</td>
<td>Lot Numbers: VFSA17007-A, exp. date Oct-2019</td>
<td>GCMP Deviations: FDA analysis confirmed presence of trace amounts of an impurity, N-nitrosodiethylamine (NDEA) found in the API used to manufacture the product.</td>
<td>Aurobindo Pharma USA Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Valsartan Tablets USP 40 mg, 30 count bottles, Rx only, Distributed by:</td>
<td>Class II</td>
<td>Lot Numbers: 470180008A, exp. date Feb 2020; 470180014A, exp. date Mar 2020; 470180016A, exp. date May 2020; 470180032A, exp. date May 2020</td>
<td>GCMP Deviations: FDA analysis confirmed presence of trace amounts of an impurity, N-nitrosodiethylamine (NDEA) found in the API used to manufacture the product.</td>
<td>Aurobindo Pharma USA Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Valsartan Tablets USP 80 mg, 90 count bottles, Rx only, Distributed by:</td>
<td>Class II</td>
<td>Lot Numbers: 471170015A, exp. date Sep 2019; 471180004A, exp. date Feb 2019</td>
<td>GCMP Deviations: FDA analysis confirmed presence of trace amounts of an impurity, N-nitrosodiethylamine (NDEA) found in the API used to manufacture the product.</td>
<td>Aurobindo Pharma USA Inc.</td>
</tr>
<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
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<tr>
<td>Drugs</td>
<td>Valsartan Tablets USP 160 mg, 90 count bottles, Rx only, Distributed by: Aurobindo Pharma USA, Inc., Dayton, NJ --- NDC 65862-572-90</td>
<td>Class II</td>
<td>Lot Numbers: 472180001A, 472180002A, 472180003A, 472180004A, exp. date Jan 2020; 472180007A, 472180008A, 472180009A, 472180010A, exp. date Mar 2020; 472180013A, 472180014A, exp. date Apr 2020</td>
<td>GCMP Deviations: FDA analysis confirmed presence of trace amounts of an impurity, N-nitrosodiethylamine (NDEA) found in the API used to manufacture the product.</td>
<td>Aurobindo Pharma USA Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Losartan Potassium and Hydrochlorothiazide Tablets, USP 100 mg/25 mg, 90 count bottles, Rx Only, Manufactured for: Macleods Pharma USA, Inc., Plainsboro, NJ 08536, Manufactured by: Macleods Pharmaceuticals Ltd., Baddi, Himachal Pradesh, India. NDC 33342-0052-10</td>
<td>Class II</td>
<td>Lot BLM715A, Jul-19</td>
<td>CGMP Deviation: Presence of NDEA (N-Nitrosodimethylamine), a carcinogen impurity, detected in the active ingredient.</td>
<td>Macleods Pharma USA Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Etomidate Injection, USP 20 mg/10mL (2mg/mL) 10 mL Single-Dose Vial, Rx only, Manufactured for: Heritage Pharmaceuticals Inc. Made in India, NDC 23155-160-31</td>
<td>Class II</td>
<td>Lot #: AMA701, Exp. March 2019; AMA702, AMA703, Exp August 2019.</td>
<td>Subpotent Drug.</td>
<td>Heritage Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Losartan Potassium Tablets USP, 25 mg, Rx only, a) 90 count (NDC 31722-700-90), b) 500 count (NDC 31722-700-05)</td>
<td>Class II</td>
<td>a) LOP17026B, LOP17050, LOP1705, LOP17052, LOP17053, Exp.</td>
<td>CGMP Deviations; trace amounts of N-Nitroso N-Methyl 4-amino</td>
<td>Camber Pharmaceuticals Inc.</td>
</tr>
<tr>
<td>Product Type</td>
<td>Product Description</td>
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<td>Drugs</td>
<td>Losartan Potassium Tablets USP, 100 mg, Rx only, a) 30 count (NDC 31722-702-30), b) 90 count (NDC 31722-702-30), c) 1000 count (NDC 31722-702-10) bottles, Manufactured for: Camber Pharmaceuticals, Inc. Piscataway, NJ 08854 By: Hetero Labs Limited, Unit V, Polepally, Jadcherla, Mahaboob Nagar -509 301, India</td>
<td>Class II</td>
<td>LOP18084, LOP18095, LOP18096 Exp Mar-20</td>
<td>CGMP Deviations; trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) detected in the active pharmaceutical ingredient</td>
<td>Camber Pharmaceuticals Inc</td>
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<tr>
<td>Product Type</td>
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<tr>
<td>Drugs</td>
<td>Losartan Potassium</td>
<td>Class II</td>
<td>LOP18125, LOP18126, LOP18127, LOP18128, LOP18129, LOP18130, LOP18131C, LOP18133, Exp Jun-20</td>
<td>CGMP Deviations: presence of an impurity, N-Methylnitrosobutyric acid (NMBA) was identified</td>
<td>AVKARE Inc.</td>
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<td>Tablets USP 50 mg</td>
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<td>50 Tablets (5x10)</td>
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<tr>
<td></td>
<td>Unit Dose boxes, Rx Only, Manufactured for: AVKARE Inc. Pulaski, TN 38478 ---- NDC 50268-517-15</td>
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<tr>
<td>Drugs</td>
<td>Losartan Potassium</td>
<td>Class II</td>
<td>Lot: 19454 Exp. 04/30/2019</td>
<td>CGMP Deviations: presence of an impurity, N-Methylnitrosobutyric acid (NMBA) was identified</td>
<td>AVKARE Inc.</td>
</tr>
<tr>
<td></td>
<td>and Hydrochlorothiazide Tablets, USP 50 mg/12.5 mg 50 Tablets (5x10) Unit Dose boxes, Rx Only Manufactured for: AVKARE Inc. Pulaski, TN 38478 ---- NDC 50268-513-15</td>
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<tr>
<td>Drugs</td>
<td>Losartan Potassium</td>
<td>Class II</td>
<td>Lot: 19326 Exp. 03/31/2019</td>
<td>CGMP Deviations: presence of an impurity, N-Methylnitrosobutyric acid (NMBA) was identified</td>
<td>AVKARE Inc.</td>
</tr>
<tr>
<td></td>
<td>and Hydrochlorothiazide Tablets, USP 100 mg/12.5 mg 50 Tablets (5x10) Unit Dose boxes, Rx Only Manufactured for: AVKARE Inc. Pulaski, TN 38478 ---- NDC 50268-514-15</td>
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<tr>
<td>Drugs</td>
<td>Valsartan Tablets</td>
<td>Class II</td>
<td>Lot 179791, Mar 2020</td>
<td>CGMP Deviation: Presence of NDEA (N-Nitrosodimethylamine), a carcinogen impurity, detected in the active</td>
<td>American Health Packaging</td>
</tr>
<tr>
<td></td>
<td>USP 160 mg, 100 Tablets (10 x 10) per Unit Dose Blisters, Rx Only, Packaged and Distributed by: American Health Packaging, Columbus, Ohio 43217 (Individual Dose NDC:60687-139-11, Carton NDC#: 60687-139-</td>
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<td>Drugs</td>
<td>Valsartan Tablets 40 mg USP, 30 tablet bottles, Rx, Only, Distributed by: Acetris Health, LLC, Saddle Brook, NJ, Manufactured by: Aurolife Pharma LLC, Dayton, NJ --- NDC 52343-122-30</td>
<td>Class II</td>
<td>470170038A, exp. date 10/31/2019 470180010A, exp. date 02/29/2019 470180012A, exp. date 03/31/2020</td>
<td>CGMP Deviations; Detection of a trace amount of unexpected impurity N-nitrosodiethylamine (NDEA) found in finished products</td>
<td>Rising Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Valsartan Tablets 80 mg USP, 90 tablet bottles, Rx only, Distributed by: Acetris Health, LLC, Saddle Brook, NJ 07663, Manufactured by: Aurolife Pharma LLC, Dayton, NJ 08810 --- NDC 52343-123-90</td>
<td>Class II</td>
<td>471170019A, exp. date 10/31/2019 471180006A, exp. date 03/31/2020 471180007A, exp. date 03/31/2020 471180016A, exp. date 05/31/2020</td>
<td>CGMP Deviations; Detection of a trace amount of unexpected impurity N-nitrosodiethylamine (NDEA) found in finished products</td>
<td>Rising Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Valsartan Tablets 160 mg USP, 90 tablet bottles, Rx only, Distributed by: Acetris Health, LLC, Saddle Brook, NJ 07663, Manufactured by: Aurolife Pharma LLC, Dayton, NJ 08810 ---- NDC 52343-124-90</td>
<td>Class II</td>
<td>472180005B, exp. date 02/29/2020 472180011A, exp. date 04/30/2020 472180012A, exp. date 04/30/2020</td>
<td>CGMP Deviations; Detection of a trace amount of unexpected impurity N-nitrosodiethylamine (NDEA) found in</td>
<td>Rising Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>Product Type</td>
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<tr>
<td>Drugs</td>
<td>Valsartan Tablets 320 mg USP, 90 tablet bottles, Distributed by: Acetris Health, LLC, Saddle Brook, NJ 07663, Manufactured by: Aurolife Pharma LLC, Dayton, NJ 08810 --- NDC 52343-125-90</td>
<td>Class II</td>
<td>473180007A, exp. date 03/31/2020 473180008A, exp. date 03/31/2020 473180011A, exp. date 04/30/2020 473180020B1, exp. date 07/31/2020 473170019B, exp. date 10/31/2019</td>
<td>finished products</td>
<td>Rising Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Hydrocortisone and Acetic Acid Otic Solution, USP, 10 mL per dropper bottle, Rx only, Hi-Tech Pharmacal Co, Inc., Amityville, NY 11701. NDC: 50383-901-10</td>
<td>Class II</td>
<td>Lot: 357647, EXP 04/2019</td>
<td>Sub Potent Drug: OOS results observed for the Hydrocortisone assay during routine stability testing at 12 month controlled room temperature.</td>
<td>Akorn Inc</td>
</tr>
<tr>
<td>Drugs</td>
<td>Volumex (Iodinated I 131 Albumin) Injection USP, 25 uCi per 1 mL syringe, Rx Only, Manufactured for Daxor Corp., NY, NY; By: Iso-Tex Diagnostics, Inc.; NDC 50914-7720-8.</td>
<td>Class II</td>
<td>Lot: V190603-922, Exp. 04/05/19</td>
<td>Lack of Assurance of Sterility: preliminary environmental monitoring report exceeds limits, therefore sterility cannot be assured.</td>
<td>Iso-Tex Diagnostics, Inc</td>
</tr>
<tr>
<td>Drugs</td>
<td>HYDROmorphone HCl 1 mg in 0.9% Sodium Chloride, QS 5 mL Injectable Solution 1 mg/5 mL (0.2 mg per mL), Sterile single use syringe, NDC: 42852-289-67 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lots: 12/03/18 4090 28967S Exp. 4/2/2019; 12/03/18 6221 28967S Exp. 4/2/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>fentaNYL 1000 mcg/100</td>
<td>Class II</td>
<td>Lot: 01/03/19 1311</td>
<td>Lack of</td>
<td>Advanced</td>
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<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
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<tr>
<td>Drugs</td>
<td>mL Injectable Solution ; Fentanyl 0.9% Sodium Chloride, QS, 100 mL, Sterile single use bag, NDC: 42852-210-10 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>21010P Exp. 5/3/2019</td>
<td>Assurance of Sterility</td>
<td>Pharma Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>fentaNYL 2500 mcg/250 mL Injectable Solution, Fentanyl 0.9% Sodium Chloride, QS, Sterile single use bags, NDC: 42852-210-25 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lot: 01/03/19 1645 21025P Exp. 5/3/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
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<tr>
<td>Drugs</td>
<td>Midazolam Benzodiazepine 50 mg/50 mL (1 mg/mL) Injectable Solution, Midazolam HCl 0.9% Sodium Chloride, QS, Sterile single use bag, NDC: 42852-401-05 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lots: 12/03/18 9479 40105P Exp. 4/2/2019; 12/3/18 6583 40105P Exp. 4/2/2019; 12/3/18 8918 40105P Exp. 4/2/2019; 12/03/18 4727 40105P Exp. 4/2/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
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<tr>
<td>Drugs</td>
<td>Phenylephrine HCl, 500 mcg in 0.9% Sodium Chloride, QS 5 mL Injectable Solution 500 mcg/5 mL (100 mcg per mL), 5mL Sterile single use syringe, NDC: 42852-830-67 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lots: 01/18/19 3261 83067S Exp. 6/17/2019; 10/18/18 0212 83067S Exp. 3/17/2019; 10/23/18 7704 83067S Exp. 3/22/2019; 11/02/18 5909 83067S Exp. 4/1/2019; 10/31/18 8995 83067S Exp. 3/30/2019; 10/22/18 2570 83067S Exp. 3/21/2019; 10/18/18 6471 83067S Exp.</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
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<td>Drugs</td>
<td>Glycopyrrolate Injectable Solution 1 mg/5 mL (0.2 mg per mL), Sterile single use syringe, NDC: 42852-828-67 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lot: 12/05/18 0710 82867S Exp. 5/4/2019; 10/24/18 0014 82867S Exp. 3/23/2019; 11/01/18 8800 82867S Exp. 3/31/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
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<tr>
<td>Drugs</td>
<td>Phenylephrine HCl, 400 mcg in 0.9% Sodium Chloride, QS 10 mL Injectable Solution 400 mcg/10 mL (40 mcg per mL), Sterile single use syringe, NDC: 42852-876-61 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lots: 10/18/18 1430 87661S Exp. 3/17/2019; 10/29/18 1805 87661S Exp. 3/28/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
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<tr>
<td>Drugs</td>
<td>Phenylephrine HCl, 1 mg in 0.9% Sodium Chloride, QS 10 mL Injectable Solution 1 mg/10 mL (100 mcg per mL), Sterile single use syringe, NDC: 42852-830-61 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lots: 10/24/18 3318 83061S Exp. 3/23/2019; 10/18/18 3354 83061S Exp. 3/17/2019; 10/23/2018 6050 83061S Exp. 3/22/2019; 10/23/18 8105 83061S Exp. 3/22/2019; 10/18/18 1961 83061S Exp.</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
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<tr>
<td>Drugs</td>
<td>Neostigmine Methylsulfate Injection Solution 5 mg/5mL (1 mg per mL), 5mL Sterile single use syringe, For IV use only, NDC: 42852-829-67 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lots: 11/02/18 9350 82967S Exp. 4/1/2019; 10/23/18 1471 82967S Exp. 3/22/2019; 10/24/18 4412 82967S Exp. 3/23/2019; 10/24/18 0733 82967S Exp. 3/22/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
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<tr>
<td>Drugs</td>
<td>Glycopyrrolate 0.6 mg/3 mL (0.2 mg per mL) Injectable Solution, 3 mL Sterile single use syringe, For IV or IM use, NDC: 42852-828-22 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lots: 10/31/18 2288 82822S Exp. 3/30/2019; 10/18/18 8371 82822S Exp. 3/17/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
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<tr>
<td>Drugs</td>
<td>2% Lidocaine HCl Injectable Solution, 60 mg/3 mL (20 mg per mL),</td>
<td>Class II</td>
<td>Lot: 10/18/18 2217 01122S Exp. 3/17/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
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<td>Product Type</td>
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<tr>
<td>Drugs</td>
<td>3mL Sterile single use syringe, NDC: 42852-011-22 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
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<tr>
<td>Drugs</td>
<td>2% Lidocaine HCl Injectable Solution, 100 mg/5 mL (20 mg per mL), 5mL Sterile single use syringe, NDC: 42852-011-67 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lot: 10/19/18 1990 01167S Exp. 3/18/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
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<td>Drugs</td>
<td>Phenylephrine HCl, 800 mcg in 0.9% Sodium Chloride, QS 10 mL Injectable Solution, 800 mcg/10 mL (80 mcg per mL), 10mL Sterile single use syringe, NDC: 42852-865-61 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lots: 10/17/18 2976 86561S Exp. 3/16/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Esmolol HCl Injectable Solution 100 mg/10 mL (10 mg per mL)10mL Sterile single use syringe, NDC: 42852-827-61 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lot: 11/06/18 5007 82761S Exp. 4/5/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Heparin 10 Units/10 mL 10 Units in 0.45% Sodium Chloride, QS 10 mL, Injectable Solution, Dwell, 10mL Sterile single use syringe, NDC: 42852-725-61 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lot: 10/23/18 1998 72561SPF Exp. 3/22/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Heparin 5,000 Units/5mL (1,000 Units per mL) Injectable Solution, 5,000 Units in 0.9% Sodium Chloride, QS 5 mL Sterile</td>
<td>Class II</td>
<td>Lot: 10/25/18 4819 73967S Exp. 3/24/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
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<tr>
<td>Drugs</td>
<td>single use syringe, NDC: 42852-739-67 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lot: 11/01/18 8847 80261S Exp. 3/31/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
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<tr>
<td>Drugs</td>
<td>Phenylephrine HCl, 1 mg in Sterile Water for Injection, QS 10 mL Injectable Solution 1 mg/10 mL (100 mcg per mL) NDC: 42852-802-61 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lots: 10/19/18 2117 24163M Exp. 3/18/2019; 11/5/18 1363 24163M Exp. 4/4/2019; 11/5/18 1511 24163M Exp. 4/4/2019; 10/19/18 2061 24163M Exp. 3/18/2019; 10/23/18 1963 14163M Exp. 3/22/2019; 10/19/18 1441 24163M Exp. 3/18/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
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<tr>
<td>Drugs</td>
<td>Morphine Sulfate 30 mg/30 mL (1 mg/mL) Injectable Solution Morphine Sulfate 30 mg 0.9% Sodium Chloride QS 30 mL Sterile singe use syringe, NDC: 42852-241-63 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lots: 10/05/18 7020 88261S, exp 4/4/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Phenylephrine HCl, 1,200 mcg in 0.9% Sodium Chloride, QS 10 mL Injectable Solution 1,200 mcg/10 mL (120 mcg per mL), Sterile single use syringe, NDC: 42852-882-61 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404</td>
<td>Class II</td>
<td>Lot: 11/05/18 7020 88261S, exp 4/4/2019</td>
<td>Lack of Assurance of Sterility</td>
<td>Advanced Pharma Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Gel Hand Sanitizer (Ethyl Alcohol 70%), packaged in a) 37 mL (1.25 fl oz) bottles (NDC 47593-487-</td>
<td>Class II</td>
<td>Lot #: a) HS091281, Exp. AUG 2020, b) HS091781, Exp.</td>
<td>Chemical Contamination: low levels of various</td>
<td>Ecolab Inc</td>
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<td>Product Type</td>
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<tr>
<td>Drugs</td>
<td>Advanced Gel Hand Sanitizer (Ethyl alcohol 62%), packaged in a) 37 mL (1.25 fl oz) bottles (NDC 47593-488-49) and b) 540 mL (18 fl oz) bottles (NDC 47593-488-31) Ecolab, 370 Wabasha Street N, St. Paul, MN 55102.</td>
<td>Class II</td>
<td>Lot #: a) HS092781, Exp. SEP 2020; b) HS091381, HS091781, and HS091881, Exp. SEP 2020</td>
<td>Chemical Contamination: low levels of various substituted benzene (aromatic) compounds identified in the product after complaints of malodor.</td>
<td>Ecolab Inc</td>
</tr>
<tr>
<td>Drugs</td>
<td>Moisturizing Gel Hand Sanitizer (Ethyl Alcohol 62%), 118 mL (4 fl oz) bottles, Ecolab, 370 Wabasha Street N, St. Paul, MN 55102. NDC 47593-489-33</td>
<td>Class II</td>
<td>Lot #: HS092781, Exp. SEP 2020</td>
<td>Chemical Contamination: low levels of various substituted benzene (aromatic) compounds identified in the product after complaints of malodor.</td>
<td>Ecolab Inc</td>
</tr>
<tr>
<td>Drugs</td>
<td>Quick-Care Foam Hand Sanitizer (Ethyl alcohol 62%), 45 mL (1.5 fl oz) bottles, Ecolab, 370 Wabasha Street N, St. Paul, MN 55102. NDC 47593-491-85</td>
<td>Class II</td>
<td>Lot #: HS103181, Exp. OCT 2020</td>
<td>Chemical Contamination: low levels of various substituted benzene (aromatic) compounds identified in the product after complaints of malodor.</td>
<td>Ecolab Inc</td>
</tr>
<tr>
<td>Drugs</td>
<td>Express Gel Hand Sanitizer</td>
<td>Class II</td>
<td>Lot #: HS092681,</td>
<td>Chemical</td>
<td>Ecolab Inc</td>
</tr>
<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
<td>Recalling Firm</td>
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<tr>
<td>Drugs</td>
<td>(Ethyl Alcohol 70%), 37 mL (1.25 fl oz) bottles, Ecolab, 370 Wabasha Street N, St. Paul, MN 55102. NDC 47593-502-49</td>
<td></td>
<td>Exp. SEP 2020</td>
<td>Contamination: low levels of various substituted benzene (aromatic) compounds identified in the product after complaints of malodor.</td>
<td></td>
</tr>
<tr>
<td>Drugs</td>
<td>Fayosim (levonorgestrel and ethinyl estradiol) tablets USP, (0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg) and ethinyl estradiol tablets USP, (0.01 mg), packaged in 1 Extended-Cycle Wallet of 91 Tablets packed in a pouch(NDC 68180-860-11); one pouch per carton (NDC 68180-860-12), Rx only, Distributed by: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202; Manufactured by: Lupin Limited, Pithampur (M.P.) - 454775, INDIA.</td>
<td>Class II</td>
<td>Lot #: L800016, Exp 12/2019; L800721, Exp 05/2020</td>
<td>Failed Impurities/Degradation Specifications: Out-of-specification results observed in related substance test (Any Other Individual Impurity and Total impurities) in Ethinyl Estradiol Tablets USP 0.01mg at 12 month long term stability study.</td>
<td>Lupin Pharmaceuticals Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Combigan (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5% 5 mL bottles, Rx only, Allergan, Inc. Irvine, CA 92612 U.S.A. NDC 0023-9211-05</td>
<td>Class II</td>
<td>Lot# : 99946 Exp. January 16, 2021</td>
<td>cGMP Deviations</td>
<td>Allergan Sales, LLC</td>
</tr>
<tr>
<td>Drugs</td>
<td>Morphine Sulfate USP Milled, Active Pharmaceutical Ingredient, Rx only, Johnson Matthey Pharmaceutical Materials, 2003 Nolte Drive, West Deptford, NJ 08066-1742</td>
<td>Class II</td>
<td>Lot# B1414-160809, Retest Date AUG 2021</td>
<td>Microbial Contamination of Non-Sterile Products: Bioburden out of specification results for Morphine Sulfate API.</td>
<td>Johnson Matthey Inc.</td>
</tr>
<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
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<td>Drugs</td>
<td>Cefuroxime 10mg/mL INJ 0.5 mg, SDV, Rx only, Pacific Compounding, Stockton, CA</td>
<td>Class II</td>
<td>Lot # 07232018@15 BUD 9/6/18 (frozen)</td>
<td>Presence of Particulate Matter: Particulate matter was reported in one lot of Cefuroxime by a physician after use of product. FDA analysis identified the particulate as coring of the rubber stopper</td>
<td>Pacific Compounding Pharmacy &amp; Consultations Inc</td>
</tr>
<tr>
<td>Drugs</td>
<td>Losartan Potassium Tablets, USP, 50 mg, 30 tablet bottles, Rx Only, Distributed by: The Kroger Co, Cincinnati, OH 45202, Manufactured for: Torrent Pharma Inc., 150 Allen Road, Suite 102, Basking Ridge, NJ 07920, Packaged by: Legacy Pharmaceutical Packaging LLC, Earth City, MO 63045 NDC 68645-494-54</td>
<td>Class II</td>
<td>Lots: 180190, 180191 (exp 10/2020) and 181597 (exp 02/2021)</td>
<td>CGMP Deviations: presence of an impurity, N-Methylnitrosobutyric acid (NMBA) detected.</td>
<td>Legacy Pharmaceutical Packaging LLC</td>
</tr>
<tr>
<td>Drugs</td>
<td>Pantoprazole Sodium Delayed-Release Tablets, USP, 40 mg*, 90-count bottle, Rx Only, Manufactured by: Jubilant Generics Ltd., Roorkee - 247661, India; Marketed by: Jubilant Cadista Pharmaceuticals Inc., Salisbury, MD 21801; NDC 59746-284-90.</td>
<td>Class II</td>
<td>Lot #: PA217060A, Exp 05/2020</td>
<td>Discoloration: Expansion of earlier recall due to the presence of dark brown discoloration on the edges of the tablets.</td>
<td>Jubilant Cadista Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Indian Herb Paste (a dietary supplement) Ingredients: Galangal, Indian Paint, Yellow Dock &amp; Licorice in an alloy of Life-Line tm and Zinc Chloride in 6 dram vials,</td>
<td>Class II</td>
<td>All lots within expiry</td>
<td>Unapproved new drug</td>
<td>McDaniel Life-Line LLC</td>
</tr>
<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
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<tr>
<td>Drugs</td>
<td>Life-Line tm Catalytic Activated Energy Water, 1 gallon container, McDaniel Life-Line LLC 1775 US Hwy 385 806-647-1741 Dimmitt, TX 79027</td>
<td>Class II</td>
<td>All lots within expiry.</td>
<td>Unapproved new drug</td>
<td>McDaniel Life-Line LLC</td>
</tr>
<tr>
<td>Drugs</td>
<td>SODIUM CHLORIDE PRES-FREE 5% OPTH STERILE* SOLUTION. 20ml eye drops, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330</td>
<td>Class II</td>
<td>Lot: 12022019@30, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>DEXAMETHASONE (NAPO4) 0.1% OPTH* PRES-FREE SOLUTION, 10ml, Eye Drops, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330</td>
<td>Class II</td>
<td>Lots: 23012019@48, 24012019@2, 24012019@36, 28012019@35, 29012019@13, 05022019@5, 11022019@13, 12022019@20, 19022019@1, 19022019@6, 19022019@57, 19022019@61, All lots within expiry distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>ACETYL-L-CYSTEINE 10% P.F. OPTH SOLUTION, 10ml, eye drops, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330</td>
<td>Class II</td>
<td>Lots: 17012019@13, 30012019@36, 01022019@4, 14022019@1, 19022019@18, 19022019@60, distributed</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<tr>
<td>Product Type</td>
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<tr>
<td>Drugs</td>
<td>HYDROXYPROGESTERONE CAPROATE 250 MG/ML OIL* INJECTABLE, (a) 10ml (b) 9ml injectable, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330</td>
<td>Class II</td>
<td>between 09-01-2018 to 02-20-2019.</td>
<td>during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>PAPAVERINE-PHENTOLAMINE-PGE1 22-0.8 MG-8 MCG/ML* INJECTABLE, (a) 5ml (b) 10ml, (c) 6ml, penile injection, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330</td>
<td>Class II</td>
<td>Lot: (a) 18092018@52, 01102018@9, 05102018@36, 08102018@11, 102018@9, 01102018@9, 01102018@9, 03102018@27, 12102018@18, 01102018@9, 12102018@18, 12102018@18, 17102018@15, 12102018@18, 2102018@18, 22102018@31, 30102018@22, 29102018@9,29102018@9, 29102018@9, 12102018@18, 21112018@38, 21112018@38, 21112018@38, 21112018@38, 21112018@38, 21112018@38, 21112018@38, 21112018@38, 11122018@7, 11122018@7, 28122018@11, 28122018@11,</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<td>Product Type</td>
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<td>Drugs</td>
<td>PGE1 40 MCG/ML* INJECTABLE, (2) 5ml (b) 10ml, (c) 6ml (d) 9ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330.</td>
<td>Class II</td>
<td>28122018@11, 03012019@17, 03012019@17, 03012019@17, 08012019@21, 08012019@21, 28018@16, 28082018@16, 28082018@16, 14092018@28, 14092018@28, 14092018@28, 18092018@52, 18092018@52, 18092018@52, 18092018@52, (b) 29102018@9, 03012019@17, 14092018@28, (c) 11012019@64, 11012019@64, 11012019@64, 05022019@27, 5022019@27, 06022019@6, 06022019@6, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>PAPAVERINE-PHENTOLAMINE 30-1 MG/ML* INJECTABLE, (a)10ml (b) 9ml, penile</td>
<td>Class II</td>
<td>Lot: (a) 10102018@30, (b) 31102018@33,051 12018@1, (c)15012019@8, (d) 30012019@33, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary</td>
<td>Health Solutions Pharmacy Center Inc</td>
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<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
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<tr>
<td>Drugs</td>
<td>PAPAVERINE-</td>
<td>Class II</td>
<td>Lot: (a)</td>
<td>Lack of</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<tr>
<td></td>
<td>PHENTOLAMINE-PGE1</td>
<td></td>
<td>03102018@27, 07112018@18, 08112018@11, 16112018@15, 28112018@7, 14122018@37, 1612018@41, 03012019@9, 2012019@32, 23012019@59, 07022019@19, 07022019@1, 19122018@25, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
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<td>30-1 MG-10 MCG/ML*</td>
<td></td>
<td>(b) 2012019@37, 22012019@31, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lot (a) 17102018@15, 14112018@3, 04122018@21, 14122018@15, 7122018@11, 28122018@69, 20092018@2, (b) 21012019@37, 22012019@31, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
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<td></td>
<td>INJECTABLE, (a) 5ml, (b) 6ml, (c) 9ml (d) 10ml</td>
<td></td>
<td>30102018@22, 15112018@5, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lot 30102018@22, 15112018@5, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs</td>
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<td>Professional</td>
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<td>Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330</td>
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<td>Drugs</td>
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<td>PAPAVERINE-</td>
<td>Class II</td>
<td>Lot: (a)</td>
<td>Lack of</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<td>PHENTOLAMINE-PGE1</td>
<td></td>
<td>03102018@27, 07112018@18, 08112018@11, 16112018@15, 28112018@7, 14122018@37, 1612018@41, 03012019@9, 2012019@32, 23012019@59, 07022019@19, 07022019@1, 19122018@25, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
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<td></td>
<td>12-1MG-10MCG/ML*</td>
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<td>(b) 2012019@37, 22012019@31, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lot (a) 17102018@15, 14112018@3, 04122018@21, 14122018@15, 7122018@11, 28122018@69, 20092018@2, (b) 21012019@37, 22012019@31, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
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<td></td>
<td>INJECTABLE, (a) 10ml, (b) 9ml</td>
<td></td>
<td>30102018@22, 15112018@5, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lot 30102018@22, 15112018@5, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs</td>
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<td>Professional</td>
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<td>Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330</td>
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<td>Drugs</td>
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<td>PAPAVERINE-</td>
<td>Class II</td>
<td>Lot: (a)</td>
<td>Lack of</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<td></td>
<td>PHENTOLAMINE-PGE1</td>
<td></td>
<td>03102018@27, 07112018@18, 08112018@11, 16112018@15, 28112018@7, 14122018@37, 1612018@41, 03012019@9, 2012019@32, 23012019@59, 07022019@19, 07022019@1, 19122018@25, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
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<tr>
<td></td>
<td>17.16-0.57MG-19.45MCG/ML*</td>
<td></td>
<td>(b) 2012019@37, 22012019@31, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lot (a) 17102018@15, 14112018@3, 04122018@21, 14122018@15, 7122018@11, 28122018@69, 20092018@2, (b) 21012019@37, 22012019@31, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
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<tr>
<td></td>
<td>INJECTABLE, 5ml,</td>
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<td>30102018@22, 15112018@5, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lot 30102018@22, 15112018@5, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs</td>
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<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
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<tr>
<td>Drugs</td>
<td>PAPAVERINE-PHENTOLAMINE-PGE1 23-0.96MG-19.2MCG/ML INJECTABLE, (a) 5ml, (b) 6.5ml,</td>
<td>Class II</td>
<td>Lot: (a) 22102018@31, (b) 09112018@33, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<tr>
<td></td>
<td>Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330</td>
<td></td>
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<td>recent FDA Inspection.</td>
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<tr>
<td>Drugs</td>
<td>PAPAVERINE-PHENTOLAMINE-PGE1 30-1.6 MG-16 MCG/ML* INJECTABLE, (a) 5ml, (b) 10ml,</td>
<td>Class II</td>
<td>Lot: 05102018@36, 27112018@49, (b) 28112018@54, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<tr>
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<td>Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330</td>
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<td>recent FDA Inspection.</td>
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</tr>
<tr>
<td>Drugs</td>
<td>PGE1-LIDOCAINE 40 MCG-1%/ML* INJECTABLE, (a) 10 ml (b) 9ml, Professional Compounding</td>
<td>Class II</td>
<td>Lot:(a) 26092018@22, 26092018@22, 09102018@47, 15102018@33, 15102018@33,</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<tr>
<td></td>
<td>Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330</td>
<td></td>
<td></td>
<td>recent FDA Inspection.</td>
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<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
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<tr>
<td>Drugs</td>
<td>PAPAVERINE-</td>
<td>Class II</td>
<td>Lot:15012019@10, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<tr>
<td></td>
<td>PHENTOLAMINE 15-0.5MG/MG/ML INJECTABLE, 9ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330.</td>
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<tr>
<td>Drugs</td>
<td>PAPAVERINE-</td>
<td>Class II</td>
<td>Lot:19022019@21, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
</tr>
<tr>
<td></td>
<td>PHENTOLAMINE 30-0.5 MG/ML INJECTABLE, 9ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330.</td>
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<tr>
<td>Drugs</td>
<td>PAPAVERINE-</td>
<td>Class II</td>
<td>Lot:15112018@40, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<tr>
<td></td>
<td>PHENTOLAMINE-PGE1 30-2 MG-30 MCG/ML* INJECTABLE, 5ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330.</td>
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<td>Drugs</td>
<td>PAPAVERINE-</td>
<td>Class II</td>
<td>Lot:17012019@27, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<td></td>
<td>PHENTOLAMINE-PGE1 15-0.5MG-10MCG/ML INJECTABLE, 9ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330.</td>
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<tr>
<td>Drugs</td>
<td>PAPAVERINE-</td>
<td>Class II</td>
<td>Lot:09112018@55, 09012019@37,</td>
<td>Lack of Processing</td>
<td>Health Solutions</td>
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<td></td>
<td>PHENTOLAMINE-PGE1</td>
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<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
<td>Recalling Firm</td>
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<tr>
<td>Drugs</td>
<td>PAPAVERINE-PHENOTOLAMINE-PGE1 16.6-0.55 MG-11.1 MCG/ML* INJECTABLE, 10 ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330.</td>
<td>Class II</td>
<td>distributed between 09-01-2018 to 02-20-2019.</td>
<td>Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>PAPAVERINE-PHENOTOLAMINE-PGE1 17.64-0.58MG-5.88MCG/ML* INJECTABLE, 9 ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330.</td>
<td>Class II</td>
<td>Lot:17012019@18, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>PAPAVERINE-PHENOTOLAMINE-PGE1 22.5-0.8MG-8.3MCG/ML INJECTABLE, 5 ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330.</td>
<td>Class II</td>
<td>Lot:26112018@68, 13122018@12, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>PAPAVERINE-PHENOTOLAMINE-PGE1 9-1 MG-10 MCG/ML* INJECTABLE, 18 ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330.</td>
<td>Class II</td>
<td>Lot:12022019@23, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>PAPAVERINE-PHENOTOLAMINE-PGE1 30-1 MG-20 MCG/ML* INJECTABLE, 5 ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330.</td>
<td>Class II</td>
<td>Lot:20092018@41, 25092018@7, 27092018@3, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<td>Product Type</td>
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<tr>
<td>Drugs</td>
<td>PAPAVERINE-</td>
<td>Class II</td>
<td>Lot:06092018@57, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>PHENTOLAMINE-PGE1</td>
<td></td>
<td>Lot:10092018@1, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>PHENTOLAMINE-PGE1</td>
<td></td>
<td>Lot:13092018@44, distributed between 09-01-2018 to 02-20-2019.</td>
<td>Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.</td>
<td>Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy</td>
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<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
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<td>Drugs</td>
<td>Pravastatin Sodium Tablets USP, 20 mg, 500-count bottle, Rx Only,</td>
<td>Class II</td>
<td>Lot 17181491 Exp. Aug. 2021</td>
<td>Presence Of Foreign Tablet: in a bottle of Pravastatin Sodium Tablets 20 mg.</td>
<td>Glenmark Pharmaceuticals Inc., USA</td>
</tr>
<tr>
<td></td>
<td>Manufactured by: Glenmark Pharmaceuticals Ltd. Plot No. 2, Phase-2, Pharma zone SEZ,</td>
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<td>Pithampur, Dist-Dhar, Madhya Pradesh 454 775, India.</td>
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<td>Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430.</td>
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<tr>
<td>Drugs</td>
<td>Losartan 50mg Tablet, 30 count each blister card.</td>
<td>Class II</td>
<td>70518-0588-01, Lot #: J0328416-101518, Exp. 10/2019</td>
<td>CGMP Deviations; Detection of trace amounts of an unexpected impurity found in an active pharmaceutical</td>
<td>Remedy Repack Inc.</td>
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<td>ingredient (API) - N-MethylNitrosobutyric acid (NMBA).</td>
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<tr>
<td>Drugs</td>
<td>Bismuth Subsalicylate Oral Suspension 262mg/15mL, unit dose cups, OTC, Rpkg.</td>
<td>Class II</td>
<td>Lot#: M030042P, Exp. 01/2020</td>
<td>Labeling: Incorrect or Missing Lot and/or Exp Date - the label contains an incorrect Exp Date.</td>
<td>Lohxa LLC</td>
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<td>By.: Lohxa Worcester, MA, NDC 70166-059-01</td>
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<td>Drugs</td>
<td>Phenobarbital Oral Solution, USP 20 mg/5mL,</td>
<td>Class II</td>
<td>Lot# M12031, Exp. 12/2019; T01241</td>
<td>Labeling: Incorrect or</td>
<td>Lohxa LLC</td>
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<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
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<tr>
<td>Drugs</td>
<td>unit dose cup, Rx Only, Rpkg. By. Lohxa Worcester, MA 01608, NDC 70166-536-02</td>
<td>Exp. 02/2020</td>
<td>Missing Lot and/or Exp Date - the label contains an incorrect Exp Date.</td>
<td>H J Harkins Company Inc dba Pharma Pac</td>
<td></td>
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<tr>
<td>Drugs</td>
<td>Losartan Potassium 100 mg Tablets # 30 Losartan potassium tablets USP, 100 mg are white to off white, film coated, tear drop shaped tablets, debossed with &quot;H&quot; on one side and &quot;145&quot; on the other side.</td>
<td>Class II</td>
<td>Pharma Pac NDC: 76519-1033-03, Pharma Pac Lot # LTO000EW, Exp. 11/19, MFG NDC 31722-0702-30, MFG Lot # LOP17087, Exp. 11/2019.</td>
<td>CGMP Deviations: Traces amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) impurity found in Active Pharmaceutical Ingredient (API).</td>
<td></td>
</tr>
<tr>
<td>Drugs</td>
<td>LOSARTAN POTASSIUM TABLETS, USP, 25 mg, a) 90-count (NDC: 13668-113-90), b) 1000-count (NDC: 13668-113-10), per bottle, Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana India. For: Torrent Pharma, Inc, 150 Allen Road, Suite 102, Basking Ridge, NJ</td>
<td>Class II</td>
<td>Count, lots, expiry: [90-count bottle] Lots 4DU1E005, 4DU1E006, 4DU1E008, exp 1/31/2021; Lots 4DU1E007, exp 1/31/2021</td>
<td>CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.</td>
<td>Torrent Pharma Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>LOSARTAN POTASSIUM TABLETS, USP, 50 mg, a) 30-count (NDC: 13668-409-30), b) 90-count (NDC: 13668-409-90), c) 1000-count (NDC: 13668-409-10), per bottle, Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana India. For: Torrent Pharma, Inc, 150 Allen Road, Suite 102, Basking Ridge, NJ</td>
<td>Class II</td>
<td>Count, lots, expiry: [30-count bottle] Lot 4DU2D077, exp 10/31/2020; [90-count bottle] Lot 4DU2D087, exp 10/31/2020; Lots 4DU2E023, 4DU2E024, 4DU2E026, 4DU2E027, 4DU2E028, 4DU2E029, 4DU2E020, exp 10/31/2020</td>
<td>CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.</td>
<td>Torrent Pharma Inc.</td>
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<tr>
<td>Product Type</td>
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<td>Code Info</td>
<td>Reason for Recall</td>
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<td>1/31/2021; Lots 4O50E007, 4O50E008, exp 8/31/2021; [1000 count bottle] Lots 4DU2D067, 4DU2D069, 4DU2D063, 4DU2D064, 4DU2D065, 4DU2D066, exp 9/30/2020; Lots 4DU2D084, 4DU2D085, 4DU2D083, 4DU2D082, 4DU2D072, 4DU2D077, 4DU2D078, 4DU2D079, 4DU2D081, 4DU2D080, 4DU2D070, 4DU2D073, 4DU2D074, 4DU2D075, 4DU2D086, 4DU2D088, 4DU2D089, exp 10/31/2020; Lots 4DU2E019, 4DU2E021, 4DU2E022, 4DU2E025, exp 1/31/2021; Lots 4DU2E032, 4DU2E033, 4DU2E034, 4DU2E035, 4DU2E036, 4DU2E037, 4DU2E038, 4DU2E039, 4DU2E041, exp 2/28/2021; Lots 4DU2E103,</td>
<td></td>
<td>million.</td>
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<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
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<tr>
<td>Drugs</td>
<td>LOSARTAN POTASSIUM TABLETS, USP, 100 mg, a) 90-count (NDC: 13668-115-90), b) 1000-count (NDC: 13668-115-10), per bottle, Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana India. For: Torrent Pharma, Inc, 150 Allen Road, Suite 102, Basking Ridge, NJ</td>
<td>Class II</td>
<td>4DU2E101, 4DU2E102, exp 6/30/2021</td>
<td>CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.</td>
<td>Torrent Pharma Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Losartan Potassium / Hydrochlorothiazide Tablets, USP 50mg/12.5mg, a) 30-count (NDC: 13668-116-30), b) 90-count (NDC: 13668-116-90), c) 1000-count (NDC: 13668-116-10) per bottle, Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana India. For: Torrent Pharma, Inc, 150 Allen Road, Suite 102, Basking Ridge, NJ</td>
<td>Class II</td>
<td>Count, lots, expiry: [30-count bottle] Lot BEF7D017, exp 6/30/2020 [90-count bottle] Lots BEF7D010, BEF7D011, exp 4/30/2020; Lot BEF7D018, exp 6/30/2020; Lot BEF7D009, exp 4/30/2020; Lots 4P02E002, 4P02E003, 4P02E004, exp 1/31/2021; [1000-count bottle] Lots BEF7D008, BEF7D012, BEF7D013, exp 4/30/2020; Lot BEF7D022, exp 8/31/2020; Lot BEF7D049, exp 11/30/2020; Lots 4P02E005, 4P02E006, exp 1/31/2021</td>
<td>CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.</td>
<td>Torrent Pharma Inc.</td>
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<td>Product Type</td>
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<tr>
<td>Drugs</td>
<td>Losartan Potassium / Hydrochlorothiazide Tablets, USP 100mg/12.5mg, a) 30-count (NDC: 13668-117-30), b) 90-count (NDC: 13668-117-90) per bottle, Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana India. For: Torrent Pharma, Inc, 150 Allen Road, Suite 102, Basking Ridge, NJ</td>
<td>Class II</td>
<td>Count, lots, expiry: [30-count bottle] Lot BEF8D058, exp 11/30/2020 [90-count bottle] Lots BEF8D009, BEF8D010, BEF8D011, BEF8D012, BEF8D013, BEF8D007, BEF8D008, exp 3/31/2020; Lots BEF8D023, BEF8D024, BEF8D025, BEF8D020, BEF8D021, BEF8D022, exp 4/30/2020; Lots BEF8D054, BEF8D055, BEF8D056, exp 10/31/2020; Lots BEF8D057, exp 11/30/2020</td>
<td>CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.</td>
<td>Torrent Pharma Inc.</td>
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<tr>
<td>Product Type</td>
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<td>Drugs</td>
<td>15% MSM, Eye Drops, Net Wt. 30ml, 1.014 oz., Manufactured by: MSM Nutraceuticals, LLC 2103 West Parkside Lane, Ste.107, Phoenix, AZ 85027, UPC 8 54582 00120 3.</td>
<td>Class II</td>
<td>10/31/2020; Lots 4P04E003, 4P04E004, 4P04E005, 4P04E006, exp 1/31/2021; [1000-count bottle] 4P04E007, 4P04E008, 4P04E009, exp 1/31/2021</td>
<td>Lack of Assurance of Sterility: Product is not terminally sterilized and not tested per USP 71.</td>
<td>MSM Nutraceuticals, LLC</td>
</tr>
<tr>
<td>Drugs</td>
<td>Dry Eye, Eye Drops, Active Ingredients: OptiMSM, Glycerin USP, Hylauronic Acid, Polyethylene Glycon, Net Wt. 15ml, 0.51 fl oz., Manufactured by: MSM Nutraceuticals, LLC, UPC 8 54582 00119 7.</td>
<td>Class II</td>
<td>Lot # 1808051, Exp. Date 01/01/22</td>
<td>Lack of Assurance of Sterility: Product is not terminally sterilized and not tested per USP 71.</td>
<td>MSM Nutraceuticals, LLC</td>
</tr>
<tr>
<td>Drugs</td>
<td>Red Eye, Eye Drops, Active Ingredients: OptiMSM, Glycerin USP, Hylauronic Acid, Naphazolene Chloride, Net Wt. 15ml, 0.15 fl oz., Manufactured by: MSM Nutraceuticals, LLC, UPC 8 54582 00118 0</td>
<td>Class II</td>
<td>Lot # 1808051, Exp. Date 01/01/22</td>
<td>Lack of Assurance of Sterility: Product is not terminally sterilized and not tested per USP 71.</td>
<td>MSM Nutraceuticals, LLC</td>
</tr>
<tr>
<td>Drugs</td>
<td>Dr. Berne's MSM DROPS 15% Solution, Net Wt. 30ml/1.014 OZ, Distributed by: Dr. Berne's Whole Health Products, 400 Hillsboro Technology Drive, Deerfield Beach, FL 33441 SKU182 UPC 00854582001036</td>
<td>Class II</td>
<td>Lot # 1808051, Exp. Date 01/01/22</td>
<td>Lack of Assurance of Sterility: Product is not terminally sterilized and not tested per USP 71.</td>
<td>MSM Nutraceuticals, LLC</td>
</tr>
<tr>
<td>Drugs</td>
<td>Testosterone Cypionate</td>
<td>Class II</td>
<td>Lot #: GH80159,</td>
<td>Presence of InvaGen</td>
<td>InvaGen</td>
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<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
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<tr>
<td>Drugs</td>
<td>Testosterone Cypionate Injection, USP, 1000 mg/10 mL (100 mg/mL), For intramuscular use only, 10 mL Vial, Multiple-Dose, Rx Only, Manufactured by: Cipla Ltd., Verna Goa, India, Manufactured for: Cipla USA, Inc., 1560 Sawgrass Corporate Parkway, Suite 130, Sunrise, Fl 33323, NDC 69097-536-37.</td>
<td>Class II</td>
<td>Lots #: GH80216 Exp 1/2020; GH80322, GH80323 Exp 2/2020; GH90072 Exp 12/2020.</td>
<td>Presence of Particulate Matter.</td>
<td>InvaGen Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Acetylcysteine 10% Ophthalmic Eye Drop 2 mL droptainer, Anderson Compounding Pharmacy 310 Bluff City Hwy Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
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<tr>
<td>Drugs</td>
<td>Atropine 0.01% Eye Drops, 1 mL and 2 mL Dropper, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>Amphotericin B 0.15% Eye Drops, 2 mL Droppers, Anderson Compounding Pharmacy 310 Bluff City Hwy Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>Vancomycin 125 mg/3mL Inhalation, 3 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>Dexamethasone 24 mg/mL Injection, 10 mL Vial, Anderson Compounding Pharmacy, 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>DMSO 50% 60 mL/Heparin 1 mL/ Sodium Bicarbonate 60 mL/ Solu-Cortef 100 mg, 41 mL syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Estradiol Cypionate 10 mg/mL, 5 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Gentamicin 120 mg/250 mL 0.9% Sodium Chloride for Irrigation, 30 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
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<td>Drugs</td>
<td>Gentamicin 250 mg/1000 mL Irrigation, 1000 mL, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>HCG 1,000 U/mL Injection, 30 mL, Vial Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>HCG 11,000 Units, 30 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<td>Drugs</td>
<td>HCG 20 Day Injection, 2625 Units/4 mL, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<td>Drugs</td>
<td>HCG 23 Day, 2876 Units/4.6 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>HCG 30 Day, 3750 Units/6 mL, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN 1-800-263-8890</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>HCG 20 Day Extra Strength, 3500 Units/4 mL, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>HCG 20,000 units/vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>HCG 23 Day Injection Extra Strength, vials, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<td>Drugs</td>
<td>HCG 4,100 Units/vial Injection, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>HCG 40 Day Injection Extra Strength, vials, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Heparin 20,000 U/Lidocaine 2% 10 mL/Sodium Bicarbonate 8.4% 10 mL/Sterile Water 5 mL, 27 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Heparin 10 mL/ Marcain 0.25% 20 mL/Sodium Bicarbonate 8.4%-40 mL/Normal Saline 5 mL, 60 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Heparin 10,000 U/Bupivacaine 0.5% 10 mL, Sodium Bicarbonate 8.4% 50 mL, 61 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Heparin 10 mL/Marcain 0.25% 20 mL/Sodium Bicarbonate 8.4%-40 mL/per 70 mL, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Heparin 2 mL/Lidocaine 2%-10 mL/Sodium Bicarbonate 8.4%-5mL/ Sterile Water 10 mL, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Methionine 15mg/Choline 100mg/ Inositol 50mg/ Methylcobalamin 1mg/ Lidocaine 10 mg, benzyl alcohol/ water, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<td>Drugs</td>
<td>Methylcobalamin 1 mg/mL Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<td>Drugs</td>
<td>Methylprednisolone 1% PF Ophthalmic, 3 mL Droppers, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<td>Drugs</td>
<td>Morphine Sulfate 5 mg/3mL Inhalation, 3 mL Vials, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<td>Drugs</td>
<td>Penicillin G 100,000/mL 10 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Phenylephrine 1 mg/mL Injection, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Polyhexamethylene Biguanide 0.02% Ophthalmic Drops, 2 mL Dropper, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Prostaglandin 20 mcg/mL, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Prostaglandin 40 mcg/mL, Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Prostaglandin 60 mcg/mL, Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Prostaglandin Quad-Mix 20:30:1:0.15 Injection, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Prostaglandin Quad with Atropine 10:30:1:0.15, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Prostaglandin Tri-Mix 20:30:1, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<td>Drugs</td>
<td>Prostaglandin Tri-Mix 50:30:1, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<td>Drugs</td>
<td>Sermorelin 0.3 mg/0.5 mL, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Sermorelin 0.4 mg/0.5 mL, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Serum Tears 20% Drops, 1 mL Droptainer, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Serum Tears 30% Drops, 1 mL Droptainer, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Streptomyacin 24 mg/Dexamethasone 10 mg/mL Otic Injection, 1 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Bacitracin 3000U/30 mL Irrigation, 30 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy</td>
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<td>Drugs</td>
<td>Testosterone Cypionate 250 mg/mL Sterile Injection, 5 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Vitamin D3 200,000 IU/mL Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Methylcobalamin 3000 mcg/mL Injection Solution, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Serum Tears 50% Ophthalmic Drops, 1 mL Dropper, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Interferon 1 Million IU/mL Eye Drops, 1 mL Droptainer, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Prostaglandin Tri-Mix 60:30:1 Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Neomycin 40 mg/Polymixin B 200,000 Bladder Irrigation Solution, 1000 mL bottle, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<td>Drugs</td>
<td>Lidocaine 1%/Dextrose 12.5% (PF) Injection, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>EDTA 1% Sterile Injection (Preservative Free), Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Sodium Bicarbonate 8.4% Injection, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Heparin 20,000U/Marcaine 0.25%, 10 mL, Sodium Bicarbonate 8.4% 48 mL, 60 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Gentamicin 160 mg/1000 mL Sterile Water for Irrigation,1000 mL Bottle, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<tr>
<td>Drugs</td>
<td>Gentamicin 240 mg/500 mL Sterile Water for Irrigation, 60 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>Heparin 10 mL/Marcaine 0.25% 20 mL/Sodium Bicarbonate 40 mL/Normal Saline 5 mL per 75 mL, 60 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>Estrone 5mg/mL Oil Injection, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>HCG 11,000Units/B 12 11,000 mcg Injection, 30 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>Papaverine 30 mg/Phentolamine 0.5 mg/mL, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
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<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
<td>Recalling Firm</td>
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</tr>
<tr>
<td>Drugs</td>
<td>Papaverine 30 mg/mL Injection, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>Phenol 10% Injection, 5 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>Prostaglandin Tri-Mix 5:15:0.5 Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>Prostaglandin Tri-Mix 2.5:7.5:0.25 Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>Prostaglandin Tri-Mix 8.33:22.5:0.833 Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Product Type</td>
<td>Product Description</td>
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<td>Code Info</td>
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</tr>
<tr>
<td>Drugs</td>
<td>Prostaglandin Tri-Mix 20:25:1 Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>Prostaglandin Tri-Mix 30:30:1 Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.</td>
<td>Class II</td>
<td>All Lots</td>
<td>Lack of sterility assurance.</td>
<td>Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy</td>
</tr>
<tr>
<td>Drugs</td>
<td>Divalproex Sodium Extended-Release Tablets, USP, a) 100-count bottle (NDC 55111-0533-01), b) 500-count bottle (NDC 55111-0533-05), Rx only, Mfd. By: Dr. Reddy's Laboratories Limited, Bachupally, - 500 090 INDIA</td>
<td>Class II</td>
<td>Lot #: a) C802629, Exp. 03/2020; C805680, Exp. 07/2020, C808821, Exp. 10/2020, b) C806561, Exp. 10/2020</td>
<td>cGMP deviations: Product was exposed above 50% relative humidity levels during packaging operations.</td>
<td>Dr. Reddy's Laboratories, Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Lansoprazole Delayed-Release Orally Disintegrating Tablets, 15 mg, 100 tablets (10 blister cards of 10 tablets each), Rx only, Manufactured in Israel By: Teva Pharmaceutical Ind. Ltd. Jerusalem, 9777402, Israel, Manufactured for: Teva Pharmaceuticals USA, Inc. North Wales, PA 19454, NDC 0093-3008-93</td>
<td>Class III</td>
<td>Lot #: 25Q002, Exp. 11/2019</td>
<td>Subpotent Drug.</td>
<td>Teva Pharmaceuticals USA</td>
</tr>
<tr>
<td>Drugs</td>
<td>Testosterone Topical Solution, 30mg/1.5mL, 110mL bottles, Rx only, Manufactured for: Lupin</td>
<td>Class III</td>
<td>Lot # K700086, Exp 11/2019</td>
<td>Defective Container: Repetitive complaints</td>
<td>Lupin Pharmaceuticals Inc.</td>
</tr>
<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
<td>Recalling Firm</td>
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<tr>
<td>Drugs</td>
<td>Diclofenac Sodium Topical Solution, 1.5% w/w, 5 FL. OZ. (150 mL) bottle, Rx Only, Manufactured for: Ingenus Pharmaceuticals, LLC, Orlando, FL.</td>
<td>Class III</td>
<td>Lot #: 31804, Exp 11/2019; 31911, 31917, Exp 02/2020; 32067, 32072, 32084, Exp 06/2020; 32248, Exp 10/2020</td>
<td>Defective Container: firm discovered samples stored horizontally as well as product quality complaints from customers for bottles leaking.</td>
<td>Ingenus Pharmaceuticals LLC</td>
</tr>
<tr>
<td>Drugs</td>
<td>Cleocin Phosphate (clindamycin injection), USP, 300 mg/2 mL (150 mg/mL), 2 mL-vial, Rx only, Distributed by Pharmacia &amp; Upjohn Co, Division of Pfizer, Inc, New York, NY 10017, NDC 0009-6582-02</td>
<td>Class III</td>
<td>Lot #: T97469, Exp. 7/2019, W28574, Exp.09/2019</td>
<td>Failed Impurities/Degradation Specifications: High out-of-specification (OOS) results were demonstrated for several specified impurities at the 24-month time point.</td>
<td>Pfizer Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Cleocin Phosphate, clindamycin injection, USP, 600 mg/4 mL (150 mg/mL), 4 mL vial, Rx only, Distributed by Pharmacia &amp; Upjohn Co, Division of Pfizer, Inc, New York, NY 10017, NDC 0009-3124-01</td>
<td>Class III</td>
<td>Lot#: T78191, Exp.04/2019, T97494, Exp.07/2019</td>
<td>Failed Impurities/Degradation Specifications: High out-of-specification (OOS) results were demonstrated for several specified impurities at the 24-month time point.</td>
<td>Pfizer Inc.</td>
</tr>
<tr>
<td>Product Type</td>
<td>Product Description</td>
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<tr>
<td>Drugs</td>
<td>Cleocin Phosphate, clindamycin injection, USP, 900 mg/6 mL (150 mg/mL), 6 mL vial, Rx only, Distributed by Pharmacia &amp; Upjohn Co, Division of Pfizer, Inc, New York, NY 10017. NDC 0009-3447-01</td>
<td>Class III</td>
<td>Lot #: T78193, Exp.04/2019</td>
<td>Failed Impurities/Degradation Specifications: High out-of-specification (OOS) results were demonstrated for several specified impurities at the 24-month time point</td>
<td>Pfizer Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Clindamycin Injection, USP, 300 mg/2 mL (150 mg/mL), 2 mL vials, Rx only, Distributed by: Alvogen, Inc., Pine Brook, NJ 07058 USA, NDC 47781-619-94</td>
<td>Class III</td>
<td>Lot: T97472 (exp 07/2019), T97473 (exp 04/2019), W28573 (exp 09/2019), W31814 (exp 10/2019)</td>
<td>Failed Impurities/Degradation Specifications: High out-of-specification (OOS) results were demonstrated for several specified impurities at the 24-month time point</td>
<td>Pfizer Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Clindamycin Injection, USP, 600 mg/4 mL (150 mg/mL), 4 mL vials, Rx only, Distributed by: Alvogen, Inc., Pine Brook, NJ 07058 USA, NDC 47781-620-94</td>
<td>Class III</td>
<td>Lot #: T97496, Exp.04/2019, T97497, Exp.07/2019, W28564 (exp 09/2019), W31812, Exp. 10/2019.</td>
<td>Failed Impurities/Degradation Specifications: High out-of-specification (OOS) results were demonstrated for several specified impurities at the 24-month time point</td>
<td>Pfizer Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Clindamycin Injection, USP, 900 mg/6 mL (150 mg/mL), 6 mL vial, Rx only, Distributed by:</td>
<td>Class III</td>
<td>Lot #: T96398, Exp.07/2019, T97492, Exp.04/2019,</td>
<td>Failed Impurities/Degradation Specifications:</td>
<td>Pfizer Inc.</td>
</tr>
<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
<td>Recalling Firm</td>
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<tr>
<td>Drugs</td>
<td>Biotin 10 mg/mL Injection, 30 mL vial, Rx only, 511 S. Harbor Blvd., Building F, La Habra, CA 90631, 562-352-9630.</td>
<td>Class III</td>
<td>Lot 190205@1, expiry 08/4/19</td>
<td>Failed pH Specification: product does not meet pH label claim.</td>
<td>Auro Pharmacies Inc. DBA Central Drugs</td>
</tr>
<tr>
<td>Drugs</td>
<td>Clonidine HCL Injection, 1000 mcg/10mL (100 mcg/mL), 10 ML Single Dose Vial, Rx only, Manufactured for: X-Gen Pharmaceuticals, Big Flats, NY 14814, NDC 39822-2000-1.</td>
<td>Class III</td>
<td>Lots #: PMXA1917, Exp 09/2020; PMXA1937, PMXA1938, Exp 11/2020;</td>
<td>Labeling: Label Error on Declared Strength: Side carton panel incorrectly lists the concentration as &quot;500 mcg Clonidine Hydrochloride&quot; rather than the correct concentration of &quot;100 mcg Clonidine Hydrochloride&quot; per mL.</td>
<td>X-Gen Pharmaceuticals Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Repairwear Laser Focus Line Smoothing Cream Broad Spectrum SPF 15, packaged in a light green folding carton containing a 50 mL silver jar with a silver cap, Clinique Laboratories, Dist. New York, NY 10022</td>
<td>Class III</td>
<td>Lot #: A68</td>
<td>Defective container: Ineffective seal between the cap and jar of the affected product.</td>
<td>Estee Lauder Inc</td>
</tr>
<tr>
<td>Drugs</td>
<td>Blue Fusion Capsules, 1-count blister pack,</td>
<td>Not Yet Classified</td>
<td>All lots</td>
<td>Marketed Without An</td>
<td>Ata Internatio</td>
</tr>
<tr>
<td>Product Type</td>
<td>Product Description</td>
<td>Classification</td>
<td>Code Info</td>
<td>Reason for Recall</td>
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<tr>
<td>Distributed by: DNS Distribution 5225 Canyon Crest Dr. Ste 71-640, Riverside, CA 92507, UPC 7 48252 66460 0</td>
<td>Reviewed NDA/ANDA: FDA analysis found this product to contain undeclared ingredients: Sildenafil, Tadalafil, desmethyl carbodenafil, dithiodesmethyl carbodenafil, scutellarin, and daidzein.</td>
<td>Approved NDA/ANDA: FDA analysis found this product to contain undeclared ingredients: Sildenafil, Tadalafil, desmethyl carbodenafil, dithiodesmethyl carbodenafil, scutellarin, and daidzein.</td>
<td>Lot #: CLC180117, Exp. June 2021</td>
<td>Presence of Particulate Matter: One vial was found to contain a hair.</td>
<td>Aurobindo Pharma USA Inc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Lidocaine HCl Injection, USP 1 % 50 mg/5 mL (10 mg/mL), 5mL vial, Rx only, Mrd. in India for: AuroMedics Pharma LLC. E Windsor, NJ 08520 NDC 55150-162-05</td>
<td>Not Yet Classified</td>
<td>Lot #: CLC180117, Exp. June 2021</td>
<td>Presence of Particulate Matter: One vial was found to contain a hair.</td>
<td>Aurobindo Pharma USA Inc.</td>
</tr>
</tbody>
</table>

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

Sodium Phosphate Injection
March 22, 2019
Reason for the Shortage
- American Regent is not currently marketing sodium phosphate injection.
- Fresenius Kabi states the reason for the shortage is increased demand.
- Pfizer has sodium phosphate injection on shortage due to manufacturing delay.

Estimated Resupply Dates
- Fresenius Kabi has sodium phosphate 3 mmol/mL 5 mL and 15 mL vials on back order and the company estimates a release date of late-April to early-May 2019.
- Pfizer has sodium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of March 2020.


BCG Live Intravesical
March 22, 2019
Reason for the Shortage
- Because of increased global demand, and as the only source of BCG Live (Intravesical) in the United States and many other countries, Merck anticipates supply constraints for Tice BCG in 2019. To minimize disruption to patient care and address the current imbalance between supply and increased global demand, Tice BCG will be under allocation when demand exceeds production plans and available inventory.

Estimated Resupply Dates
- Merck has Tice BCG on allocation.


Alcohol Dehydrated Injection (Ethanol)
March 22, 2019
Reason for the Shortage
- Akorn states the back order is due to manufacturing delays.
- American Regent is not currently marketing dehydrated alcohol.
- 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.
- BPI has Ablysinol available. It is the only FDA-approved dehydrated alcohol product currently marketed.

Estimated Resupply Dates
- Akorn has dehydrated alcohol 5 mL vials on allocation.

**Thiothixene Capsules**  
**March 25, 2019**  
**Reason for the Shortage**  
- Mylan did not provide a reason for the shortage.  
- Mylan is the sole supplier of thiothixene.

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


**Potassium Acetate Injection**  
**March 25, 2019**  
**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**  
- All marketed presentations are available


**Flumazenil Injection**  
**March 25, 2019**  
**Reason for the Shortage**  
- Baxter did not provide a reason for the shortage.  
- Hikma did not provide a reason for the shortage.  
- Mylan Institutional did not provide a reason for the shortage

**Estimated Resupply Dates**  
- Mylan Institutional has flumazenil 0.1 mg/mL 10 mL vials on back order and the company cannot estimate a release date.


**Diltiazem Hydrochloride Injection**  
**March 25, 2019**  
**Reason for the Shortage**  
- Akorn states the reason for the shortage was increased demand due to market conditions. They are not currently producing the 25 mL vials in 10 count.  
- Pfizer states the reasons for the shortage is manufacturing delays and increases in demand.  
- Hikma has diltiazem injection on shortage due to manufacturing delays caused by increased demand due to current market conditions

**Estimated Resupply Dates**  
- Akorn has diltiazem 5 mg/mL 5 mL, 10 mL, and 25 mL vials on allocation.
- Hikma has diltiazem 5 mg/mL 25 mL vials on allocation.
- Pfizer has 100 mg ADD-Vantage vials on back order and the company estimates a release date of May 2019. The 5 mg/mL 5 mL and 10 mL vials are also on back order and the company estimates a release date of March 2020 for the 5 mL vials and September 2019 for the 10 mL vials.


**Daptomycin Injection**  
**March 25, 2019**  
Reason for the Shortage
- Fresenius Kabi has daptomycin available.
- Mylan Institutional did not provide a reason for the shortage.
- Pfizer has daptomycin on shortage due to manufacturing delays.
- Teva had daptomycin on shortage due to increased demand.
- Merck has Cubicin and Cubicin RF available.
- Xellia Pharmaceuticals has daptomycin available.

Estimated Resupply Dates
- Pfizer has daptomycin 500 mg vials on back order and the company estimates a release date of March 2020.
- Mylan Institutional has daptomycin 500 mg vials on back order and the company estimates a release date of early-April 2019.


**Cefotaxime Sodium Injection**  
**March 25, 2019**  
Reason for the Shortage
- Hospira has discontinued Claforan. Sanofi-Aventis manufactured Claforan for Hospira and is no longer making the product.
- Baxter discontinued Claforan in late-2015.
- Hikma is not currently marketing cefotaxime injection.

Estimated Resupply Dates
- There are no marketed presentations available.


**Ascorbic Acid Injection**  
**March 25, 2019**  
Reason for the Shortage
- Mylan Institutional did not provide a reason for the shortage

Estimated Resupply Dates
- Mylan Institutional has ascorbic acid 500 mg/mL 50 mL vials on back order and the company estimates a release date of late-April 2019.

Amiodarone Injection
March 25, 2019
Reason for the Shortage
- Baxter has Nexterone premixed bags on shortage due to manufacturing delays.
- Mylan Institutional did not provide a reason for the shortage.
- Hikma did not provide a reason for the shortage; however, the 50 mg/mL, 3 mL 10 count presentation was discontinued in December 2018.

Estimated Resupply Dates
- AuroMedics has amiodarone 50 mg/mL 3 mL, 9 mL, and 18 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Baxter has Nexterone 150 mg/100mL and 360 mg/200mL premixed bags on allocation.
- Fresenius Kabi has amiodarone 50 mg/mL 3 mL vials on back order and the company estimates a release date of late-April 2019. There are short-dated 9 mL vials available with an expiration date of <2 months.
- Hikma has amiodarone 50 mg/mL 3 mL vials on allocation.
- Saget has amiodarone 50 mg/mL 3 mL vials on back order and the company cannot estimate a release date.


Aminophylline Injection
March 25, 2019
Reason for the Shortage
- Pfizer has aminophylline injection on shortage due to manufacturing delays.

Estimated Resupply Dates
- Pfizer has aminophylline 25 mg/mL 20 mL vials on back order and the company estimates a release date of September 2019


Sufentanil Injection
March 26, 2019
Reason for the Shortage
- Akorn had Sufenta injection on shortage due to increased demand for the product.
- Hikma stopped marketing sufentanil injection in October 2018.
- Pfizer has sufentanil injection on shortage due to manufacturing delays.

Estimated Resupply Dates
- Pfizer has sufentanil 0.5 mg/mL 2 mL vials on back order and the company estimates a release date of April 2019.

Physostigmine Salicylate Injection  
March 26, 2019  
Reason for the Shortage  
• Akorn did not provide a reason for the shortage. They are the sole suppliers of physostigmine salicylate injection.

Estimated Resupply Dates  
• Akorn has physostigmine salicylate 1 mg/mL 2 mL ampules temporarily unavailable and the company cannot estimate a release date.


Methadone Injection  
March 26, 2019  
Reason for the Shortage  
• Akorn did not provide a reason for the shortage.  
• Mylan Institutional has methadone injection available.

Estimated Resupply Dates  
• Akorn has methadone 10 mg/mL 20 mL vials on allocation.


Cyclosporine Injection  
March 26, 2019  
Reason for the Shortage  
• Novartis has Sandimmune available.  
• Perrigo has cyclosporine injection available


Progesterone Injection  
March 27, 2019  
Reason for the Shortage  
• American Regent is not currently marketing progesterone injection.  
• Fresenius Kabi had progesterone on shortage due to increased demand and manufacturing delays.  
• Hikma did not provide a reason for the shortage.  
• Teva did not provide a reason for the shortage.

Estimated Resupply Dates  
• Hikma has progesterone in oil 50 mg/mL 10 mL vials for intramuscular injection on allocation.  
• Teva has progesterone in oil 50 mg/mL 10 mL vials for intramuscular injection on back order and the company estimates a release date of mid-May 2019.

Valsartan and Hydrochlorothiazide Tablets
March 28, 2019
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 probable human carcinogen. Additional information is available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
- Solco and Teva valsartan/hydrochlorothiazide tablets were affected by the recall. Detailed information on the products is available at https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615703.pdf.
- 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 all valsartan/hydrochlorothiazide presentations on back order and the company cannot estimate a release date.

Prochlorperazine Maleate Tablets
March 28, 2019
Reason for the Shortage
- Cadista has prochlorperazine maleate tablets on shortage due to increased demand.
- Mylan did not provide a reason for the shortage.

Estimated Resupply Dates
- Cadista has prochlorperazine maleate 5 mg and 10 mg tablets on allocation.
- Mylan has prochlorperazine maleate 5 mg and 10 mg tablets in 100 count bottles on back order and the company estimates a release date of late-August 2019.
- Mylan Institutional has prochlorperazine maleate 10 mg tablets in 100 count unit-dose packs on back order and the company estimates a release date of mid-September 2019.

Diclofenac Sodium 1% Topical Gel
March 28, 2019
Reason for the Shortage
- Amneal has diclofenac 1% topical gel available.
- Cipla USA has diclofenac 1% topical gel available.
- Endo did not provide a reason for the shortage.
- Par has diclofenac 1% topical gel available.

Estimated Resupply Dates
- Endo has Voltaren 1% topical gel in 20 gram and 100 gram tubes on back order and the company cannot estimate a release date.
Cefepime Injection
March 28, 2019
Reason for the Shortage
- Apotex has cefepime injection available.
- Baxter has cefepime on allocation due to increased demand.
- BBraun has cefepime on shortage due to manufacturing delays.
- Fresenius Kabi has cefepime injection available.
- Pfizer has Maxipime on shortage due to manufacturing delays.
- Sagent has cefepime injection on shortage due to increased demand.
- Samson Medical Technologies has cefepime injection available.
- Sandoz discontinued cefepime injection in early-2016.
- WG Critical Care has cefepime injection available.

Estimated Resupply Dates
- Baxter has cefepime 2 gram premixed bags on allocation.
- BBraun has cefepime 1 gram and 2 gram premixed bags on allocation.
- Pfizer has Maxipime 1 gram and 2 gram vials and 1 gram and 2 gram ADD-Vantage vials on back order and the company estimates a release date of March 2020.
- Sagent has cefepime 2 gram vials on allocation.


Sodium Acetate Injection
March 29, 2019
Reason for the Shortage
- American Regent is not currently marketing sodium acetate injection.
- Fresenius Kabi has sodium acetate injection available.
- Pfizer has sodium acetate injection available.

Estimated Resupply Dates
- Pfizer has sodium acetate 2 mEq/mL 50 mL vials available in limited supply


Metronidazole Hydrochloride Injection
March 29, 2019
Reason for the Shortage
- Pfizer has metronidazole injection on shortage due to manufacturing delay.
- BBraun has metronidazole injection available.

Estimated Resupply Dates
- Baxter has metronidazole 100 mL bags (NDC 36000-0001-24) on back order and the company cannot estimate a release date.
- Pfizer has metronidazole 100 mL bags in 24 count available in limited supply

Meropenem Injection  
March 29, 2019  
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 discontinued meropenem injection.

Estimated Resupply Dates  
- Amneal has meropenem 500 mg vials on allocation.  
- Pfizer has Merrem 500 mg vials (NDC 00310-0325-20) and 1 gram vials (NDC 00310-0321-30) on back order and the company estimates a release date of March 2020. Pfizer has generic meropenem 500 mg and 1 gram vials on back order and the company estimates a release date of March 2020.

Fentanyl Citrate Injection  
March 29, 2019  
Reason for the Shortage  
- Akorn has fentanyl injection on shortage due to increased demand. They are not currently marketing 25 count fentanyl ampules.  
- 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  
- Pfizer has fentanyl 50 mcg/mL 2 mL vials on back order and the company estimates a release date of April 2019. The 2 mL ampules and 20 mL vials are available in limited supply. The 2 mL Carpuject syringes are on back order and the company estimates a release date of October 2019.

Epinephrine Injection  
March 29, 2019  
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 April 2019.
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

Atropine Sulfate Injection
March 29, 2019
Reason for the Shortage
- American Regent had atropine injection on shortage due to market demand.
- Amphastar has atropine injection available.
- Fresenius Kabi has atropine injection available.
- Hikma has atropine injection available.
- Pfizer has atropine injection on shortage due to manufacturing delays

Estimated Resupply Dates
- Pfizer has atropine 0.1 mg/mL 10 mL LifeShield syringes on back order and the company estimates release dates of April 2019. The 0.1 mg/mL 10 mL Ansyr syringes are on back order and the company estimates a release date of April 2019. The 0.1 mg/mL 5 mL LifeShield syringes are on back order and the company estimates release dates of July 2019. The 0.05 mg/mL 5 mL Ansyr syringes are available with an expiration date of May 2019.

Thrombin Topical Solution (Bovine)
April 1, 2019
Reason for the Shortage
- Pfizer has Thrombin-JMI on shortage due to manufacturing delays.
- Recombinant thrombin is not affected by this shortage.

Estimated Resupply Dates
- Pfizer has Thrombin-JMI 20,000 unit syringe spray kits, 5,000 unit epistaxis kits, and 5,000 unit vials available in limited supply. The 20,000 unit pump spray kits are on back order and the company estimates a release date of July 2019. The 5,000 unit syringe spray kits are on back order and the company estimates a release date of April 2019.

Phenytoin Sodium Injection
April 1, 2019
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.


**Erythromycin Lactobionate Injection**  
April 1, 2019  
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 July 2019 for the regular vials and October 2019 for the ADD-Vantage vials.


**Enalaprilat Injection**  
April 1, 2019  
Reason for the Shortage  
- Hikma has enalaprilat injection on shortage due to increased demand.  
- Pfizer has enalaprilat injection on shortage due to manufacturing delays

Estimated Resupply Dates  
- Hikma has enalaprilat 1.25 mg/mL 1 mL and 2 mL vials on allocation.  
- Pfizer has enalaprilat 1.25 mg/mL 1 mL and 2 mL vials on back order and the company estimates a release date of March 2020.


**Hydroxyzine Pamoate Oral Capsules**  
April 2, 2019  
Reason for the Shortage  
- Amneal did not provide a reason for the shortage.  
- Mylan did not provide a reason for the shortage.  
- Pfizer did not provide a reason for the shortage.  
- Rising discontinued hydroxyzine pamoate capsules.  
- Sandoz did not provide a reason for the shortage.  
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates  
- Amneal has hydroxyzine pamoate capsules on back order and the company estimates a release date in mid-April 2019.
- Mylan has hydroxyzine pamoate 25 mg and 50 mg capsules in 100 count unit dose packages on back order and the company estimates release dates in early-June 2019 for the 25 mg capsules and early-May 2019 for the 50 mg capsules.
- Pfizer has Vistaril 25 mg and 50 mg capsules in 100 count bottles on back order and the company estimates a release date in mid-May 2019.
- Teva has hydroxyzine pamoate 25 mg, 50 mg, and 100 mg capsules on back order and the company estimates a release date in late-June 2019.

Clotrimazole Lozenges (Clotrimazole Troches)
April 2, 2019

Reason for the Shortage
- Hikma did not provide a reason for the shortage.
- Perrigo has clotrimazole lozenges on shortage due to increased demand.

Estimated Resupply Dates
- Hikma has clotrimazole 10 mg lozenges in 70 count and 140 count bottles on allocation. The 10 mg lozenges in 70 count unit-dose packs are on allocation.
- Perrigo has clotrimazole 10 mg lozenges in 70 count and 140 count bottles on back order and the company estimates a release date of April 2019 for the 70 count bottles and July 2019 for the 140 count bottles. The 10 mg lozenges in 70 count unit-dose packs are on back order and the company estimates a release date of July 2019.


Orphenadrine Citrate Injection
April 3, 2019

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

Estimated Resupply Dates
- Akorn has orphenadrine 30 mg/mL 2 mL vials on back order and the company cannot estimate a release date.
- Hikma has orphenadrine 30 mg/mL 2 mL vials on allocation.


Morphine Injection
April 3, 2019

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

Estimated Resupply Dates
- Fresenius Kabi has morphine 2 mg/mL 1 mL syringes on back order and the company estimates a release date of late-April 2019. The morphine 4 mg/mL 1 mL syringes are on back order and the company estimates a release date of 2nd quarter 2019. The morphine 5 mg/mL 1 mL syringes are on back order and the company estimates a release date of late-April to early-May 2019. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of
late-April 2019. The 8 mg/mL 1 mL vials are on back order and the company cannot estimate a release date. Check wholesalers for inventory.

- Pfizer has morphine 2 mg/mL 1 mL Carpuject syringes available in limited supply. The 0.5 mg/mL 10 mL preservative-free vials are on back order and the company estimates a release date of May 2019. The 1 mg/mL 10 mL preservative-free vials are on back order and the company estimates a release date of April 2019. The 2 mg/mL 1 mL iSecure syringes, 4 mg/mL 1 mL iSecure syringes, 8 mg/mL 1 mL iSecure syringes, and 10 mg/mL 1 mL iSecure syringes are on back order and the company estimates a release date of September 2019. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of April 2019. The 8 mg/mL 1 mL Carpuject syringes and 10 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of February 2020. The 25 mg/mL 1 mL preservative-free vials are on back order and the company estimates a release date of June 2019. The 50 mg/mL 20 mL vials are on back order and the company estimates a release date of April 2019. The 50 mg/mL 50 mL vials are on back order and the company estimates a release date of May 2019.


**Hydroxyprogesterone Caproate Injection**

**April 3, 2019**

Reason for the Shortage

- AMAG has Makena vials on shortage due to manufacturing delay.
- American Regent has hydroxyprogesterone injection available.
- Mylan has hydroxyprogesterone injection available.
- Prasco has hydroxyprogesterone injection available.
- Slayback Pharma launched hydroxyprogesterone injection in early 2019.

Estimated Resupply Dates

- AMAG has Makena 250 mg/mL 1 mL and 5 mL vials on back order and the company estimates cannot estimate a release date.


**Fluorouracil Injection**

**April 3, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

- Sagent has fluorouracil 50 mg/mL 100 mL vials on back order and the company estimates a release date of April 2019.

**Fluorescein Sodium Ophthalmic Strips**
April 3, 2019

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

Estimated Resupply Dates
- Akorn has Ful-Glo 0.6 mg and 1 mg strips on allocation.
- Hub has Bio-Glo 1 mg strips in 300 count in limited supply.


**Deferoxamine Injection**
April 3, 2019

Reason for the Shortage
- Fresenius Kabi had deferoxamine on shortage due to increased demand.
- Pfizer has deferoxamine on shortage due to manufacturing delays.
- Novartis has Desferal available.
- Alvogen did not provide a reason for the shortage. Alvogen launched deferoxamine injection in mid-2018.
- Apo-Pharma launched deferoxamine injection in mid-2018.

Estimated Resupply Dates
- Alvogen has deferoxamine 500 mg vials available with short expiration dating (January 2020). The 2 gram vials are on back order and the company cannot estimate a release date.
- Pfizer has deferoxamine 500 mg vials on back order and the company estimates a release date of June 2019.


**Ciprofloxacin Ophthalmic Solution**
April 3, 2019

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

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


**Amyl Nitrite Inhalation**
April 3, 2019

Reason for the Shortage
- James Alexander has amyl nitrite inhalation on shortage because they are in the process of serializing the product.
• James Alexander has amyl nitrite inhalation on back order and the company estimates a release date in late-May to early-June 2019.

**Albuterol Inhalation Solution**
**April 3, 2019**
Reason for the Shortage
• Akorn did not provide a reason for the shortage

Estimated Resupply Dates
• Akorn has albuterol 0.5% 20 mL bottles on back order and the company cannot estimate a release date.

**0.9% Sodium Chloride 10 mL, 20 mL, and 50 mL Preservative Free Vials and Syringes**
**April 3, 2019**
Reason for the Shortage
• Fresenius Kabi has recalled multiple lots of 0.9% sodium chloride 10 mL and 20 mL vials due to labels incorrectly stating the stoppers are latex-free. The letter and the lot numbers affected can be found at https://www.fresenius-kabi.com/us/news/fresenius-kabi-issues-voluntary-nationwide-recall-of-sodium.
• Pfizer has 0.9% sodium chloride preservative-free vials on shortage due to manufacturing delays.

Estimated Resupply Dates
• Pfizer has 0.9% sodium chloride preservative free 20 mL vials on back order and the company estimates a release date of May 2019. The 50 mL vials are available in limited supply. The 10 mL LifeShield syringes are on back order and the company estimates a release date of May 2019.

**Sterile Water for Injection - Small Volume Vials**
**April 4, 2019**
Reason for the Shortage
• American Regent has sterile water for injection available.
• Fresenius Kabi has sterile water on shortage due to increased demand.
• Hikma has sterile water for injection available.
• Pfizer has sterile water for injection in vials on shortage due to increased demand.

Estimated Resupply Dates
• Fresenius Kabi has sterile water for injection 100 mL vials on back order and the company cannot estimate a release date. The 50 mL vials are on back order and the company estimates a release date of early-June 2019. Check wholesalers for inventory.
• Pfizer has sterile water for injection 50 mL and 100 mL vials on back order and the company estimates a release date of April 2019. The 20 mL vials are available in limited supply.
Rocuronium Injection
April 4, 2019
Reason for the Shortage
- Athenex has rocuronium available.
- AuroMedics did not provide a reason for the shortage.
- Fresenius Kabi has rocuronium available.
- Mylan Institutional did not provide a reason for the shortage.
- Pfizer has rocuronium on shortage due to manufacturing delays.
- Sagent has rocuronium available.
- Sandoz has rocuronium available.
- X-Gen has rocuronium available.

Estimated Resupply Dates
- AuroMedics has rocuronium 10 mg/mL 5 mL and 10 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Mylan Institutional has rocuronium 10 mg/mL 10 mL vials on back order and the company cannot estimate a release date.
- Pfizer has rocuronium 10 mg/mL 5 mL and 10 mL vials available in limited supply.

Potassium Chloride Injection
April 4, 2019
Reason for the Shortage
- Baxter had their highly concentrated potassium chloride in sterile water on shortage because a manufacturing facility was affected by Hurricane Maria. Baxter did not provide a reason for the shortage of their other potassium chloride products.
- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has potassium chloride injection on shortage due to increased demand. Pfizer discontinued 2 mEq/mL 250 mL bottles in mid-2018.
- ICU Medical has potassium chloride injection on shortage due to increased demand.

Estimated Resupply Dates
- Fresenius Kabi has potassium chloride 10 mEq/5 mL vials on back order and the company estimates a release date of late-April 2019.
- ICU Medical has all potassium chloride injection presentations available to current customers.

Mannitol Injection
April 4, 2019
Reason for the Shortage
- American Regent is not currently marketing mannitol.
- Baxter did not provide a reason for the mannitol shortage.
- BBraun has mannitol 500 mL premixed bags available. The 250 mL premixed bags were discontinued.
- Fresenius Kabi had mannitol on shortage due to increased demand.
- Pfizer has mannitol on shortage due to manufacturing delays.

**Estimated Resupply Dates**
- Pfizer has mannitol 250 mg/mL 50 mL vials available in limited supply


**Magnesium Sulfate Injection**

**April 4, 2019**

**Reason for the Shortage**
- American Regent is not currently marketing magnesium sulfate which has been unavailable since late 2012.
- Fresenius Kabi had 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**
- Pfizer has magnesium sulfate 500 mg/mL 20 mL vials on back order and the company estimates a release date of December 2019. The 500 mg/mL 10 mL syringes are on back order and the company estimates a release date of June 2019. The 80 mg/mL 50 mL bags are available in limited supply


**Heparin Sodium Premixed Bags**

**April 4, 2019**

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

**Estimated Resupply Dates**
- Baxter has heparin 2000 units/1,000 mL premixed bags on back order and the company cannot estimate a release date.
- Pfizer has heparin 2,000 units/1,000 mL 0.9% sodium chloride premixed bags on back order and the company estimates a release date of April 2019. The 25,000 units/250 mL 0.45% sodium chloride premixed bags and 25,000 units/250 mL 5% dextrose premixed bags are on back order and the company estimates a release date of April 2019. Heparin 1,000 units/500 mL 0.9% sodium chloride premixed bags are available in limited supply.

Ceftazidime Injection
April 4, 2019

Reason for the Shortage
- Pfizer has Tazicef available.
- Sagent has ceftazidime injection on shortage due to increased demand and manufacturing delays.
- 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
- Sagent has ceftazidime 2 gram and 6 gram vials on back order and the company estimates a release date of April 2019.
- Teligent has Fortaz 500 mg vials, 1 gram vials, 1 gram TwistVials, and 2 gram TwistVials on long-term back order and the company cannot estimate a release date.

Cefoxitin Sodium Injection
April 4, 2019

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

Estimated Resupply Dates
- Apotex has temporarily discontinued cefoxitin 1 gram, 2 gram, and 10 gram vials and the company cannot estimate when product will be available again.
- BBraun has cefoxitin 1 gram and 2 gram DUPLEX bags on back order and the company cannot estimate a next release date.
- Fresenius Kabi has cefoxitin 1 gram and 2 gram vials on back order and the company estimates a release date of mid-May 2019 for the 1 gram vials and mid-April 2019 for the 2 gram vials.
- Sagent has cefoxitin 2 gram and 10 gram vials on back order and the company estimates a release date of April 2019. The 1 gram vials are on allocation.
- WG Critical Care has cefoxitin 1 gram vials on back order and the company estimates a release date of April 2019. The 2 gram and 10 gram vials are on back order and the company estimates a release date of May 2019.

Bacteriostatic 0.9% Sodium Chloride Vials
April 4, 2019
Reason for the Shortage
- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has bacteriostatic sodium chloride vials on shortage due to manufacturing delays.

Estimated Resupply Dates
- Fresenius Kabi has bacteriostatic 0.9% sodium chloride 30 mL vials on back order and the company estimates a release date of early-May 2019.
- Pfizer has bacteriostatic 0.9% sodium chloride 20 mL vials available in limited supply.

Azithromycin Injection
April 4, 2019
Reason for the Shortage
- Apotex will be discontinuing azithromycin injection once available supplies are gone.
- AuroMedics did not provide a reason for the shortage.
- Fresenius Kabi has azithromycin injection on shortage due to increased demand.
- Pfizer has azithromycin injection on shortage due to manufacturing delays.
- Sun Pharma is not currently manufacturing azithromycin injection.

Estimated Resupply Dates
- AuroMedics has azithromycin 500 mg vials on intermittent back order and the company is releasing product as it becomes available.
- Pfizer has azithromycin 500 mg ADD-Vantage vials on back order and the company estimates a release date of March 2020. Zithromax 500 mg vials are on back order and the company estimates a release date of October 2019.

Valsartan Tablets
April 5, 2019
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 probable human carcinogen. Additional information is available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
- Camber, Major, Solco, and Teva valsartan tablets were affected by the recall. Detailed information on the products is available at https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615703.pdf.
- Major, Solco, and Teva discontinued valsartan tablets in July 2018.
- Alembic, Aurobindo, Cadista, Mylan, Macleods, and Novartis are not affected by this recall.
- Aurobindo refused to provide updated availability information.
- Lupin is not actively marketing valsartan tablets.
- Repackagers may have some presentations affected depending on the source supplier.

Estimated Resupply Dates
• Cadista has valsartan tablets on back order and the company estimates a release date of mid- to late-April 2019.
• Camber has valsartan tablets on back order and the company cannot estimate a release date.
• Mylan has valsartan tablets on back order and the company cannot estimate a release date.


Tropicamide 1% Ophthalmic Solution
April 5, 2019
Reason for the Shortage
• Akorn did not provide a reason for the shortage.
• Alcon has Mydriacyl available.
• Bausch Health discontinued tropicamide 1% ophthalmic drops in mid-2018.
• Sandoz did not provide a reason for the shortage.

Estimated Resupply Dates
• Akorn has tropicamide 1% ophthalmic drops in 15 mL bottles on allocation.


Sodium Polystyrene Sulfonate Oral or Rectal Suspension
April 5, 2019
Reason for the Shortage
• CMP Pharma reports that increased demand has led to a shortage of raw material required to manufacture the products. They are using available powder to manufacture the suspension.
• Perrigo has temporarily discontinued their Kionex suspension and sodium polystyrene sulfonate (sorbitol-free) suspension. They cannot estimate when these products will be manufactured again.
• Hikma is not currently marketing sodium polystyrene sulfonate suspension.


Prednisolone Acetate 1% Ophthalmic Suspension
April 5, 2019
Reason for the Shortage
• Allergan did not provide a reason for the shortage.
• Greenstone did not provide a reason for the shortage.
• Novartis discontinued Omnipred 1% in 2018.
• Sandoz has prednisolone acetate on shortage due to increased demand.

Estimated Resupply Dates
• Allergan Pred Forte 10 mL bottles on back order and the company estimates a release date of April 2019.
• Greenstone has all prednisolone acetate 1% presentations on back order. The company estimates a release date of mid-April 2019 for the 10 mL and 15 mL bottles, and 2nd quarter 2019 for the 5 mL bottles.
• Sandoz has prednisolone acetate 1% 5 mL and 15 mL bottles on back order and the company estimates a release date of early-April 2019 for the 5 mL bottles and late-April 2019 for the 15 mL bottles.

Mupirocin Calcium 2% Nasal Ointment
April 5, 2019
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.

Mupirocin Calcium 2% Cream
April 5, 2019
Reason for the Shortage
- GlaxoSmithKline is looking for an alternative supply source.
- Glenmark did not provide a reason for the shortage.
- 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.
- Glenmark has mupirocin 2% cream in 15 gram tubes on back order and the company cannot estimate a release date.

Metoclopramide Injection
April 5, 2019
Reason for the Shortage
- Pfizer has metoclopramide injection on shortage due to manufacturing delays.
- Teva had metoclopramide injection on shortage due to increased demand.
- Fresenius Kabi had metoclopramide injection on shortage due to increased demand.

Estimated Resupply Dates
- Pfizer has metoclopramide 5 mg/mL 2 mL vials on back order and the company estimates a release date of April 2019.

Methocarbamol Tablets
April 5, 2019
Reason for the Shortage
- Bayshore states the shortage is due to increased demand.
- 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.
- Solco states the shortage is due to an API shortage.
Estimated Resupply Dates

- Camber has all methocarbamol tablets available for contracted customers. All presentations are on allocation for non-contracted customers.
- Hikma has methocarbamol 500 mg and 750 mg tablets in 500 count on back order and the company estimates a release date of April to May 2019. Methocarbamol 500 mg and 750 mg tablets in 100 count are on back order and the company cannot estimate a release date.
- Solco has all methocarbamol presentations on allocation.
- Virtus has all methocarbamol tablets on back order and the company cannot estimate a release date.
- Endo has Robaxin 750 mg tablets in 100 count on back order and the company cannot estimate a release date.


**Melphalan Injection**

**April 5, 2019**

Reason for the Shortage

- Mylan Institutional did not provide a reason for the shortage.
- Par did not provide a reason for the shortage.
- Sagent has melphalan injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Par has short-dated melphalan 50 mg vials available with an expiration date of April 2019.
- Sagent has melphalan 50 mg vials on back order and the company cannot estimate a release date.


**Levetiracetam Immediate-Release Tablets**

**April 5, 2019**

Reason for the Shortage

- Accord has levetiracetam immediate-release tablets available.
- Aurobindo did not provide updated availability information.
- Camber has most presentations available.
- Lupin did not provide a reason for the shortage.
- Major did not provide a reason for the shortage.
- Mylan did not provide a reason for the shortage.
- OWP did not provide a reason for the Roweepra shortage.
- Torrent did not provide a reason for the shortage.
- UCB has Keppra immediate-release tablets available.

Estimated Resupply Dates

- Camber has levetiracetam 500 mg immediate-release tablets in 500 count on intermittent back order and the company is allocating product as it becomes available.
- Lupin has levetiracetam immediate-release tablets on allocation.
- Major has levetiracetam 500 mg immediate-release tablets on back order and the company estimates a release date in late-April 2019.
- Mylan has levetiracetam 250 mg and 1000 mg immediate-release tablets in all sizes on back order and the company cannot estimate a release date. The 500 mg and 750 mg immediate-
release tablets in 120 and 500 count bottles are on back order and the company estimates a release date in early-April 2019. The 500 mg immediate-release tablets in 100 count unit dose packages are on intermittent back order and the company is releasing supplies as they become available. The 750 mg immediate-release tablets in 100 count unit dose packages are on back order and the company estimates a release date of mid-May 2019.

- OWP has Roweepra immediate-release tablets on back order and the company cannot estimate a release date.
- Torrent has levetiracetam immediate-release tablets on allocation.


**Doxorubicin Injection**

**April 5, 2019**

**Reason for the Shortage**

- Hikma did not provide a reason for the shortage of Adriamycin.
- Teva had doxorubicin solution for injection on shortage due to increased demand. They discontinued doxorubicin presentations with NDCs starting in 00703 in early-January 2019.
- Fresenius Kabi did not provide a reason for the shortage.
- Caraco has discontinued doxorubicin solution for injection 25 mL and 100 mL vials.
- Pfizer has doxorubicin on shortage due to manufacturing delays.
- 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 on back order and the company cannot estimate a release date. The 100 mL vials have short expiration dating of April 2019.
- Fresenius Kabi has doxorubicin 10 mL and 25 mL vials available with short-expiration dating (< 6 months).
- Hikma has Adriamycin 25 mL vials are on allocation. There are short-dated 2 mg/mL 10 mL vials available with an expiration date of June 2019. The 50 mg vials are on allocation.
- Pfizer has doxorubicin 2 mg/mL 5 mL vials on back order and the company estimates a release date in April 2019. The 100 mL vials are available in limited supply.
- Sagent has doxorubicin 2 mg/mL 5 mL, 10 mL, and 25 mL vials on back order and the company estimates a relaunch date of mid-April 2019.
- Teva has doxorubicin 2 mg/mL 10 mL vials on intermittent back order and the company is allocating product upon release.

**Dopamine Hydrochloride Injection**  
April 5, 2019  

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

**Estimated Resupply Dates**  
- Pfizer has dopamine 40 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of August 2019 for the 5 mL vials and June 2019 for the 10 mL vials. The 400 mg/250 mL premixed bags are available in limited supply.


**Diazepam Injection**  
April 5, 2019  

**Reason for the Shortage**  
- Pfizer has diazepam on shortage due manufacturing delays.  
- DASH Pharmaceuticals launched diazepam injection in early-April 2019.

**Estimated Resupply Dates**  
- Pfizer has diazepam 5 mg/mL 2 mL Carpuject syringes available in limited supply.


**Sterile Talc**  
April 8, 2019  

**Reason for the Shortage**  
- Lymol has Sclerosol and talc powder on shortage due to manufacturing delays.  
- Novatech SA did not provide a reason for the shortage.

**Estimated Resupply Dates**  
- Lymol has Sclerosol and talc powder on long-term back order and the company cannot estimate a release date.  
- Novatech SA has Steritalc 4 gram powder on back order and the company cannot estimate a release date.


**Sincalide Injection**  
April 8, 2019  

**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.

Secobarbital Capsules
April 8, 2019
Reason for the Shortage
- Bausch Health is the sole supplier of secobarbital capsules. The company states that Seconal capsules are on back order due to a short-term stock out.

Estimated Resupply Dates
- Bausch Health has Seconal (secobarbital) 100 mg capsules on back order and the company cannot estimate a release date.

Rosuvastatin Calcium Tablets
April 8, 2019
Reason for the Shortage
- Accord, Biocon, Glenmark, Mylan, Sandoz, and Rising did not provide a reason for the shortage.
- Apotex has discontinued production of all rosuvastatin presentations.
- Aurobindo refuses to provide updated availability information.
- Mylan has discontinued all rosuvastatin presentations.
- Sun Pharma will be discontinuing production of all rosuvastatin presentations.

Estimated Resupply Dates
- Accord has rosuvastatin 5 mg tablets in 90 count and 1,000 count on intermittent back order and the company is releasing supplies as they become available. The 10 mg tablets in 1,000 count bottles are on back order and the company estimates a release date of early- to mid-April 2019. The 10 mg tablets in 90 count, 20 mg in 1,000 count, and 40 mg in 30 count bottles are on intermittent back order and the company is releasing supplies as they become available. The 40 mg tablets in 1,000 count bottles are on back order and the company estimates a release date in mid-April 2019.
- Biocon has rosuvastatin 40 mg tablets in limited supply.
- Rising has all rosuvastatin presentations on allocation.
- Sandoz has rosuvastatin 20 mg tablets in 90-count bottles on back order and the company estimates a release date in April 2019.
- Sun Pharma will be discontinuing production of rosuvastatin 5 mg, 10 mg, 20 mg, and 40 mg tablets in 90 count bottles.

Recombinant Zoster Vaccine (Shingrix)
April 8, 2019
Reason for the Shortage
- GlaxoSmithKline has Shingrix on shortage due to high demand for the product.

Estimated Resupply Dates
- GlaxoSmithKline has Shingrix on intermittent back order and the company is shipping orders according to order date and supply available.
Nystatin Oral Suspension
April 8, 2019
Reason for the Shortage
- Akorn did not provide a reason for the shortage.
- Pharmaceutical Associates, Inc. did not provide a reason for the shortage.
- Precision Dose has nystatin suspension on allocation due to increased demand.
- Vista Pharma did not provide a reason for the shortage.
- Wockhardt USA did not provide a reason for the shortage.


Nelfinavir Mesylate Tablets
April 8, 2019
Reason for the Shortage
- Viiv Healthcare states the shortage is due to a manufacturing issue.
- Viiv Healthcare is the sole supplier of nelfinavir.

Estimated Resupply Dates
- Viiv Healthcare has Viracept 250 mg tablets on back order and the company cannot estimate a release date.


Mineral Oil and Petrolatum Ophthalmic Ointment
April 8, 2019
Reason for the Shortage
- Allergan states the shortage is due to production delays.
- Bausch Health has Soothe Night Time ointment available.
- Major did not provide a reason for the shortage.
- Alcon states the shortage is due to manufacturing issues.
- 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 on back order and the company cannot estimate a release date.
- Alcon has Systane Nighttime ointment and Genteal PM ointment on back order and the company estimates a release date in late-April 2019.


Methylphenidate Extended-Release Oral Suspension and Chewable Tablets
April 8, 2019
Reason for the Shortage
- Tris Pharma has Quillivant XR oral suspension and QuilliChew ER chewable tablets available.

Leuprolide Acetate 14-Day Kit
April 8, 2019
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.

Latanoprost Ophthalmic Solution
April 8, 2019
Reason for the Shortage
- Akorn has discontinued latanoprost ophthalmic solution.
- Bausch Health has latanoprost ophthalmic solution available.
- Greenstone did not provide a reason for the shortage of latanoprost ophthalmic solution.
- Rising did not provide a reason for the shortage.
- Sandoz (Falcon) has latanoprost ophthalmic solution available.

Estimated Resupply Dates
- Greenstone has latanoprost ophthalmic solution on allocation.
- Rising has latanoprost ophthalmic solution on allocation.

Ketorolac Injection
April 8, 2019
Reason for the Shortage
- Alvogen did not provide a reason for the shortage.
- Amphastar did not provide a reason for the shortage.
- Thenex has ketorolac available.
- BD RX is now part of Fresenius Kabi.
- Fresenius Kabi has most ketorolac presentations available.
- Pfizer has ketorolac injection on back order due to manufacturing delays.
- Sagent states the reason for the shortage is manufacturing delay.
- Hikma did not provide a reason for the shortage.
- 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 ketorolac 30 mg/mL 1 mL and 2 mL vials on back order and the company cannot estimate a release date.
- Amphastar has ketorolac 30 mg/mL 1 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has ketorolac 15 mg/mL 1 mL prefilled syringes on back order and the company cannot estimate a release date. The 30 mg/mL 1 mL prefilled syringes are on back order with an estimated release date of early-May 2019. The 30 mg/mL 2 mL syringes for intramuscular use are on back order and the company estimates a release date of 2nd quarter 2019. Product is available with short expiration dating for ketorolac 15 mg/mL 1 mL prefilled syringes (< 3 months), 30 mg/mL 1 mL prefilled syringe (< 1 month), and 30 mg/mL 2 mL prefilled syringes for intramuscular use (< 4 months).
- Hikma has ketorolac 30 mg/mL 1 mL vials on allocation.
- 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 September 2019. The ketorolac 30 mg/mL 1 mL vials are available in limited supply.
- Sagent has ketorolac 15 mg/mL 1 mL vials, 30 mg/mL 1 mL vials, and 30 mg/mL 2 mL vials for intramuscular injection are on back order and the company estimates a release date of August 2019.


**Iron Dextran Injection**  
**April 8, 2019**

**Reason for the Shortage**
- Allergan had INFeD on shortage due to manufacturing delays. They changed NDC numbers in early-2019.
- American Regent discontinued Dexferrum injection in 2014

**Estimated Resupply Dates**
- Allergan has INFeD 50 mg/mL 2 mL vials available


**Furosemide Injection**  
**April 8, 2019**

**Reason for the Shortage**
- American Regent is not actively marketing furosemide injection.
- Amneal did not provide a reason for the shortage.
- Baxter (formerly Claris) did not provide a reason for the shortage.
- Fresenius Kabi did not provide a reason for the shortage.
- Heritage has furosemide injection available.
- Pfizer had furosemide injection on shortage due to manufacturing delays and increased demand

**Estimated Resupply Dates**
- Amneal has furosemide 10 mg/mL 2 mL and 10 mL vials on back order and the company cannot estimate a release date. There are short-dated 4 mL vials available with an expiration date of
- Fresenius Kabi has furosemide 10 mg/mL 10 mL vials on back order and the company estimates a release date of late-April to early-May 2019.
- Pfizer has furosemide 10 mg/mL 4 mL syringes and 2 mL vials on back order and the company estimates a release date of May 2019.

Copper Chloride Injection
April 8, 2019
Reason for the Shortage
- Pfizer has copper chloride on shortage due to manufacturing delays. They are the sole supplier of copper chloride.

Estimated Resupply Dates
- Pfizer has copper chloride available in limited supply.


Ceftriaxone Sodium Injection
April 8, 2019
Reason for the Shortage
- Apotex has ceftriaxone available.
- Fresenius Kabi states the reason for the shortage was increased demand.
- Pfizer had ceftriaxone injection on shortage due to increased demand and manufacturing delays.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz did not provide a reason for the shortage.
- Hikma states the reason for the shortage is manufacturing delay.
- Wockhardt has discontinued their ceftriaxone presentations.

Estimated Resupply Dates
- Baxter has ceftriaxone premixed bags on back order and the company cannot estimate a release date.
- Lupin has all ceftriaxone presentations on back order and the company cannot estimate a release date.
- Hikma has ceftriaxone 250 mg and 500 mg vials on back order and the company cannot estimate a release date. The 1 gram vials are on allocation.
- Sagent has ceftriaxone 500 mg and 1 gram vials on back order and the company estimates a release date in April 2019. There are short-dated 500 mg vials available with an expiration date of April 2019.
- Sandoz has ceftriaxone 500 mg vials on back order and the company estimates a release date in May 2019.


Asparaginase Erwinia chrysanthemi
April 8, 2019
Reason for the Shortage
- Jazz Pharmaceuticals did not provide a reason for the shortage.

Estimated Resupply Dates
- Jazz Pharmaceuticals has Erwinaze 10,000 unit vials in 1 count and 5 count on back order and the company estimates a release date in late-May 2019. There is a new process for ordering Erwinaze. Additional information regarding the new ordering process is available at www.erwinazesupply.com.
Valganciclovir HCl Oral Powder for Solution
April 9, 2019
Reason for the Shortage
• Teva did not provide a reason for the shortage.

Estimated Resupply Dates
• Teva has valganciclovir 50 mg/mL 100 mL bottles on back order and the company estimates a release date of mid-May 2019

Iopamidol Injection
April 9, 2019
Reason for the Shortage
• Bracco Diagnostics is the sole supplier of iopamidol and did not provide a reason for the shortage.

Estimated Resupply Dates
• Bracco Diagnostics has Isovue-200 (iopamidol 41%) in 50 mL vials on back order and the company cannot estimate a release date. Isovue-300 (iopamidol 61%) in 30 mL, 75 mL, 150 mL, 500 mL, 200 mL imaging bulk package, and 500 mL imaging bulk package bottles are on back order and the company cannot estimate a release date. Isovue 370 (iopamidol 76%) in 50 mL vials and 75 mL, 200 mL, 500 mL, 200 mL imaging bulk package, and 500 mL imaging bulk package bottles are on back order and the company estimates a release date in late-June 2019. Isovue-370 (iopamidol 76%) in 125 mL bottles are on back order and the company cannot estimate a release date.

5% Dextrose Injection (PVC-free and DEHP-free)
April 9, 2019
Reason for the Shortage
• Baxter is not currently marketing 5% dextrose PVC/DEHP-free bags.
• BBraun had 5% dextrose PVC/DEHP-free bags on shortage due to manufacturing delays.
• BD has 5% dextrose PVC/DEHP-free bags available.
• Fresenius Kabi has 5% dextrose PVC/DEHP-free bags available.
• ICU Medical has 5% dextrose PVC/DEHP-free bags due to manufacturing delays.

Estimated Resupply Dates
• ICU Medical has 5% dextrose PVC/DEHP-free 50 mL and 250 mL bags on allocation to contracted customers only
Verapamil Extended-Release Tablets
April 11, 2019
Reason for the Shortage
  • Glenmark did not provide a reason for the shortage.
  • Mylan did not provide a reason for the shortage.
  • Pfizer did not provide a reason for the shortage.

Estimated Resupply Dates
  • Glenmark has verapamil 180 mg extended-release tablets in 100 count and 500 count and 240 mg extended-release tablets in 100 count and 500 count on back order and the company estimates a release date of late-April 2019.
  • Mylan has verapamil 120 mg extended-release tablets in 100 count, 180 mg tablets extended-release tablets in 100 count and 500 count, and 250 mg extended-release tablets in 90 count, 100 count, and 500 count on back order and the company estimates a release date of mid-July 2019. The 120 mg extended-release tablets, 180 mg extended-release tablets, and 240 mg extended-release tablets in 100 count unit-dose packs are on back order and the company estimates a release date of late-July to early-August 2019.
  • Pfizer has Calan SR 180 mg extended-release tablets on back order and the company estimates a release date of July 2019.

Lorazepam Injection
April 11, 2019
Reason for the Shortage
  • Bedford discontinued lorazepam injection in May, 2011.
  • Hikma has product on shortage due to manufacturing delays.
  • Pfizer has product on shortage due to increased demand and manufacturing delays. Pfizer discontinued 4 mg/mL 10 mL vials in December 2017.
  • Akorn has not provided a reason for the shortage.
  • Amphastar has product available.

Estimated Resupply Dates
  • Akorn has lorazepam 2 mg/mL 1 mL vials on back order and the company estimates a release date of late-April 2019.
  • Hikma has Ativan 2 mg/mL 10 mL vials on back order and the company estimates a release date of late-April to mid-May 2019.
  • Pfizer has lorazepam 2 mg/mL 1 mL Carpuject syringes and 4 mg/mL 1 mL vials on back order and the company estimates a release date of April 2019. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of March 2020.

Diclomine Oral Presentations
April 11, 2019
Reason for the Shortage
  • Hikma did not provide a reason for the shortage.
  • Lannett did not provide a reason for the shortage.
  • Mylan did not provide a reason for the shortage.
Par Pharmaceuticals has dicyclomine oral solution available.
Teva did not provide a reason for the shortage.

Estimated Resupply Dates
- Hikma has 10 mg capsules in 100 and 1,000 count bottles and 20 mg tablets in 100 and 1,000 count bottles available on allocation.
- Lannett has 10 mg capsules in 100 and 1,000 count bottles on back order and the company estimates a release date of mid-May 2019. The 20 mg tablets in 100 count bottles are on back order and the company cannot estimate a release date. The 20 mg tablets in 1,000 count bottles are on back order with an estimated release date of early-May 2019.
- Mylan has 10 mg capsules in 100 and 500 count bottles on back order and the company estimates a release date of mid-June 2019 for the 100 count bottles and mid-August for the 500 count bottles. The 20 mg tablets in 100 and 500 count bottles are on back order and the company estimates a release date of mid-June 2019.
- Mylan Institutional has 10 mg capsules and 20 mg tablets on back order and the company estimates a release date of early-September 2019 for the 10 mg capsules and late-July 2019 for the 20 mg tablets.
- Teva has 20 mg tablets in 1,000 count bottles on back order and the company estimates a release date of early-May 2019.

Clindamycin Phosphate Injection
April 11, 2019
Reason for the Shortage
- Alvogen did not provide a reason for the shortage.
- 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 premixed bags in 2018.
- Sagent has clindamycin injection available.
- Sandoz has clindamycin injection available.

Estimated Resupply Dates
- Akorn has all clindamycin in dextrose premixes on back order and the company cannot estimate a release date.
- Alvogen has clindamycin 150 mg/mL 2 mL, 4 mL, and 6 mL ADD-Vantage vials on long term back order and the company cannot estimate a release date. Clindamycin 150 mg/mL 6 mL vials and 60 mL vials are short-dated with expiration dates of February 2020 for the 6 mL vials and August 2019 for the bulk 60 mL vials.
- Fresenius Kabi has short-dated clindamycin 150 mg/mL 2 mL, 4 mL, and 6 mL vials available with an expiration date of <8 months for the 2 mL vials, <9 months for the 4 mL vials, and <7 months for the 6 mL vials.
- 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 July 2019 for the 2 mL and 6 mL vials and August 2019 for the 4 mL vials.
- Sagent has short-dated clindamycin 150 mg/mL 2 mL vials with an expiration date of November 2019.

**Proparacaine Hydrochloride Ophthalmic Solution**

**April 12, 2019**

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

**Estimated Resupply Dates**
- Akorn has proparacaine 0.5% ophthalmic drops on allocation.
- Sandoz has proparacaine 0.5% ophthalmic drops on back order and the company estimates a release date of May 2019.

**Olanzapine Intramuscular Injection**

**April 12, 2019**

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

**Estimated Resupply Dates**
- American Regent has olanzapine 10 mg vials for intramuscular injection available in limited supply.

**Octreotide Injection**

**April 12, 2019**

**Reason for the Shortage**
- Fresenius Kabi has octreotide available.
- Hikma did not provide a reason for the shortage.
- Mylan Institutional did not provide a reason for the shortage.
- Sagent has octreotide on shortage due to increased demand.
- Sun Pharma is not currently marketing octreotide.
- Teva did not provide a reason for the shortage.
- Novartis has Sandostatin available. The 200 mcg/mL 5 mL vials were discontinued in early-2018.

**Estimated Resupply Dates**
- Hikma has octreotide 100 mcg/mL 1 mL vials, 500 mcg/mL 1 mL vials, 200 mcg/mL 5 mL vials, and 1000 mcg/mL 5 mL vials on back order and the company cannot estimate a release date.
- Mylan has octreotide 50 mcg/mL 1 mL syringes and 100 mcg/mL 1 mL syringe on back order and the company estimates a release date of mid-May 2019.
- Novartis has Sandostatin 50 mcg/mL 1 mL ampules available with short expiration dating (September 2019).
Sagent has ocreotide 50 mcg/mL 1 mL vials on back order and the company estimates a release date of August 2019. The 100 mcg/mL 1 mL vials and 500 mcg/mL 1 mL vials are on back order and the company estimates a release date of June 2019.


**Midodrine Tablets**  
**April 12, 2019**  
**Reason for the Shortage**
- Impax discontinued midodrine tablets in July 2018.
- Mylan did not provide a reason for the shortage.
- Sandoz discontinued midodrine tablets in mid-2018.
- Upsher-Smith has midodrine tablets on allocation due to increased demand.

**Estimated Resupply Dates**
- Mylan has midodrine 5 mg tablets on back order and the company estimates a release date of early-July 2019.
- Upsher-Smith has midodrine 2.5 mg, 5 mg, and 10 mg tablets on allocation.


**Labetalol Injection**  
**April 12, 2019**  
**Reason for the Shortage**
- Akorn did not provide a reason for the shortage.
- Alvogen did not provide a reason for the shortage.
- Pfizer has labetalol injection on shortage due to manufacturing delays.
- Hikma has labetalol injection on shortage due to increased 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 allocation.
- Hikma has labetalol 5 mg/mL 20 mL vials 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 December 2019 for the 20 mL vials and July 2019 for the 40 mL vials. The 5 mg/mL 4 mL Carpuject syringes are on back order and the company estimates a release date of May 2019.


**Hydroxyethyl Starch in Sodium Chloride Injection**  
**April 12, 2019**  
**Reason for the Shortage**
- BBraun did not provide a reason for the shortage of Hespan.
- Pfizer has 6% hetastarch in 0.9% sodium chloride injection available.
- Pfizer has Voluven available.

**Estimated Resupply Dates**
- BBraun has Hespan injection on allocation to current customers.
Gentamicin Sulfate Ophthalmic Ointment
April 12, 2019
Reason for the Shortage
• Akorn has Gentak ophthalmic ointment on shortage due to manufacturing delays.
• Gentamicin ophthalmic solutions are not affected by this shortage.

Estimated Resupply Dates
• Akorn has Gentak 3.5 gram tubes on back order and the company cannot estimate a release date.

Erythromycin Ophthalmic Ointment
April 12, 2019
Reason for the Shortage
• Akorn did not provide a reason for the shortage.
• Bausch Health did not provide a reason for the shortage.
• Perrigo has erythromycin ophthalmic ointment on shortage due to increased demand.

Estimated Resupply Dates
• Akorn has erythromycin 0.5% ophthalmic ointment in 3.5 gram tubes on back order and the company cannot estimate a release date.
• Bausch Health has erythromycin 0.5% ophthalmic ointment in 1 gram and 3.5 gram tubes on back order and the company estimates a release date of late-April 2019.
• Perrigo has erythromycin 0.5% ophthalmic ointment in 1 gram tubes in 50 count and 3.5 gram tubes in 24 count on back order and the company estimates a release date of late-April 2019 for the 1 gram tubes and August 2019 for the 3.5 gram tubes.

Calcitriol Injection
April 12, 2019
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 allocation
Bumetanide Injection
April 12, 2019
Reason for the Shortage
• Pfizer has bumetanide injection on shortage due to manufacturing delays.
• Hikma has bumetanide injection available.

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 December 2019 for the 4 mL vials and March 2020 for the 10 mL vials.

Atropine Ophthalmic Solution
April 12, 2019
Reason for the Shortage
• Akorn did not provide a reason for the atropine ophthalmic solution shortage.
• Altaire has homatropine ophthalmic solution available.

Estimated Resupply Dates
• Akorn has atropine ophthalmic solution in 2 mL bottles on back order and the company cannot estimate a release date.

2% Lidocaine Hydrochloride Topical Jelly
April 12, 2019
Reason for the Shortage
• Akorn has 2% lidocaine jelly on shortage due to increased demand.
• Teva discontinued lidocaine jelly in early-2018.
• Glydo and Uro-Jet prefilled syringes are not affected by this shortage.

Estimated Resupply Dates
• Akorn has 2% lidocaine jelly 5 mL and 30 mL tubes available.

Yellow Fever Vaccine
April 15, 2019
Reason for the Shortage
• Sanofi Pasteur states the shortage of YF-Vax is due to production delays.
• 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.
• 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. The product information can be found at https://s3.amazonaws.com/filecache.drivetheweb.com/mr5str_sanofipasteur/202281/969800.pdf. The initial rollout began in April 2017. More information can be found at https://www.cdc.gov/mmwr/volumes/66/wr/mm6617e2.htm?s_cid=mm6617e2_w or at https://www.vaccineshoppe.com/index.cfm/fa=anon.content&n=YellowFever&title=.

- Stamaril on allocation due to supply demand.


Letermovir Injection
April 15, 2019
Reason for the Shortage
- Merck has Prevymis on shortage due to a supply disruption.

Estimated Resupply Dates
- Merck has Prevymis 20 mg/mL 12 mL and 24 mL vials on back order and the company cannot estimate a release date.


Hyoscymine Sulfate Injection
April 15, 2019
Reason for the Shortage
- Mylan did not provide a reason for the shortage.

Estimated Resupply Dates
- Mylan Institutional has Levsin 0.5 mg/mL 1 mL ampules on back order and the company cannot estimate a release date.


Repetase Injection
April 16, 2019
Reason for the Shortage
- Chiesi USA acquired Cornerstone Therapeutics in March 2014.
- Cornerstone Therapeutics acquired EKR Therapeutics in June 2012. EKR Therapeutics had previously purchased Retavase from PDL BioPharma.
- Cornerstone Therapeutics was seeking FDA approval of a new supplier of the active pharmaceutical ingredient for Retevase: http://crtx.mwnewsroom.com/press-releases/cornerstone-therapeutics-completes-acquisition-of--nasdaq-crtx-0903873


Ropivacaine Injection
April 17, 2019
Reason for the Shortage
- Akorn has ropivacaine on shortage due to increased demand.
- AuroMedics did not provide a reason for the shortage.
- Fresenius Kabi has Naropin on shortage due to increased demand and manufacturing delays.
- Pfizer had ropivacaine on shortage due to manufacturing delays.
Estimated Resupply Dates

- Akorn has ropivacaine 5 mg/mL 30 mL vials on back order and the company cannot estimate a release date.
- AuroMedics has ropivacaine 7.5 mg/mL 20 mL vials and 5 mg/mL 30 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has Naropin 5 mg/mL 30 mL Steripak ampules on back order and the company estimates a release date of early-July 2019. The 5 mg/mL 100 mL bottles are on back order and the company estimates a release date of late-April 2019. The 5 mg/mL 30 mL vials are on back order and the company estimates a release date of mid-May 2019. Check wholesalers for inventory.
- Pfizer has ropivacaine 2 mg/mL 10 mL and 20 mL vials, 5 mg/mL 30 mL vials and 7.5 mg/mL 20 mL vials, and 10 mg/mL 10 mL and 20 mL vials on back order and the company estimates a release date of July 2019.


Mepivacaine Injection
April 17, 2019
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 2% Polocaine 50 mL vials on back order and the company estimates a release date of late-April 2019. The 2% Polocaine-MPF 20 mL vials are on back order and the company estimates a release date of late-April 2019. 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 March 2020.


Hydroxocobalamin Injection
April 17, 2019
Reason for the Shortage
- Meridian Medical Technologies reports that the shortage was due to manufacturing delays and increased demand.

Estimated Resupply Dates

- Meridian Medical Technologies has Cyanokit injection 5 gram vials available. Check with your wholesaler for inventory.


Dexamethasone Sodium Phosphate Injection
April 17, 2019
Reason for the Shortage
- American Regent is not marketing dexamethasone sodium phosphate injection at this time.
- AuroMedics has dexamethasone sodium phosphate on intermittent back order.
Fresenius Kabi has dexamethasone sodium phosphate presentations available.
Mylan Institutional has dexamethasone sodium phosphate available.
Hikma did not provide a reason for the shortage.

Estimated Resupply Dates
- AuroMedics has dexamethasone sodium phosphate 4 mg/mL 1 mL, 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 mid-June 2019. The 10 mg/mL 1 mL preservative-free vials are on back order and the company estimates a release date of mid-April 2019. The 4 mg/mL 1 mL, 5 mL, and 30 mL vials are on back order and the company estimates a release date of late-April 2019 for the 1 mL vials, late-April to early-May 2019 for the 5 mL vials, and mid-May 2019 for the 30 mL vials. The 10 mg/mL 10 mL vials are on back order and the company estimates release date of late-May 2019.
- 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 allocation.
- Mylan Institutional has dexamethasone 40 mg/mL 5 mL and 30 mL vial on back order and the company estimates a release date of mid- to late-June 2019.


Busulfan Injection
April 17, 2019
Reason for the Shortage
- American Regent did not provide a reason for the shortage.
- Amneal did not provide a reason for the shortage.
- Athenex launched busulfan injection in March 2019.
- Sagent has busulfan on shortage due to manufacturing delays.

Estimated Resupply Dates
- American Regent has busulfan 6 mg/mL 10 mL vials available in limited supply.
- Amneal has busulfan 6 mg/mL 10 mL vials on back order and the company cannot estimate a release date.
- Mylan has busulfan 6 mg/mL 10 mL vials on back order and the company estimates a release date of late-April 2019. Short dated (February 2020) vials are available.
- Sagent has busulfan 6 mg/mL 10 mL vials on allocation.


Bupivacaine with Epinephrine Injection
April 17, 2019
Reason for the Shortage
- Fresenius Kabi has bupivacaine and epinephrine on shortage due to increased demand and manufacturing delays.
- Pfizer has bupivacaine with epinephrine on shortage due to manufacturing delays.

Estimated Resupply Dates
- Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 10 mL vials on back order and the company estimates a release date of late-April 2019. The 0.25% Sensorcaine-MPF with
epinephrine 30 mL vials are on back order and the company estimates a release date of late-April 2019. The 0.25% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of late-April 2019. The 0.5% Sensorcaine-MPF with epinephrine 10 mL vials are on back order and the company estimates a release date of late-April 2019. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of late-April 2019. The 0.5% Sensorcaine-MPF with epinephrine 50 mL vials are on back order and the company estimates a release date of late-April 2019. The 0.5% Sensorcaine-MPF with epinephrine 30 mL sterile packs are on back order and the company cannot estimate a release date. The 0.75% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of late-April 2019.

- Pfizer has 0.25% bupivacaine with epinephrine 30 mL preservative-free vials on back order and the company estimates a release date of December 2019. The 0.25% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of December 2019. The 0.5% bupivacaine with epinephrine 10 mL preservative-free vials are on back order and the company estimates a release date of February 2020. The 0.5% bupivacaine with epinephrine 30 mL preservative-free vials are on back order and the company estimates a release date of April 2019. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of December 2019.

- Pfizer has 0.25% Marcaine with epinephrine 10 mL preservative-free vials on back order and the company estimates a release date of September 2019. The 0.25% Marcaine with epinephrine 30 mL preservative-free vials are on back order and the company estimates a release date of January 2020. The 0.25% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of January 2020. 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 January 2020. The 0.5% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of January 2020.


Bupivacaine Injection
April 17, 2019
Reason for the Shortage

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

Estimated Resupply Dates

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

- Pfizer has 0.25% Marcaine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of January 2020 for the 10 mL vials and July 2019 for the 30 mL vials. The 0.25% 50 mL vials are on back order and the company estimates a release date of January 2020. The 0.5% Marcaine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of September 2019 for the 10 mL vials and January 2020 for the 30 mL vials. The 0.5% 50 mL vials are on back order and the company estimates a release date of July 2019. The 0.75% Marcaine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of January 2020.


**Bisoprolol Fumarate Tablets**

**April 17, 2019**

Reason for the Shortage

- Mylan reports that product is on shortage due to manufacturing delays.
- Unichem Pharmaceuticals has product on shortage due to market demand.

Estimated Resupply Dates

- Mylan has bisoprolol 5 mg tablets in 30 and 100 count bottles and 10 mg tablets in 30 and 100 count bottles on back order and the company estimates a release date of mid-July 2019.
- Unichem has bisoprolol 5 mg tablets in 30 count and 100 count bottles and 10 mg tablets in 30 count and 100 count bottles on allocation.


**Benztropine Mesylate Injection**

**April 17, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

- Akorn has benztropine 1 mg/mL 2 mL ampules and Cogentin 1 mg/mL 2 mL ampules on back order and the company cannot estimate a release date.

23.4% Sodium Chloride Injection
April 17, 2019
Reason for the Shortage
- Fresenius Kabi has 23.4% sodium chloride injection on shortage due to increased demand.
- Pfizer has 23.4% sodium chloride injection on shortage due to increased demand.

Estimated Resupply Dates
- Fresenius Kabi has 23.4% sodium chloride 100 mL and 200 mL vials on back order and the company estimates a release date of mid-May 2019 for the 100 mL vials and late-April to early-May 2019 for the 200 mL vials. Check wholesalers for inventory.
- Pfizer has 23.4% sodium chloride 200 mL vials on back order and the company estimates a release date of September 2019.


Valproate Sodium Injection
April 18, 2019
Reason for the Shortage
- Abbvie did not provide a reason for the shortage.
- Hikma did not provide a reason for the shortage.
- Fresenius Kabi did not provide a reason for the shortage.

Estimated Resupply Dates
- Abbvie has Depacon vials available with an expiration date of November 2019.
- Fresenius Kabi has valproate sodium injection 100 mg/mL 5 mL vials on back order and the company estimates a release date of late-May 2019.


Metoprolol Injection
April 18, 2019
Reason for the Shortage
- Alvogen has metoprolol injection available.
- American Regent is not currently marketing metoprolol injection.
- Athenex has metoprolol injection available.
- Baxter did not provide a reason for the shortage.
- Fresenius Kabi had metoprolol injection on shortage due to increased demand.
- 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 estimates a release date of April 2019.
- Hikma has metoprolol 1 mg/mL 5 mL vials on back order and the company estimates a release date of May to June 2019. The 10 mL vials are 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 January 2020. The 1 mg/mL 5 mL ampules are on back order and the company estimates a release date of December 2019. The 1 mg/mL 5 mL vials are on intermittent back order and the company is releasing product as it becomes available. https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=363

Levetiracetam Injection
April 18, 2019
Reason for the Shortage
• American Regent did not provide a reason for the shortage.
• Athenex has product available.
• AuroMedics did not provide a reason for the shortage.
• Fresenius Kabi has product available.
• Mylan has product available.
• Pfizer has product available.
• Sagent has product available.
• Sun Pharma did not provide a reason for the shortage.
• UCB has product available.
• Hikma has product available.
• X-Gen has product available.

Estimated Resupply Dates
• 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.
• Sun Pharma has levetiracetam 100 mg/mL 5 mL vials on back order and the company cannot estimate a release date.

Dicyclomine Injection
April 18, 2019
Reason for the Shortage
• Allergan has Bentyl injection available.
• American Regent did not provide a reason for the shortage.
• Hikma did not provide a reason for the shortage.
• Nexus has dicyclomine injection for intramuscular use available.

Estimated Resupply Dates
• Hikma has dicyclomine 10 mg/mL 2 mL vials on back order and the company cannot estimate a release date. There are short-dated dicyclomine 10 mg/mL 2 mL vials available with an expiration date of May 2019.

Cosyntropin Injection
April 18, 2019
Reason for the Shortage
• Amphastar has Cortrosyn on shortage due to increased demand.
• Mylan Institutional did not provide a reason for the shortage.
• Sandoz did not provide a reason for the shortage

Estimated Resupply Dates
• Mylan Institutional has cosyntropin 0.25 mg vials on back order and the company estimates a release date of late-August 2019.
• Sandoz has cosyntropin 0.25 mg vials temporarily unavailable and the company cannot estimate a release date.
• Amphastar has Cortrosyn 0.25 mg vials on intermittent back order with regular releases.


Carbidopa and Levodopa Extended-Release Tablets
April 18, 2019
Reason for the Shortage
• Accord has discontinued carbidopa and levodopa 25 mg/100 mg extended-release tablets. The 50 mg/200 mg tablets are on shortage due to problems obtaining active ingredient.
• Sun Pharma had carbidopa and levodopa extended-release tablets on shortage due to increased demand.
• Merck had Sinemet CR on shortage due to increased demand.
• Mylan did not provide a reason for the carbidopa and levodopa extended-release tablet shortage.

Estimated Resupply Dates
• Accord has carbidopa and levodopa 50 mg/200 mg extended-release tablets on allocation.
• Mylan has carbidopa and levodopa 25 mg/100 mg extended-release tablets and 50 mg/200 mg extended-release tablets in 100 count unit-dose packs on back order and the company estimates a release date of early-September 2019. The 50 mg/200 mg extended release tablets and 25 mg/100 mg extended release tablets in 100 count bottles are on back order and the company estimates a release date of late-July 2019.
• Merck has Sinemet CR 25 mg/100 mg extended release tablets in 100 count bottles on back order and the company cannot estimate a release date.


Betamethasone Acetate/Betamethasone Sodium Phosphate Suspension for Injection
April 18, 2019
Reason for the Shortage
• American Regent has betamethasone acetate/betamethasone sodium phosphate on shortage due to minor shipping delays.
• Merck did not provide a reason for the shortage.
• Exela Pharma Sciences has betamethasone acetate/betamethasone sodium phosphate on shortage due to increased demand.

Estimated Resupply Dates
• American Regent has betamethasone acetate/betamethasone sodium phosphate 6 mg/mL 5 mL vials available in limited supply.
• Exela has betamethasone acetate/betamethasone sodium phosphate 6 mg/mL 5 mL vials available in limited supply.
Merck has Celestone Soluspan 5 mL vials on back order and the company estimates a release date of April 2019. 

Scopolamine Transdermal System 
April 19, 2019
Reason for the Shortage
- Baxter did not provide a reason for the shortage.
- GlaxoSmithKline states the shortage was due to increased demand.
- Perrigo did not provide a reason for the shortage.

Estimated Resupply Dates
- Baxter has Transderm Scop 1.5 mg patches in 24 count on back order and the company cannot estimate a release date.
- Perrigo has scopolamine patches on back order and the company cannot estimate a release date.


Ondansetron Hydrochloride Injection
April 19, 2019
Reason for the Shortage
- Apotex has ondansetron injection available.
- Athenex had ondansetron injection on shortage due to increased demand.
- AuroMedics did not provide a reason for the shortage.
- Fresenius Kabi has ondansetron injection available.
- Heritage had ondansetron on shortage due to increased demand. Heritage discontinued ondansetron 2 mg/mL 2 mL vials in 10 count in late-2018.
- Hikma did not provide a reason for the shortage.
- Mylan Institutional has ondansetron injection available.
- Pfizer has ondansetron injection on shortage due to manufacturing delays.
- Sagent has ondansetron injection on shortage due to increased demand and manufacturing delays.
- Novartis discontinued Zofran 20 mL vials in May 2018.

Estimated Resupply Dates
- AuroMedics has ondansetron 2 mg/mL 2 mL vials and 20 mL vials on intermittent back order and the company is releasing supplies as they become available.
- Hikma has ondansetron 2 mg/mL 20 mL vials in 10 count on back order and the company cannot estimate a release date.
- Pfizer has ondansetron 2 mg/mL 2 mL isecure syringes and 2 mg/mL 20 mL vials on back order and the company estimates a release date in September 2019. The 2 mg/mL 2 mL vials are available in limited supply.
- Sagent has ondansetron 2 mg/mL 2 mL vials and 20 mL vials on back order and the company estimates a release date of July 2019 for the 2 mL vials and August 2019 for the 20 mL vials.

Losartan and Hydrochlorothiazide Tablets  
April 19, 2019

Reason for the Shortage

- Alembic did not provide a reason for the shortage.
- Aurobindo refused to provide updated availability information.
- Cadista did not provide a reason for the shortage.
- Lupin did not provide a reason for the shortage.
- Merck has Hyzaar tablets available.
- Rising did not provide a reason for the shortage.
- Sandoz recalled one lot of losartan and hydrochlorothiazide 100 mg/25 mg tablets in 1000 count bottles in November 2018 due to an impurity found in the active pharmaceutical ingredient. Additional information can be found at https://www.fda.gov/Safety/Recalls/ucm625492.htm.
- Torrent recalled certain lots of losartan and hydrochlorothiazide 50 mg/12.5 mg tablets in 90 and 1000 count bottles and 100 mg/12.5 mg tablets in 90 and 1000 count bottles in December 2018, January 2019, March 2019, and April 2019 due to an impurity found in the active pharmaceutical ingredient. Additional information can be found at https://www.fda.gov/Safety/Recalls/ucm629693.htm and https://www.fda.gov/Safety/Recalls/ucm636296.htm.
- Torrent has losartan and hydrochlorothiazide tablets available in all presentations (from lots unaffected by the recall).
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates

- Alembic has losartan and hydrochlorothiazide tablets on allocation to contracted customers.
- Cadista has losartan and hydrochlorothiazide tablets on back order and the company estimates a release date of mid- to late-April 2019.
- Lupin has losartan and hydrochlorothiazide tablets on allocation.
- Rising has losartan and hydrochlorothiazide tablets on back order and the company cannot estimate a release date.
- Sandoz has losartan and hydrochlorothiazide tablet presentations on back order and the company cannot estimate a release date.
- Teva has losartan and hydrochlorothiazide 50 mg/12.5 mg tablets in 30, 90, and 1000 count bottles and 100 mg/12.5 mg tablets in 90 count bottles on back order and the company estimates a release date in early-June 2019. The 100 mg/12.5 mg tablets in 30 count and 1000 count bottles are on back order and the company estimates a release date in late-May 2019. The 100 mg/25 mg tablets in 30, 90, and 1000 count bottles are on back order and the company estimates a release date in late-June 2019.


Fluticasone and Salmeterol Powder for Inhalation  
April 19, 2019

Reason for the Shortage

- Teva Respiratory did not provide a reason for the shortage.
- Other fluticasone and salmeterol dry powder inhalers are not affected by the shortage.

Estimated Resupply Dates
- Teva Respiratory has AirDuo Respliclick 113 mcg/14 mcg on back order and the company estimates a release date in late-April 2019. The 232 mcg/14 mcg dry powder inhalers are on back order and the company estimates a release date in late-summer 2019.
- Teva Respiratory has fluticasone and salmeterol 232 mcg/14 mcg dry powder inhalers on back order and the company estimates a release date in early-May 2019.


0.9% Sodium Chloride Small Volume Bags (< 150 mL)
April 19, 2019

Reason for the Shortage
- Baxter did not provide a reason for the 0.9% sodium chloride small volume bags shortage. Most presentations are available.
- Bbraun has 0.9% sodium chloride small volume bags available.
- BD has 0.9% sodium chloride small volume bags available.
- Fresenius Kabi 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 has 0.9% sodium chloride small volume presentations on shortage due to increased demand.

Estimated Resupply Dates
- ICU Medical has 0.9% sodium chloride bags readily available except the 0.9% sodium chloride 50 mL VisIV and 100 mL VisIV bags are available to current customers only.
- Pfizer has 0.9% sodium chloride 50 mL preservative-free vials on back order and the company estimates a release date of April 2019.


0.9% Sodium Chloride Large Volume Bags
April 19, 2019

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 has 0.9% sodium chloride bags for injection available.
- BD has 0.9% sodium chloride bags for injection available.
- ICU Medical cited increased demand as the reason for the shortage.
- Fresenius Kabi did not provide a reason for the shortage.
- Baxter has received FDA approval for 0.9% sodium chloride in Viaflo containers manufactured in an FDA-approved facility in Spain. Additional information about this product is available at: http://www.baxter.com/information/saline_supply.html.

Estimated Resupply Dates
- Fresenius Kabi has 0.9% sodium chloride bags available with short expiration dating (< 7 months dating).
- ICU Medical has all 0.9% sodium chloride bags readily available except the 0.9% sodium chloride 250 mL PVC/DEHP-free bags are available to current customers only.

**Thiamine Injection**  
April 22, 2019  
Reason for the Shortage  
- Fresenius Kabi has thiamine injection on shortage due to short manufacturing delay.  
- Mylan Institutional has thiamine injection available.

Estimated Resupply Dates  
- Fresenius Kabi has thiamine 100 mg/mL 2 mL vials on back order and the company estimates a release date of late-April 2019.  
- Mylan Institutional has thiamine 100 mg/mL 2 mL vials on back order and the company estimates a release date of mid-May 2019.  


**Sodium Bicarbonate Injection**  
April 22, 2019  
Reason for the Shortage  
- Amphastar has sodium bicarbonate injection available.  
- Pfizer has sodium bicarbonate injection on shortage due to manufacturing delays.  
- Fresenius Kabi had sodium bicarbonate injection temporarily available, but have run out of stock, there is more in production at this time.

Estimated Resupply Dates  
- Fresenius Kabi has 8.4% sodium bicarbonate 50 mL vials on back order and the company estimates a release date of late-April 2019.  
- Pfizer has 4.2% sodium bicarbonate 10 mL LifeShield syringes, 7.5% sodium bicarbonate 50 mL syringes, and 8.4% sodium bicarbonate 10 mL syringes available in limited supply. The 8.4% sodium bicarbonate 50 mL vials are on back order and the company estimates a release date of April 2019. The 8.4% 50 mL LifeShield syringes are on back order and the company estimates a release date of May 2019.  
- Pfizer has Neut 4% 5 mL vials on back order and the company estimates a release date of December 2019.


**Promethazine Injection**  
April 22, 2019  
Reason for the Shortage  
- Hikma did not provide a reason for the shortage.  
- X-Gen has promethazine injection available.

Estimated Resupply Dates  
- Hikma has short-dated Phenergan 50 mg/mL 1 mL ampules available with an expiration date of August 2019. The 25 mg/mL 1 mL ampules are on back order and the company estimates a release date of May 2019.  

PCA Sterile Empty Vials and Injector  
April 22, 2019

Reason for the Shortage
- ICU Medical has LifeCare PCA sterile empty vials and injectors on shortage due to manufacturing delays.

Estimated Resupply Dates
- ICU Medical has LifeCare PCA sterile empty vials and injectors on allocation to contracted customers.


Multiple Vitamins for Infusion  
April 22, 2019

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, M.V.I. Adult 2 X 50 mL vials, and Pediatric 5 mL vials on back order and the company estimates a release date of December 2019.


Morphine PCA Vials  
April 22, 2019

Reason for the Shortage
- ICU Medical has morphine PCA vials on shortage due to manufacturing delays.
- Amphastar's morphine PCA vials are not affected by the shortage.

Estimated Resupply Dates
- ICU Medical has morphine 20 mL PCA vials on allocation to contracted customers. The 30 mL PCA vials are on back order and the company estimates a release date of late-July 2019.


Lidocaine with Epinephrine Injection  
April 22, 2019

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

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

- Pfizer has 1% lidocaine with epinephrine (1:100,000) 20 mL vials on back order and the company estimates a release date of April 2019. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are on back order and the company estimates a release date of April 2019. The 1% lidocaine with epinephrine (1:100,000) 50 mL vials are on back order and the company estimates a release date of April 2019. The 1.5% lidocaine with epinephrine (1:200,000) 30 mL vials are on back order and the company estimates a release date of July 2019. The 1.5% lidocaine with epinephrine (1:200,000) 5 mL glass ampules are on back order and the company estimates a release date of June 2019. The 2% lidocaine with epinephrine (1:100,000) 20 mL vials are on back order and the company estimates a release date of May 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 June 2019.


**Lidocaine Injection**

**April 22, 2019**

**Reason for the Shortage**

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

**Estimated Resupply Dates**

- Amphastar has 2% lidocaine 5 mL syringes on intermittent back order and the company is releasing product as it becomes available.
- AuroMedics has 1% lidocaine 5 mL ampules and 5 mL vials on intermittent back order and the company is releasing product as it becomes available. AuroMedics has 2% lidocaine 5 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has 1% Xylocaine 20 mL vials on back order and the company estimates a release date of late-April to early-May 2019. The 1% Xylocaine-MPF 30 mL vials are on back order and the company estimates a release date of late-April to early-May 2019. The 1% lidocaine 2 mL vials are on back order and the company cannot estimate a release date. 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 10 mL ampules are on back order and the company cannot estimate a release date. The 2% Xylocaine 20 mL vials are on back order and the company estimates a release date of late-April 2019. Check wholesalers for inventory.
- Pfizer has 1% lidocaine 5 mL preservative-free ampules on back order and the company estimates a release date of March 2020. The 1% lidocaine 20 mL vials are available in limited supply. The 1% lidocaine 30 mL preservative-free vials are on back order and the company estimates a release date of May 2019. The 1% lidocaine 50 mL vials are on back order and the company estimates a release date of May 2019. The 1% lidocaine 5 mL Lifeshield syringes are on back order and the company estimates a release date of August 2019. The 1.5% lidocaine 10
mL preservative-free ampules are on back order and the company cannot estimate a release date. The 1.5% lidocaine 20 mL preservative-free ampules are on back order and the company estimates a release date of July 2019. The 2% lidocaine 10 mL ampules are on back order and the company estimates a release date of June 2019. The 2% lidocaine 5 mL vials are on back order and the company estimates a release date of June 2019. The 2% lidocaine 20 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 2% lidocaine 50 mL vials are available in limited supply. The 2% lidocaine 5 mL Lifeshield syringes are on back order and the company estimates a release date of July 2019. The 4% lidocaine 5 mL ampules are available in limited supply.


Hydromorphone Hydrochloride Injection
April 22, 2019

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

Estimated Resupply Dates
- Fresenius Kabi has Dilaudid 2 mg/mL 1 mL syringes on back order and the company estimates a release date of mid-May 2019. The hydromorphone 1 mg/mL 1 mL vials are on back order and the company estimates a release date of mid-May 2019. The hydromorphone 10 mg/mL 1 mL vials are on back order and the company cannot estimate a release date. Check wholesalers for inventory.
- Pfizer has 1 mg/mL 1 mL Carpuject syringes available in limited supply. The 10 mg/mL 50 mL vials are on back order and the company estimates a release date of May 2019. The 10 mg/mL 5 mL vials are on back order and the company estimates a release date of April 2019. The 0.5 mg/0.5 mL iSecure syringes and 2 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of June 2019. The 1 mg/mL 1 mL ampules, 2 mg/mL 1 mL ampules, and 4 mg/mL 1 mL ampules are on back order and the company estimates a release date of September 2019 for the 1 mL and 2 mL ampules and June 2019 for the 4 mL ampules. The 1 mg/mL 1 mL iSecure syringes, 2 mg/mL 1 mL iSecure syringes, and 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of September 2019. The 2 mg/mL 1 mL vials are on back order and the company estimates a release date of April 2019.
- Teva has 10 mg/mL 1 mL, 5 mL, and 50 mL vials on intermittent back order and the company is allocating upon release.

Hydralazine injection  
April 22, 2019  
Reason for the Shortage  
- Akorn has product on back order due to increased demand.  
- American Regent is not currently marketing hydralazine injection.  
- Fresenius Kabi did not provide a reason for the shortage.  
- X-Gen did not provide a reason for the shortage.

Estimated Resupply Dates  
- Akorn has hydralazine 20 mg/mL 1 mL vials on allocation.  
- Fresenius Kabi has 20 mg/mL 1 mL vials on back order and the company estimates a release date of late-April to early-May 2019.  
- X-Gen has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of late-May 2019.


Cefuroxime Sodium Injection  
April 22, 2019  
Reason for the Shortage  
- Sagent has cefuroxime injection on shortage due to manufacturing delays.  
- Teligent discontinued all Zinacef presentations in February 2018.  
- Hikma did not provide a reason for the cefuroxime injection shortage. They are not currently marketing the 7.5 gram vials.

Estimated Resupply Dates  
- Sagent has cefuroxime 750 mg and 1.5 gram vials on back order and the company cannot estimate a release date.  
- Hikma has cefuroxime 750 mg vials on back order and the company estimates a release date of late-April to early-May 2019.


Cefazolin Injection  
April 22, 2019  
Reason for the Shortage  
- Apotex has discontinued all presentations except cefazolin 1 gram vials.  
- Baxter did not provide a reason for the shortage.  
- BBraun has cefazolin on shortage due to manufacturing delays.  
- Fresenius Kabi has cefazolin on shortage due to increased demand. They are not manufacturing the 20 gram vials at this time to focus on the other sizes.  
- Hikma did not provide a reason for the shortage.  
- Pfizer states the reason for the shortage is manufacturing delay.  
- Sagent states the reason for the shortage is manufacturing delays and increased demand.  
- Samson Medical Technologies did not provide a reason for the shortage.  
- Sandoz has cefazolin injection available.  
- WG Critical Care did not provide a reason for the shortage.

Estimated Resupply Dates
• Baxter has cefazolin 2 gram/100 mL premixed bags on allocation.
• B Braun has 1 gram/50 mL and 2 gram/50 mL premixed bags on allocation.
• Fresenius Kabi has cefazolin 500 mg vials and 1 gram vials on back order and the company estimates a release date of late-April 2019. The 10 gram vials are on back order and the company estimates a release date of 2nd quarter 2019.
• Hikma has cefazolin 500 mg vials on back order and the company estimates a release date of late-April to early-May 2019. The 1 gram and 10 gram vials are on allocation.
• Pfizer has 1 gram and 10 gram vials on back order and the company estimates a release date of March 2021. The 1 gram ADD-Vantage vials are on back order and the company estimates a release date of May 2019.
• Sagent has cefazolin 500 mg, 1 gram, and 10 gram vials on intermittent back order and the company will release product on a monthly basis.
• Samson Medical Technologies has cefazolin 100 gram SmartPak bags on back order and the company estimates a release date in April 2019.
• WG Critical Care has cefazolin 500 mg vials on back order and the company cannot estimate a release date. The 1 gram vials are on intermittent back order with regular releases. The 10 gram vials are on back order and the company estimates a release date of late-April 2019.


**Amphotericin B Injection**

_April 22, 2019_

_Reason for the Shortage_

- X-Gen has amphotericin B on shortage due to manufacturing delays. They are the sole suppliers of amphotericin B lyophilized powder for injection.
- Lipid-based amphotericin is not affected by this shortage.

_Estimated Resupply Dates_

- X-Gen has amphotericin B 50 mg vials on back order and the company estimates a release date of late-April 2019.


**5% Lidocaine and 7.5% Dextrose Injection**

_April 22, 2019_

_Reason for the Shortage_

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

_Estimated Resupply Dates_

- Pfizer has 5% lidocaine and 7.5% dextrose 2 mL ampules on long-term back order and the company estimates a release date of March 2020.


**Vecuronium Bromide Injection**

_April 23, 2019_

_Reason for the Shortage_

- Pfizer has vecuronium on shortage due to manufacturing delays.
- Teva has vecuronium on allocation due to increased demand.
Pfizer sold vecuronium injection to Mylan Institutional in December 2013. Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014. Sun Pharma has vecuronium available. Sagent is not marketing vecuronium 10 mg and 20 mg vials. Fresenius Kabi has vecuronium available.

Estimated Resupply Dates
- Mylan Institutional has vecuronium 20 mg vials on back order with an estimated release date of mid-May 2019.
- Pfizer has vecuronium 10 mg and 20 mg vials on back order and the company estimates a release date of September 2019.


Vancomycin Hydrochloride Injection
April 23, 2019
Reason for the Shortage
- Alvogen has vancomycin injection available.
- Athenex has vancomycin injection available.
- AuroMedics has vancomycin injection available.
- Pfizer has vancomycin vials on back order due to manufacturing delays.
- Fresenius Kabi has vancomycin injection on shortage due to increased demand.
- Mylan Institutional has vancomycin injection available.
- Baxter has vancomycin injection available.
- Samson Medical Technologies has vancomycin injection available.
- Sagent has vancomycin injection available.
- Xellia Pharmaceuticals has vancomycin injection available.

Estimated Resupply Dates
- Baxter has all vancomycin presentations on allocation.
- Pfizer has 500 mg ADD-Vantage vials, 500 mg vials, 750 mg vials, 750 mg ADD-Vantage vials, 1 gram vials, and 10 gram vials available in limited supply. The 1 gram ADD-Vantage vials are on back order and the company estimates a release date of April 2019.


Trifluoperazine Tablets
April 23, 2019
Reason for the Shortage
- Mylan did not provide a reason for the shortage.
- Upsher-Smith did not provide a reason for the shortage.

Estimated Resupply Dates
- Mylan has trifluoperazine 1 mg, 2 mg, and 5 mg tablets in 100 count bottles on back order and the company estimates a release date of early-May 2019 for the 1 mg tablets, late-April to early-May 2019 for the 2 mg tablets, and late-April 2019 for the 5 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 mid- to late-June 2019 for the 1 mg tablets and early-June 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 available in limited supply. 

**Remifentanil Injection**  
**April 23, 2019**

**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 5 mg vials on back order and the company estimates a release date of late-April 2019.
- Fresenius Kabi has remifentanil 2 mg and 5 mg vials on back order and the company cannot estimate a release date.


**Penicillamine**  
**April 23, 2019**

**Reason for the Shortage**

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

**Estimated Resupply Dates**

- Mylan has Depen 250 mg tablets on back order and the company estimates a release date of mid- to late-August 2019.


**Norepinephrine Bitartrate Injection**  
**April 23, 2019**

**Reason for the Shortage**

- Baxter did not provide a reason for the shortage.
- Pfizer has Levophed on shortage due to manufacturing delays.
- Teva had 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 March 2020


**Mycophenolate Mofetil Capsules and Tablets**  
**April 23, 2019**

**Reason for the Shortage**

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

Estimated Resupply Dates
• Accord has all mycophenolate mofetil presentations on allocation.
• Ascend has all mycophenolate mofetil presentations on intermittent back order and the company is releasing product as it becomes available.
• Hikma has mycophenolate mofetil 250 mg capsules in 100 count and 500 count and 500 mg tablets in 100 count and 500 count on allocation.
• Mylan has mycophenolate mofetil 250 mg capsules in 500 count on back order and the company estimates a release date of mid-June 2019. The 500 mg tablets in 500 count are on back order and the company estimates a release date of mid-June 2019. The 250 mg capsules and 500 mg tablets in unit-dose blister packs are on back order and the company estimates a release date of early-July 2019 for the 250 mg capsules and late-May 2019 for the 500 mg tablets.
• Sandoz has mycophenolate mofetil 250 mg capsules in 1440 count are on back order and the company estimates a release date of late-April 2019.


Meperidine Hydrochloride Injection
April 23, 2019
Reason for the Shortage
• Pfizer has Demerol injection on shortage due to manufacturing delays.
• ICU Medical discontinued meperidine 30 mL PCA vials.

Estimated Resupply Dates
• Hikma has meperidine 50 mg/mL 1 mL vials and 100 mg/mL 1 mL vials on back order and the company estimates a release date of May to June 2019.
• Pfizer has Demerol 100 mg/mL 20 mL vials and on back order and the company estimates a release date of March 2020. The 25 mg/mL 1 mL Carpuject syringes, 50 mg/mL 1 mL Carpuject syringes, and 100 mg/mL 1 mL syringes are on back order and the company estimates a release date of October 2019. The 75 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of September 2019. The 50 mg/mL 30 mL vials are on back order and the company estimates a release date of December 2019.


Ketamine Injection
April 23, 2019
Reason for the Shortage
• Hikma did not provide a reason for the shortage.
• Mylan Institutional did not provide a reason for the shortage.
• Par has Ketalar on shortage due to increased demand.
• Pfizer has ketamine on shortage due to manufacturing delays.

Estimated Resupply Dates
Hikma has ketamine 50 mg/mL 10 mL and 100 mg/mL 5 mL vials on back order and the company estimates a release date of late-April 2019.

Mylan Institutional has ketamine 50 mg/mL 10 mL vials and 100 mg/mL 10 mL vials on back order and the company estimates a release date of late-April 2019.

Pfizer has ketamine 50 mg/mL 10 mL vials on back order and the company estimates a release date of January 2020. The 100 mg/mL 5 mL vials are on back order and the company estimates a release date of April 2020.

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.


**Haloperidol Tablets**
**April 23, 2019**
Reason for the Shortage
- Mylan is discontinuing their haloperidol tablets in bottles.
- Sandoz has discontinued all haloperidol tablet presentations.

Estimated Resupply Dates
- Mylan has haloperidol 0.5 mg, 1 mg, 2 mg, 5 mg, and 10 mg tablets in 100 count unit-dose packs on back order and the company estimates a release date of late-July to early-August 2019.
- Zydus has all haloperidol tablet presentations on allocation.


**Furosemide Tablets**
**April 23, 2019**
Reason for the Shortage
- Major discontinued furosemide tablets in early-2018.
- Mylan did not provide a reason for the shortage.
- Hikma states the shortage is due to manufacturing delays.
- Sandoz discontinued furosemide tablets in late-August 2017.
- Teva discontinued furosemide tablets in June 2018

Estimated Resupply Dates
- Hikma has furosemide 20 mg tablets in 100 count unit dose packs, 20 mg tablets in 100 count and 1,000 count bottles, 40 mg tablets in 100 count unit dose packs, 40 mg tablets in 100 count and 1,000 count bottles, 80 mg tablets in 100 count bottles, and 80 mg tablets in 100 count unit dose packs on allocation.


**Diphenhydramine Injection**
**April 23, 2019**
Reason for the Shortage
- Fresenius Kabi had diphenhydramine injection on shortage due to increased demand.
- Hikma did not provide a reason for the shortage.
- Mylan did not provide a reason for the shortage.
- Pfizer has diphenhydramine injection on shortage due to manufacturing delays.
Estimated Resupply Dates

- Mylan Institutional has diphenhydramine 50 mg/mL 10 mL vials on back order and the company estimates a release date of late-April 2019.
- Pfizer has diphenhydramine 50 mg/mL 1 mL vials on back order and the company estimates a release date of September 2019.


**Diltiazem Extended-Release Capsules (Twice-Daily Dosing)**

**April 23, 2019**

Reason for the Shortage

- Mylan did not provide a reason for the shortage.

Estimated Resupply Dates

- Mylan Institutional has diltiazem extended-release 90 mg and 120 mg capsules in 100 count unit-dose packs on back order and the company estimates a release date of late-April to early-May 2019.


**Dexrazoxane Injection**

**April 23, 2019**

Reason for the Shortage

- Cumberland Pharmaceuticals relaunched Totect in late-July 2017.
- Hikma did not provide a reason for the shortage.
- Mylan Institutional did not provide a reason for the shortage.
- Pfizer states manufacturing delay as the reason for the shortage.

Estimated Resupply Dates

- Mylan Institutional has dexrazoxane 250 mg and 500 mg vials on back order and the company estimates a release date of early-May 2019.
- Pfizer has Zinecard 500 mg vials on back order and the company estimates a release date of December 2019.
- Hikma has short-dated dexrazoxane 500 mg vials available with an expiration date of < March 2020.


**Ciprofloxacin Injection**

**April 23, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

- All marketed presentations are available.

Acetazolamide Injection
April 23, 2019
Reason for the Shortage
- Hikma did not provide a reason for the shortage.
- Mylan Institutional did not provide a reason for the shortage.
- X-Gen had acetazolamide on shortage due to manufacturing delays

Estimated Resupply Dates
- Hikma has acetazolamide 500 mg vials on back order and the company estimates a release date of May to June 2019.
- Mylan Institutional has acetazolamide 500 mg vials on back order and the company estimates a release date of mid- to late-June 2019.


Spironolactone Tablets
April 24, 2019
Reason for the Shortage
- Accord, Amneal, Cadista, Mylan, and Sun Pharma did not provide a reason for the shortage.
- Par discontinued spironolactone tablets in August 2018.
- Pfizer states Aldactone is on shortage due to manufacturing delays

Estimated Resupply Dates
- Accord has spironolactone 50 mg and 100 mg tablets in 500 count bottles on back order and the company estimates a release date in late-April 2019.
- Cadista has all presentations on allocation.
- Mylan has spironolactone 50 mg tablets in 100 and 500 count bottles and 25 mg tablets in 100 count bottles on back order and the company estimates a release date of mid-June 2019 for the 25 mg and 50 mg tablets in 100 count bottles and late-May 2019 for the 50 mg tablets in 500 count bottles. The 50 mg tablets in 100 count unit-dose packs are on back order and the company estimates a release date of early-June 2019. The 100 mg tablets in 100 count unit-dose packs are on back order and the company cannot estimate a release date.
- Pfizer has Aldactone 50 mg tablets in 100 count bottles on back order and the company estimates a release date of June 2019.
- Sun Pharma has spironolactone 25 mg tablets in 100 and 1000 count, 50 mg tablets in 60 and 500 count, and 100 mg in 100 count on back order and the company cannot estimate a release date.


Sodium Polystyrene Sulfonate Powder
April 24, 2019
Reason for the Shortage
- CMP Pharma has sodium polystyrene sulfonate on back order due to a raw material shortage. They are using available powder to make suspension.
- ECI Pharmaceuticals did not provide a reason for the shortage.
- KVK-Tech did not provide a reason for the shortage.
- Sunrise Pharmaceuticals has sodium polystyrene sulfonate on back order due to a raw material shortage.
Trigen did not provide a reason for the shortage.

Estimated Resupply Dates
- CMP Pharma has sodium polystyrene sulfonate in 454 gram bottles on back order and the company cannot estimate a release date.
- ECI Pharmaceuticals has sodium polystyrene sulfonate in 454 gram bottles on allocation.
- KVK Tech has sodium polystyrene sulfonate in 454 gram bottles on back order and the company estimates a release date in early-May 2019.
- Sunrise Pharmaceuticals has sodium polystyrene sulfonate in 15 gram and 454 gram bottles on intermittent back order and the company cannot estimate release dates.
- Trigen has sodium polystyrene sulfonate in 454 gram bottles on allocation.


Nitrofurantoin Oral Suspension
April 24, 2019
Reason for the Shortage
- Amneal did not provide a reason for the shortage.
- Casper Pharma did not provide a reason for the Furadantin shortage.
- Lupin is no longer manufacturing this product.
- Nostrum has nitrofurantoin oral suspension available.
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates
- Amneal has nitrofurantoin oral suspension on back order and the company cannot estimate a release date.
- Casper has Furadantin oral suspension on back order and the company cannot estimate a release date.
- Teva has nitrofurantoin oral suspension on back order and the company cannot estimate a release date.


Methotrexate Injection
April 24, 2019
Reason for the Shortage
- Accord has methotrexate injection on back order due to increased demand.
- Fresenius Kabi has methotrexate injection available.
- Mylan Institutional has methotrexate injection available. Mylan Institutional discontinued the 40 mg/mL 2 mL, 4 mL, and 8 mL vials in late-2017.
- Pfizer has methotrexate injection available.
- Teva has methotrexate injection available.
- Hikma has methotrexate injection available.

Estimated Resupply Dates
- Accord has methotrexate 25 mg/mL 2 mL preservative-free vials on back order and the company estimates a release date of early-May 2019.

**Lorazepam Tablets**

**April 24, 2019**

**Reason for the Shortage**

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

**Estimated Resupply Dates**

- Leading has all lorazepam tablets on allocation.
- Major has lorazepam 0.5 mg, 1 mg, and 2 mg tablets in 100 count bottles on back order and the company estimates a release date in mid-May 2019. The 0.5 mg, 1 mg, and 2 mg tablets in 100 count unit-dose packages are on back order and the company estimates a release date in early-June 2019 for the 0.5 mg tablets and 1 mg tablets in 100 count unit-dose packages and early-May 2019 for the 2 mg tablets in 100 count unit-dose packages.
- Mylan Institutional has lorazepam 0.5 mg, 1 mg, and 2 mg tablets in 100-count unit-dose packages on back order and the company estimates release dates of late-April to early-May 2019.
- Teva has lorazepam 2 mg tablet in 1000 count bottles on back order and the company estimates a release date of mid-June 2019. Most other lorazepam tablet presentations are on back order and the company estimates a release date in early-May 2019.


**Immune Globulin, Subcutaneous (Human)**

**April 24, 2019**

**Reason for the Shortage**

- Baxalta has HyQvia and Cuvitru on shortage due to increased demand.
- CSL Behring has Hizentra available.

**Estimated Resupply Dates**

- Baxalta has Cuvitru on allocation and the company is reviewing all orders.
- Baxalta has HyQvia on allocation and the company is reviewing all orders.


**Immune Globulin, Intravenous or Subcutaneous (Human)**

**April 24, 2019**

**Reason for the Shortage**

- Grifols has Gamunex-C on shortage due to increased market demand.
- Takeda has Gammagard Liquid on shortage due to increased demand.

**Estimated Resupply Dates**

- Grifols has all Gamunex-C presentations on allocation.
- Takeda has all Gammagard Liquid presentations on intermittent back order and the company is allocating product as it becomes available.
Hepatitis B Vaccine (Recombinant)
April 24, 2019
Reason for the Shortage
- Merck has Recombivax HB on shortage due to increase in global demand.
- GlaxoSmithKline has Engerix B products available.
- GlaxoSmithKline discontinued Engerix B pediatric vials in October 2017.

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

Hepatitis A Virus Vaccine Inactivated
April 24, 2019
Reason for the Shortage
- Merck has Vaqta available.
- Merck discontinued Vaqta adult formulation 50 U/1 mL vials in 1 count in January 2019.
- GlaxoSmithKline has Havrix available.
- GlaxoSmithKline discontinued the Havrix pediatric vials in March 2019. The Havrix adult vials were discontinued in November 2017.

Heparin Injection
April 24, 2019
Reason for the Shortage
- Fresenius Kabi has heparin on shortage due to increased demand.
- Hikma did not provide a reason for the shortage.
- Mylan has most heparin presentations available.
- Pfizer did not provide a reason for the shortage.
- Sagent has heparin on shortage due to manufacturing issues and increased demand.

Estimated Resupply Dates
- Fresenius Kabi has heparin 1,000 unit/mL 2 mL vials on back order and the company estimates a release date of late-April to early-May 2019. The 10,000 unit/mL 0.5 mL preservative free vials and 5 mL vials are on back order and the company estimates a release date of late-April 2019 for the 0.5 mL vials and late-May 2019 for the 5 mL vials. The 10,000 unit/mL 4 mL vials are on back order and the company cannot estimate a release 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 1,000 unit/mL 2 mL vials are on back order and the company estimates a release date of May 2019.
Mylan has 5,000 unit/mL 1 mL vials on back order and the company estimates a release date in mid-May 2019.

Pfizer has 5,000 unit/mL 1 mL Carpuject syringes and 10,000 unit/mL 1 mL glass vials on back order and the company estimates a release date of June 2019. The 1,000 unit/mL 10 mL vials are on back order and the company cannot estimate a release date. The 1,000 unit/mL 1 mL glass vials, 5,000 unit/mL 1 mL glass vials, and 10,000 unit/mL 0.5 mL Carpuject syringes are on back order and the company estimates a release date of May 2019. The 5,000 unit/mL 10 mL vials are on back order and the company estimates a release date in December 2019.

Sagent has 1,000 unit/mL 1 mL vials, 1,000 unit/mL 2 mL vials, 1,000 unit/mL 10 mL, 5,000 unit/mL 1 mL vials, 10,000 unit/mL 4 mL vials, and 20,000 unit/mL 1 mL vials on allocation. The 5,000 unit/mL 10 mL vials and 10,000 unit/mL 1 mL vials are on back order and the company estimates a release date of May 2019.


Fludrocortisone Acetate Tablets
April 24, 2019
Reason for the Shortage
- Impax did not provide a reason for the shortage.
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates
- Impax has fludrocortisone acetate 0.1 mg tablets on intermittent back order and the company is releasing product regularly.
- Teva has fludrocortisone acetate 0.1 mg tablets temporarily unavailable and the company cannot estimate a release date.


Etomidate Injection
April 24, 2019
Reason for the Shortage
- American Regent is not currently marketing etomidate.
- Athenex did not provide a reason for the current shortage.
- AuroMedics did not provide a reason for the current shortage.
- Hikma has etomidate available.
- Mylan did not provide a reason for the current shortage.
- Par Sterile Products discontinued etomidate in early 2015.
- Pfizer has Amidate on shortage due to manufacturing delays. Pfizer discontinued etomidate ampules in October 2016.
- Sagent is no longer marketing etomidate.
- Zydus has etomidate available

Estimated Resupply Dates
- Athenex has etomidate 2 mg/mL 10 mL and 20 mL vials on back order and the company cannot estimate a release date.
- AuroMedics has etomidate 2 mg/mL 10 mL and 20 mL vials on intermittent back order and the company is releasing product as it becomes available.
Pfizer has Amidate 2 mg/mL 10 mL vials on back order and the company estimates a release date of May 2019. The 2 mg/mL 20 mL LifeShield syringes on back order and the company estimates a release date of March 2020.


**Enoxaparin Sodium Injection**

**April 24, 2019**

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

**Estimated Resupply Dates**
- Fresenius Kabi has enoxaparin 120 mg/0.8 mL prefilled syringes on back order and the company estimates a release date of mid-May 2019.
- Sanofi-Aventis has all Lovenox prefilled syringes on allocation.
- Teva has enoxaparin 150 mg/1 mL and 120 mg/0.8 mL prefilled syringes on allocation.
- Winthrop has all enoxaparin prefilled syringes on allocation.


**Dorzolamide 2% and Timolol 0.5% Ophthalmic Solution**

**April 24, 2019**

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

**Estimated Resupply Dates**
- Akorn has Cosopt 2%/0.5% ophthalmic solution in 10 mL bottles and dorzolamide 2% and timolol 0.5% ophthalmic solution in 10 mL bottles on allocation.
- Bausch Health has dorzolamide 2% and timolol 0.5% ophthalmic solution in 10 mL bottles on back order and the company estimates a release date of late-April to mid-May 2019.
- 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 May 2019.

Dexmedetomidine Hydrochloride 4 mcg/mL Premix for Injection
April 24, 2019
Reason for the Shortage
- Pfizer did not provide a reason for the shortage.
- WG Critical Care began marketing premixed bags in November 2018.
- Baxter has dexmedetomidine premixed bags available.

Estimated Resupply Dates
- Pfizer has Precedex 4 mcg/mL 20 mL glass vials and 4 mcg/mL 50 mL and 100 mL premixed bottles available in limited supply.


Dexmedetomidine Hydrochloride 100 mcg/mL Vials for Injection
April 24, 2019
Reason for the Shortage
- Accord has dexmedetomidine vials available.
- Akorn has dexmedetomidine vials available.
- Athenex has dexmedetomidine vials available.
- AuroMedics has dexmedetomidine vials available.
- Fresenius Kabi has dexmedetomidine vials available.
- Hikma has dexmedetomidine vials available.
- Mylan did not provide a reason for the shortage.
- Par has dexmedetomidine vials available.
- Pfizer has dexmedetomidine vials available.
- Sandoz has dexmedetomidine vials available.
- Sun Pharma has dexmedetomidine vials available.
- Teva did not provide a reason for the temporary discontinuation of dexmedetomidine vials.
- WG Critical Care has dexmedetomidine vials on back order due to manufacturing delays.

Estimated Resupply Dates
- Mylan has dexmedetomidine 100 mcg/mL 2 mL vials available with an expiration date of September 2019.
- Teva has temporarily discontinued dexmedetomidine 100 mcg/mL 2 mL vials and the company cannot estimate a resupply date.
- WG Critical Care has dexmedetomidine 100 mcg/mL 4 mL and 10 mL vials on back order and the company estimates a release date of early-May 2019.


Clonidine Hydrochloride Injection
April 24, 2019
Reason for the Shortage
- American Regent and Fresenius Kabi are not currently marketing clonidine injection.
- Hikma did not provide a reason for the shortage.
- Mylan Institutional did not provide a reason for the shortage.
- X-Gen did not provide a reason for the shortage.

Estimated Resupply Dates
• Hikma has clonidine 0.1 mg/mL 10 mL vials on back order and the company estimates a release date of May 2019. The 0.5 mg/mL 10 mL vials are on back order and the company cannot estimate a release date.
• X-Gen has clonidine 0.1 mg/mL 10 mL vials on back order and the company estimates a release date of early-May 2019.
• Mylan Institutional has Duraclon 0.1 mg/mL 10 mL vials on back order and the company estimates a release date of late-April 2019.


**Calcium Chloride Injection**
**April 24, 2019**

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

Estimated Resupply Dates
• Pfizer has calcium chloride 100 mg/mL 10 mL Ansyrsyringes and 100 mg/mL 10 mL LifeShield syringes on back order and the company estimates a release date of May 2019.


**Argatroban Injection**
**April 24, 2019**

Reason for the Shortage
• AuroMedics has argatroban available.
• Chiesi has argatroban available.
• Fresenius Kabi 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.
• Par has argatroban available.
• Pfizer had argatroban on shortage due to manufacturing delay.
• Sandoz did not provide a reason for the shortage.
• Teva has argatroban temporarily unavailable.

Estimated Resupply Dates
• Fresenius Kabi has argatroban 100 mg/mL 2.5 mL vials on back order and the company estimates a release date in early-May 2019.
• Hikma has argatroban 1 mg/mL 50 mL vials and 100 mg/mL 2.5 mL vials on allocation.
• Mylan has argatroban 100 mg/mL 2.5 mL vials on back order and the company estimates a release date in mid-May 2019.
• Novartis has argatroban 100 mg/mL 2.5 mL vials available with short expiration dating (November 2019).
• Sandoz has argatroban 1 mg/mL 50 mL vials on back order and the company cannot estimate a release date.
Ampicillin Sodium and Sulbactam Sodium Injection  

April 24, 2019  
Reason for the Shortage  
- Pfizer has discontinued generic ampicillin sulbactam except for the 1.5 gram and 3 gram ADD-Vantage vials.  
- Sagent has ampicillin sulbactam vials on back order due to manufacturing delays and increased demand.  
- Sandoz cannot provide a reason for the shortage.  
- WG Critical Care states the shortage is 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 vials on allocation. The 3 gram and 15 gram vials are on back order and the company cannot estimate a release date.  
- 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 mid-May 2019 for the 1.5 and 3 gram vials and mid-July 2019 for the 15 gram vials.  
- Pfizer has Unasyn 15 gram vials available in limited supply. Unasyn 3 gram bulk vials are on back order and the company estimates a release date of April 2019. The 1.5 gram vials and 3 gram ADD-Vantage vials are on back order and the company estimates a release date of July 2019.  
- 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 vials and 15 gram bulk vials on back order and the company cannot estimate a release date. The 3 gram vials are on back order and the company estimates a release date of May 2019.  
- WG Critical Care has ampicillin sulbactam 1.5 gram and 3 gram vials on back order and the company estimates a release date of late-May 2019. The 15 gram bulk vials are on back order and the company cannot estimate a release date.

Abciximab Injection  

April 24, 2019  
Reason for the Shortage  
- Janssen has Reopro on shortage due to a production interruption at their third party manufacturing site. The contract manufacturer cannot guarantee supply continuity in 2018 and beyond.  
- There are no other suppliers of abciximab.

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

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