



Drug Information Update

February 2019



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NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
VIGABATRIN	500 MG TABLET	ACTAVIS TEVA	SABRIL
DESFLURANE	100% INHALATION LIQUID	SANDOZ	SUPRANE
BUPRENORPHINE HCL/NALOXONE HCL	8 MG-2 MG FILM	DR. REDDY'S LAB	SUBOXONE
TOREMIFENE CITRATE	60 MG TABLET	RISING PHARM	FARESTON
SIROLIMUS	1 MG/ML ORAL SOLUTION	VISTAPHARM	RAPAMUNE
HYDROCORTISONE/MINERAL OIL/WHITE PETROLATUM	1% OINTMENT	SOLUBIOMIX LLC	HYDROCORTISONE
GANIRELIX ACETATE	250 MCG/ 0.5 ML SYRINGE	ORGANON PHARM	ANTAGON
SEVELAMER HCL	800 MG TABLET	WINTHROP US	RENAGEL
BUPRENORPHINE HCL/NALOXONE HCL	2 MG – 0.5 MG, 4 MG – 1 MG, 12 MG – 3MG FILM	ALVOGEN INC	SUBOXONE
MINOCYCLINE HCL	80MG, 105 MG ER TABLET	ASCEND LABORATO	SOLODYN
FLUTICASONE/SALMETEROL	100 MCG- 50 MCG, 250 MCG- 50 MCG, 500 MCG – 50 MCG BLST W/ DEV	PRASCO LABS	ADVAIR DISKUS
ACYCLOVIR	5% CREAM	PERRIGO CO	ZOVIRAX

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
INSULINS	AFREZZA	INSULIN REGULAR, HUMAN	8 UNITS (90) CARTRIDGE FOR INHALATION	NEW COMBINATION PACKAGE
OPIOID ANALGESICS	LEVORPHANOL TARTRATE	LEVORPHANOL TARTRATE	3 MG TABLET	NEW STRENGTH
OPIOID ANALGESICS	DSUVIA	SUFENTANIL CITRATE	30 MCG SUBLINGUAL TABLET	NEW DOSE FORM, NEW STRENGTH
ESTROGEN AND PROGESTIN COMBINATIONS	BIJUVA	ESTRADIOL - PROGESTERONE	1 MG- 100 MG CAPSULE	NEW COMBINATION
OPIOID ANALGESIC AND NON-SALICYLATE ANALGESICS	APADAZ	BENZHYDROCODONE - ACETAMINOPHEN	4.08 - 325 MG, 6.12 - 325 MG, 8.16 - 325 MG, TABLET	NEW ENTITY
ANTIPARKINSONISM DRUGS, OTHER	INBRIJA	LEVODOPA	42 MG CAP W/ DEVICE FOR INHALATION	NEW DOSAGE FORM, NEW STRENGTH
INTESTINAL MOTILITY STIMULANTS	MOTTEGRITY	PRUCALOPRIDE SUCCINATE	1 MG, 2 MG TABLET	NEW ENTITY

NEW INDICATIONS (EXISTING DRUGS)

IMBRUVICA®

January 28, 2019

The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the U.S. Food and Drug Administration (FDA) approval of IMBRUVICA® (ibrutinib) in combination with obinutuzumab in treatment-naïve patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), the most common form of leukemia in adults. This is the first approval for a non-chemotherapy combination regimen for treatment-naïve patients with CLL/SLL, and marks the tenth FDA approval for IMBRUVICA® since its U.S. launch in November 2013. The approval expands the label for IMBRUVICA® in frontline CLL/SLL beyond its use as a monotherapy to include combination use with obinutuzumab. IMBRUVICA®, a Bruton's tyrosine kinase (BTK) inhibitor, is jointly developed and commercialized by Janssen Biotech, Inc. and Pharmacyclics LLC, an AbbVie company.

Source: The Janssen Pharmaceutical Companies of Johnson & Johnson

KEYTRUDA®

February 19, 2019

Merck, known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved KEYTRUDA®, Merck's anti-PD-1 therapy, for the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection based on results from the EORTC1325/KEYNOTE-054 trial. This pivotal Phase 3 trial, which was conducted in collaboration with the European Organization for Research and Treatment of Cancer (EORTC), demonstrated that KEYTRUDA® significantly prolonged recurrence-free survival (RFS), reducing the risk of disease recurrence or death by 43 percent compared to placebo in patients with resected, high-risk stage III melanoma (HR=0.57 [95% CI, 0.46, 0.70]; p<0.001). KEYTRUDA® is the first anti-PD-1 therapy studied in the adjuvant setting across patients with stage IIIA (>1 mm lymph node metastasis), IIIB and IIIC melanoma.

Source: Merck



DARZALEX®

February 12, 2019

The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the U.S. Food and Drug Administration (FDA) has approved a split-dosing regimen for DARZALEX® (daratumumab), providing healthcare professionals and patients with multiple myeloma an option to split the first infusion over two consecutive days. The U.S. FDA approval is based on data from the Phase 1b EQUULEUS (MMY1001) clinical study, which demonstrated DARZALEX® pharmacokinetic (PK) concentrations were comparable at the end of weekly dosing, regardless of whether the first dose was administered as a split infusion or as a single infusion.

Source: The Janssen Pharmaceutical Companies of Johnson & Johnson

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Tris Pharma, Inc. Expands Its Voluntary Nationwide Retail Recall of Ibuprofen Oral Suspension Drops, USP, 50 mg per 1.25 mL, Due to Higher Concentration of Ibuprofen

[Posted 1/29/2019]

Tris Pharma, Inc. is expanding the scope of its November 2018 recall by adding three (3) additional lots of Ibuprofen Oral Suspension Drops, USP, 50 mg per 1.25 mL, to the retail (pharmacy) level. Some units from these batches have been found to have higher levels of Ibuprofen concentration.

Infants already susceptible to the adverse effects of ibuprofen may be at a slightly higher risk if they receive medication from an impacted bottle. There is a remote probability that infants, who may be more susceptible to a higher potency level of drug, may be more vulnerable to permanent NSAID-associated renal injury. Some units from these six (6) lots have been found to contain Ibuprofen as high as 10% above the specified limit. Studies have shown that safety issues or toxicity is generally accepted to be a concern in infants at doses in excess of 700% of the recommended dose. To date, no serious adverse events have been reported related to this recall.

The product is used as a pain reliever/fever reducer and is packaged in ½ oz. and 1 oz. bottles. This voluntarily recall includes the six (6) lots listed below:

Lot No.	NDC	Expiration	Description	Company
4718	59779-925-23	12/19	CVS Health: Infants' Ibuprofen Concentrated Oral Suspension, USP, 50 mg per 1.25 mL, in 0.5 oz. bottle	CVS Pharmacy
00717005A	49035-125-24	02/19	Equate: Infants' Ibuprofen Concentrated Oral Suspension, USP, 50 mg per 1.25 mL, in 1.0 oz. bottle	Wal-Mart Stores Inc.
00717009A (Previously announced)	49035-125-23	02/19	Equate: Ibuprofen Oral Suspension Drops, USP, 50 mg per 1.25 ml, in 0.5 oz. bottle	Wal-Mart Stores Inc.
00717015A (Previously announced)	49035-125-23	04/19	Equate: Ibuprofen Oral Suspension Drops, USP, 50 mg per 1.25 ml, in 0.5 oz. bottle	Wal-Mart Stores Inc.
00717024A (Previously announced)	49035-125-23	08/19	Equate: Ibuprofen Oral Suspension Drops, USP, 50 mg per 1.25 ml, in 0.5 oz. bottle	Wal-Mart Stores Inc.

Lot No.	NDC	Expiration	Description	Company
	49035-125-23		CVS Health: Ibuprofen Oral Suspension Drops, USP, 50 mg per 1.25 ml, in 0.5 oz. bottle	CVS Pharmacy
	55319-250-23		Family Wellness: Ibuprofen Oral Suspension Drops, USP, 50 mg per 1.25 ml, in 0.5 oz. bottle	Family Dollar Services Inc.

Tris Pharma, Inc. manufactures Ibuprofen Oral Suspension Drops, USP for a single customer, who markets and distributes the product to retailers. The retailers should stop further distribution of the affected lots, which are being recalled. Tris Pharma, Inc. has notified its customer by urgent recall notice and has arranged for the return of recalled products from retailers and distributors.

Consumers with questions regarding this recall may contact Tris Customer Service by 732-940-0358 (Monday through Friday, 8:00 AM ET- 5:00 PM PT) or via email at micc_tris@vigilarebp.com. Consumers, who may be concerned, should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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

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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA). The FDA has approved a class II retail level recall for this recall.

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

FDA warns compounders not to use glutathione from Letco Medical to compound sterile drugs

[Posted 2/1/2019]

FDA is warning compounders not to use glutathione-L-reduced powder distributed by Letco Medical, Decatur, Alabama, to compound sterile injectable drugs for patients. Based on reported adverse events, the agency has concerns with use of the Letco distributed glutathione to compound injectable drugs due to potential endotoxins.

Letco supplied this glutathione powder to about 100 compounders in 30 states. FDA urges compounders that use glutathione to make sterile injectable drugs to ensure the glutathione powder is appropriate for compounding sterile drugs, including checking with their supplier.

FDA is aware of seven patients who experienced various adverse events ranging from nausea and vomiting to difficulty breathing, which required one patient to be hospitalized immediately after receiving glutathione 200mg/mL intravenous injection. FDA believes high levels of endotoxin may have contributed to these adverse events. Following these reports, FDA has received varying third-party test results on the levels of endotoxin that may be present in Letco's glutathione powder. FDA testing is underway.

Letco repackaged the glutathione into five sizes – 25gm, 50gm, 100gm, 500gm and 1kg – and distributed 13 lots with an expiration date of 6/17/2020:

- 1808030041
- 1808030042
- 1808030043
- 1808030044
- 1808030045
- 1808290090
- 1808290091
- 1808290092
- 1808290093
- 1810150048
- 1810150049
- 1810150050
- 1810150051

Health care professionals should check with their compounders regarding the source of the glutathione used to make sterile drugs for their patients. Patients who have concerns should talk to their health care professionals.

FDA is investigating this incident and will provide additional information as it becomes available.

Patients and health care professionals should report any adverse reactions related to the use of compounded glutathione to FDA's MedWatch program:

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

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

Dr. Reddy's Laboratories Continues its Voluntary Nationwide Recall of Levetiracetam in 0.54% Sodium Chloride Injection 1500mg/100mL Due to Mislabeling

[Posted 2/4/2019]

Dr. Reddy's Laboratories Ltd. announced that its wholly owned subsidiary, Dr. Reddy's Laboratories, Inc. is continuing its voluntary nationwide recall of lot ABD807 of Levetiracetam in 0.54% Sodium Chloride Injection, 1,500 mg/100 mL (15 mg/mL) single-dose infusion bags to the hospital level in U.S.A.

The recall, which began in October 2018, was originally initiated due to a product complaint received for mislabeling. The pre-printed text content on the infusion bag (primary container) for the lot indicates product information as Levetiracetam in 0.75% Sodium Chloride Injection (1000mg/100ml). The label on the external foil pouch has the product information as Levetiracetam in 0.54% Sodium Chloride Injection (1500mg/100ml). To date, there have been no reports of adverse events related to this recall.

Patients who may have been administered the mislabeled product could experience adverse reactions such as somnolence, agitation, aggression, depressed level of consciousness, respiratory depression and coma related to over dosage.

Levetiracetam Injection is an antiepileptic drug indicated for adjunct therapy in adults (more than 16 years of age) with the following seizure types when oral administration is temporarily not feasible: Partial onset seizures, Myoclonic seizures inpatients with juvenile myoclonic epilepsy, Primary generalized tonic-clonic seizures.

The batch was distributed in U.S.A. between August 14, 2018 and September 5, 2018.

The recalled batch is as follows:

Item Description	Manufacturer	NDC	Lot	Expiry Date
Levetiracetam in 0.54% Sodium chloride Injection, 1500mg/100mL	Gland Pharmaceuticals	43598-637-52	ABD807	05/2020

Dr. Reddy's Laboratories, Inc. has notified the distributors to arrange for return of any recalled product. Wholesalers, distributors, hospitals and pharmacies with an existing inventory of the lot being recalled, should stop use and distribution and quarantine the product immediately for return/replacement/etc. of all recalled products. Wholesalers, distributors and pharmacies that have further distributed the recalled product should notify any accounts or additional locations which may have received the

recalled product from them. For instructions on returning product or additional assistance, call Inmar at 1-800-967-5952 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

If patients have questions regarding this recall or to report an adverse event, please contact the Company's Medical Information Call Center at 1-888-375-3784 (1-888-DRL-DRUG) between the hours of 8 a.m. to 10 p.m. ET, Monday through Friday. Patients should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.

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

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

Important Safety Information: Levetiracetam in Sodium Chloride Injection

What important information should I know about Levetiracetam in Sodium Chloride Injection?

- Levetiracetam is an antiepileptic drug indicated for adult patients 16 years of age and older when oral administration is temporarily not feasible.
- Treatment with Levetiracetam may cause changes in behavior such as aggression, agitation, anger, anxiety, apathy, depression, hostility, irritability, and psychotic symptoms.
- Levetiracetam may cause drowsiness, sleepiness, and fatigue.
- Levetiracetam may cause serious dermatological reactions. Levetiracetam should be discontinued at the first sign of rash.
- Levetiracetam should be gradually withdrawn to minimize potential of increased seizure frequency.
- Levetiracetam blood levels may decrease during pregnancy. It is recommended that patients be monitored carefully during pregnancy.

Who should not use Levetiracetam in Sodium Chloride Injection?

- Patients with a known hypersensitivity to levetiracetam should not take this drug as angioedema and anaphylaxis have been reported.

What should I tell my healthcare provider before taking Levetiracetam in Sodium Chloride Injection?

Before taking Levetiracetam in Sodium Chloride Injection, tell your healthcare provider if you:

- Have or have had suicidal thoughts or behavior
- Have or have had kidney problems
- Become pregnant or intend to become pregnant

- Are nursing

Tell your healthcare provider about all medications and herbal products you take, including prescription and over-the-counter medications, vitamins and herbal supplements.

What are possible side effects of Levetiracetam in Sodium Chloride Injection?

- Headache
- Pain
- Depression
- Nervousness
- Ataxia
- Vertigo
- Amnesia
- Anxiety
- Pharyngitis
- Rhinitis
- Diplopia
- Fatigue

These are not all the possible side effects of Levetiracetam. Please refer to the Package Insert for a complete list of possible side effects.

Call your healthcare provider right away if you have any of the following:

- Changes in mood or behavior
- Signs or symptoms of an allergic reaction or increased swelling
- Signs or symptoms of a rash

The most common side effects of Levetiracetam in Sodium Chloride Injection?

- Drowsiness
- Sleepiness
- Fatigue
- Infection
- Dizziness

What should I avoid while taking Levetiracetam in Sodium Chloride Injection?

- Avoid driving or operating machinery until you know how levetiracetam affects you as levetiracetam may cause dizziness and sleepiness.

For more information, ask your healthcare provider or pharmacist. You are encouraged to report negative side effects of prescription drugs. To report suspected side effects, call Dr. Reddy's Laboratories Medical Information Call Center at 1-888-DRL-DRUG (1-888-375-3784) or via email to



medinfo@drreddys.com or contact the USFDA at 1-800-FDA-1088 (1-800-332-1088) or online at www.fda.gov/medwatch/report.htm.

Indication and Usage

Levetiracetam in Sodium Chloride Injection is an antiepileptic drug indicated for adult patients (16 years and older) when oral administration is temporarily not feasible. Levetiracetam in Sodium Chloride Injection is indicated as adjunctive therapy in the treatment of:

- Partial onset seizures in adults with epilepsy,
- Myoclonic seizures in adults with juvenile myoclonic epilepsy,
- Primary generalized tonic-clonic seizures in adults with idiopathic generalized epilepsy.

Levetiracetam in Sodium Chloride Injection is a clear, colorless, sterile solution that is available in a single-dose 100 mL dual port bag with an aluminum overwrap.

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

STUDIES AND RECENT TOPICS

[More blood pressure drugs may have shortages after recalls: FDA](#)

January 25, 2019

Additional shortages of blood pressure drugs in the United States are possible following recent recalls related to traces of a probable carcinogen found in some versions a particular class of hypertension medicines, the U.S. Food and Drug Administration said on Friday.

Source: Reuters

[Benzodiazepine Use May Increase Risk for Pneumonia](#)

January 29, 2019

Patients who either are currently or have recently taken benzodiazepines may have an increased risk of developing pneumonia, according to study results published in The International Journal of Geriatric Psychiatry.

System Source: pulmonologyadvisor.com

[Exclusive: Teva's generic EpiPen launch stalls months after approval](#)

January 31, 2019

Many of the largest U.S. pharmacies and drug distributors do not have Teva Pharmaceutical Industries Ltd's generic version of the life-saving EpiPen allergy treatment five months after it was approved for sale in the United States, pharmacy chains and a group that tracks drug shortages told Reuters.

Source: Reuters.com

[More over-75s should take statins, experts say](#)

February 1, 2019

There had been a lack of evidence about how much the cholesterol-lowering drugs benefit this age group. But the review found they cut the risk of major cardiovascular disease in all ages studied, including the over-75s.

Source: bbc.com



[FDA declines to approve Alkermes opioid-based depression drug](#)

February 1, 2019

The U.S. Food and Drug Administration on Friday declined to approve Alkermes PLC's opioid-based depression treatment, citing the need for additional data to prove the effectiveness of the drug.

The largely expected decision comes months after an advisory panel to the FDA strongly voted against the drug and raised questions on its safety and efficacy.

Source: Reuters.com

[Using Imodium for opioid-related withdrawal linked to heart complications](#)

February 4, 2019

Researchers from Rutgers University found that most patients who overdosed on Imodium did so because they were misusing it or abusing it as an opioid substitute, according to study results published in Clinical Toxicology.

Misuse of Imodium (loperamide, Johnson & Johnson) — which is inexpensive and available without a prescription — has become more problematic with the rise of the opioid epidemic, according to the study's authors.

Source: healio.com

[Acetaminophen undetectable in more than half of related DILI cases](#)

February 11, 2019

More than half of patients who presented in hospital with acetaminophen-induced acute liver injury or acute liver failure had undetectable levels of acetaminophen, according to a study recently published in Clinical Gastroenterology and Liver Disease.

Source: healio.com



Viaskin Peanut Application to be Resubmitted to the FDA

February 13, 2019

DBV Technologies has announced plans to again submit Biologics License Application (BLA) to the US Food and Drug Administration (FDA) for potential pediatric peanut allergy therapy Viaskin Peanut.

The company's BLA for the investigative drug was originally submitted late last year, and withdrawn by DBV after the FDA requested additional data on its manufacturing procedures and quality controls. The company now anticipates the application will be resubmitted in the second half of 2019.

Source: mdmag.com

Insurers Making It Harder to Treat Opioid Addiction: Study

February 15, 2019

Insurance rules that limit access to the addiction treatment medication buprenorphine may be worsening the U.S. opioid epidemic, a new study suggests.

"Buprenorphine is a safe and effective treatment that decreases deaths due to opioids and stops heroin and other opioid use. People on buprenorphine are able to get their lives back together," said study co-author Dr. Todd Korthuis. He's chief of the addiction medicine section at Oregon Health and Science University (OHSU) in Portland.

Source: healthday.com

U.S. top court rejects bid to block Indivior opioid drug copycat

February 19, 2019

The U.S. Supreme Court dealt a blow to Indivior Plc on Tuesday, clearing the way for a copycat version of the British pharmaceutical firm's lucrative opioid addiction treatment Suboxone Film in a victory for India-based generic drug maker Dr. Reddy's Laboratories.

Source: Reuters.com



Codeine: An Opioid Threat to Kids

February 19, 2019

Codeine is one of the drugs at the center of the opioid epidemic affecting adults and teens across the United States. There are also concerns about its effects on very young children -- not addiction, but life-threatening events and deaths due to codeine's side effects.

Source: healthday.com

RECALLS

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drug	5K Premium Enhancement capsule, 5000 mg, 1 count blister card, box of 30, Happy Together Inc., Boynton, FL UPC 649964965644	Class I	All lots within expiry	Marketed without an Approved NDA/ANDA; FDA analysis found product to be tainted with undeclared sildenafil and tadalafil	Happy Together, Inc. 1060 Audace Ave Apt 106 Boynton Beach, FL 33426-3346
Drugs	the silver bullet 10x Capsules, 725 mg each (proprietary blend of: Mucuna Pruriens Extract, Horny Goat Weed, Ginger Root Extract, Icariin, Wolf Berry (fruit) Lactase, Tribulus Terrestris Extract, Piperine), 10 count mylar package, Nature's Rx, Claremont, CA	Class I	All lots within expiry	Marketed without an Approved NDA/ANDA; FDA analysis found product to be tainted with undeclared sildenafil and tadalafil	Natures Rx 310 N Indian Hill Blvd Ste 600 Claremont, CA 91711-4611
Drugs	Levetiracetam in 0.54 % Sodium Chloride Injection 1,500/mg/100mL (15mg/mL), For intravenous Infusion Only, 1 x 100 mL Infusion bag, Manufactured by: Gland Pharma Limited Hyderabad - 500 043, India Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 UPC 343598637525 ---- NDC 43598-637-52	Class I	ABD807, exp 05/2020	Labeling: Label Error on Declared Strength; the pre-printed text on the primary infusion bag and the NDC incorrectly identifies the product as Levetiracetam in 0.75% Sodium Chloride (1000 mg/100 mL) however, the external foil pouch correctly identifies the product as Levetiracetam in 0.54% Sodium Chloride Injection (1,500/100 mL).	Dr. Reddy's Laboratories, Inc. 107 College Rd E Princeton, NJ 08540-6623

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drug	<p>Curaplex Epi Safe Administration and Training Kits, #8600-01100, Contains: 2 Epi Safe Administration Kit (8600-01101), 1 Epi Safe Training Kit (8600-01102), Rx Only, Distributed by Sarnova HC, LLC s family of companies: Bound Tree Medical, LLC, Cardio Partners, Inc., Emergency Medical Products, Inc. & Trianim Health Services, Inc. 5000 Tuttle Crossing Blvd. Dublin, OH 43016</p>	Class II	All Lots	<p>Labeling Incorrect Instructions: This recall has been initiated because the Instructions for Use included in the Epi-Safe Kits for the Epi-Safe Syringe (and/or the Safety Lok Syringe in Model 8600-01120) recommend a midpoint dosage of epinephrine for children between 0 lbs. and 66 lbs. of 0.15mL that has not been approved by FDA for children. Reliance on the current IFU and/or use of the Epi-Safe Syringe as instructed may result in the administration of an inappropriate dosage of epinephrine to young children experiencing anaphylaxis, especially those under 33 lbs. Additionally the Epi Safe syringe does not have the correct markings to allow a health care provider to draw up the correct dosage for children under 33 kg</p>	<p>Bound Tree Medical, LLC 1420 Lakeside Parkway Dallas, TX 75208</p>

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Zinc Sulfate, 10mg/ml injection, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 10302018 @7, BUD 12/14/2018	Lack of sterility assurance	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Folic Acid, 5mg/ml injection, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 10302018 @8, BUD 12/14/2018	Lack of sterility assurance	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drug	Fluocinolone Acetonide Topical Solution, USP, 0.01 %, 60 mL bottle, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, MD 21202; Manufactured by: Novel Laboratories, Inc., Somerset, NJ 08873; NDC 43386-069-60.	Class II	Lot #: S700214, Exp Apr-19; S700447, Exp Jun-19; S700787, Exp Oct-19; S701057, Exp Nov-19; S800107, Exp Feb-20; S800266, Exp Mar-20; S800524, Exp May-20; S800791, Exp Jul-20	Failed Impurities/Degradation Specifications: Expansion of October 2018 recall due to elevated out of specification results for total impurities that have been chemically identified as oxidative degradation products of the fluocinolone active pharmaceutical ingredient.	LUPIN SOMERSET 400 Campus Dr Somerset, NJ 08873-1145

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drug	Ezetimibe and Simvastatin Tablets 10mg/80 mg, 1000-count bottles, Rx only, Manufactured by: Teva Pharmaceuticals Ind. Ltd. Jerusalem, 9777402, Israel; Distributed by: Dr. Reddy's Laboratories Inc. Princeton, NJ 08540 USA, NDC 43598-586-10	Class II	Lot #: 43E021 and 43E023, Exp. 01/2020	Presence of Foreign Substance: Product complaint of black speckles observed on tablets.	Dr. Reddy's Laboratories, Inc. 107 College Rd E Princeton, NJ 08540-6623
Drug	HEPERAIN 50 mg/50 mL (1mg/mL) Injectable Solution, Heparin Sodium 0.45% Sodium Chloride QS Heparin 50 Units 50 mL, Sterile single use syringe, Avella of Houston an FDA Registered 503B Outsourcing Facility 9265 Kirby Dr. Houston, TX 77054 (877) 794-0404 ---- NDC: 42852-725-65	Class II	Lot: 12/19/18 0242 72565S BUD: 3/31/19	Labeling; Label Error on Declared Strength; label incorrectly states the concentration as 50 mg/50 mL (1 mg/mL) rather than the fully accurate concentration as 50 Units/50 mL (1 Unit/mL)	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drug	Gentamicin Sulfate Ophthalmic Solution, USP 0.3%, 5 mL dropper bottle, Rx Only, Manufactured by: Akorn, Inc. Lake Forest, IL 60045, NDC 17478-283-10	Class II	Lots: 6C02A Exp. 02/19; 5K42A Exp. 09/2018; 7D47A Exp. 03/2020	Presence of Particulate Matter: Crystalline particles were noticed at the 24 month clarity testing.	Akorn, Inc. 1925 W Field Ct Ste 300 Lake Forest, IL 60045-4862
Drug	GENTAMICIN OPTH-SOL 5ml Compare: Garamycin. 5-mL plastic dropper bottle, Mfg: AKORN 17478-0283-10. NDC 52959-0103-00	Class II	Lot # GNT01AK, Exp. 02/19 & GNT07AK, Exp. 3/20	Presence of Particulate Matter: Crystalline particles were noticed by manufacturer at the 24 month clarity testing	H J Harkins Company Inc dba Pharma Pac 1400 W Grand Ave Ste F Grover Beach, CA 93433-4221

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drug	Omeprazole 4 mg/mL Suspension, 150cc to 300 cc per prescription, Rx only, Duren's Health Mart Pharmacy 215 Dexter Woods Blvd. Waynesboro, TN 38485, NDC 00000-0001-07	Class II	N/A	Lack of Processing Controls	Duren Health Mart Pharmacy 215 Dexter L Woods Memorial Blvd Waynesboro, TN 38485-2416
Drugs	Progesterone 10% cream, 12gm to 30gm per prescription, Rx only, Duren's Health Mart Pharmacy 215 Dexter Woods Blvd. Waynesboro, TN 38485, NDC 00000-0002-99	Class II	N/A	Lack of Processing Controls	Duren Health Mart Pharmacy 215 Dexter L Woods Memorial Blvd Waynesboro, TN 38485-2416
Drugs	Testosterone 0.1% cream, 30 grams, Rx only, Duren's Health Mart Pharmacy 215 Dexter Woods Blvd. Waynesboro, TN38485, NDC 00000-0000-98	Class II	N/A	Lack of Processing Controls	Duren Health Mart Pharmacy 215 Dexter L Woods Memorial Blvd Waynesboro, TN 38485-2416
Drugs	Promethazine Gel 50 mg/mL, 1cc to 10cc per prescription, Rx only, Duren's Health Mart Pharmacy 215 Dexter Woods Blvd. Waynesboro, TN38485, NDC 00002-1901-03	Class II	N/A	Lack of Processing Controls	Duren Health Mart Pharmacy 215 Dexter L Woods Memorial Blvd Waynesboro, TN 38485-2416

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Progesterone 100 mg SR capsules, 30-180 capsules per prescription, Rx only, Duren's Health Mart Pharmacy 215 Dexter Woods Blvd. Waynesboro, TN38485, NDC 00311-2003-01	Class II	N/A	Lack of Processing Controls	Duren Health Mart Pharmacy 215 Dexter L Woods Memorial Blvd Waynesboro, TN 38485-2416
Drugs	Domperidone 10 mg capsules, 100-count per prescription, Rx only, Duren's Health Mart Pharmacy 215 Dexter Woods Blvd. Waynesboro, TN 38485, NDC 00507-2011-00	Class II	N/A	Lack of Processing Controls	Duren Health Mart Pharmacy 215 Dexter L Woods Memorial Blvd Waynesboro, TN 38485-2416
Drug	Cephalexin for Oral Suspension USP 250mg/5 mL, Rx Only Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland, Manufactured by: Lupin Limited Mandideep 462 046 India --- NDC 68180-441-01	Class II	lot F801282, Expiry June 2020	CGMP Deviations; presence of extraneous material in the was observed in area that is between the primary package that is heat sealed and secondary packaging (poly-woven bag) of sucrose (an excipient) used in the finished product	Lupin Pharmaceuticals Inc. 111 S Calvert St Fl 21ST Baltimore, MD 21202-6174

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Irbesartan Tablets 300 mg 90 count Rx only Manufactured by: Zhejiang Huahai Pharmaceutical Co., Xunqiao, Linhai, Zhejiang 317024 China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 NDC 43547-376-09, NDC 43547-331-03 NDC 43547-331-09 43547-330-03	Class II	331B18009 327A18001 327A18002 327B18008 327B18009 325D18004 325D18005	CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million	Princeton Pharmaceutical Inc 700 Atrium Dr Somerset, NJ 08873-4107
Drugs	Fexofenadine HCl Tablets, USP, 180 mg, packaged in a) 30-count bottles (NDC 0378-0782-93) and b) 500-count bottles (NDC 0378-0782-05); Manufactured by: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA.	Class II	Lot #: a) 3085490, 3085491, Exp 04/19; b) 3085492, 3085493, 3085494, 3085495, 3085496, Exp 04/19	Failed Impurities/Degradation Specifications: Related compound results obtained during routine stability testing was slightly elevated above specification.	Mylan Pharmaceuticals Inc. 781 Chestnut Ridge Rd Morgantown, WV 26505-2730
Drugs	BromSite (bromfenac ophthalmic solution) 0.075%, 5 mL bottles, Rx Only, Distributed by : Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, NDC 49708-754-41	Class II	Lot #: V18E01, Exp. 05/2020	Bromfenac Ophthalmic Solution, 0.075% (Sterile 5 mL) may have a lack of sterility assurance.	Sun Pharmaceutical Industries, Inc. 270 Prospect Plains Rd Cranbury, NJ 08512-3605
Drugs	Soothe & Cool Protect Moisture Guard Skin Protectant (petrolatum 59%), 3.5 oz tubes, Manufactured in USA for: Medline Industries, Inc., Mundelein, IL 60060 USA NDC 53329-303-22	Class II	Lot #: 50G17, Exp. 5/2019; 76J17, Exp. 7/2019	GMP Deviations: Out of specification results for Total Aerobic Microbial count in excipient purified water sample	US Pharmaceuticals Inc. 681 Main St Ste 27 Belleville, NJ 07109-3471

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Hydrocortisone Cream 1% MS Anti itch Cream with Intensive Healing 2 oz tubes, Distributed by: Walgreen Co. 200 Wilmot Rd. Deerfield, IL 60015, NDC 0363-0237-03	Class II	Lot #: 36G17, 47G17, Exp. 5/2019; 84J17, Exp. 7/2019	GMP Deviations: Out of specification results for Total Aerobic Microbial count in excipient purified water sample	US Pharmaceuticals Inc. 681 Main St Ste 27 Belleville, NJ 07109-3471
Drugs	Medline Remedy Essential Barrier Skin Protectant Ointment (petrolatum 59%) packaged in a) 2 oz tubes (NDC 53329-302-14) and b) 6 oz tubes (NDC 53329-302-41), Medline Industries Inc., Manufactured for Medline Industries Inc., Mundelien, IL 60060.	Class II	Lot # a) and b): 44G17, Exp. 05/2019	GMP Deviations: Out of specification results for Total Aerobic Microbial count in excipient purified water sample	US Pharmaceuticals Inc. 681 Main St Ste 27 Belleville, NJ 07109-3471
Drugs	Dymista (azelastine hydrochloride and fluticasone propionate) Nasal Spray, 137 mcg/50 mcg per spray, 120 Metered Sprays, 23 g net fill weight bottle, Rx Only, Manufactured by: Cipla Ltd., Goa, India, M.L. No. 546; For: Meda Pharmaceuticals Inc., Somerset, New Jersey 08873-4120, NDC 0037-0245-23.	Class II	Lot: GA70535, Exp. April 2019	Defective Container: Potential for broken glass in the neck area of the glass bottles.	Mylan Pharmaceuticals Inc. 781 Chestnut Ridge Rd Morgantown, WV 26505-2730
Drugs	CIDOFOVIR DIHYDRATE, (Non-Sterile, For Manufacturing Use), 10g, Rx only, ALP PHARM BEIJING CO., LTD, 12-2-620, Jia 69, Fushi Rd., Haidian, Beijing 100049, China. Batch Number JD-BP-37-20150801	Class II	Lot number: JD-BP-37-20150801	CGMP Deviations: Active Pharmaceutical Ingredient (API) manufacturer is on FDA Import Alert	LGM Pharma LLC 2758 Circleport Dr Erlanger, KY 41018-1079
Drugs	Acetylcysteine Ophthalmic Solution, 100mg/ml, 10%, Rx only, Promise Pharmacy Compounding Specialist, 31818 US Hwy 19N, Palm Harbor FL 34684.	Class II	Lot: 11072018 @10 BUD: 12/22/2018	Lack of sterility assurance.	Lack of sterility assurance.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Prednisolone and Moxifloxacin Ophthalmic Solution 1%/0.5%, Combo Drops 3 mL, Rx Only, Compounded Prescription, Promise Pharmacy 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 10252018 @8 BUD: 2/10/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Prednisolone and Gatifloxacin Ophthalmic Solution 1%/0.5%, Combo Drops 3 mL, Rx Only, Compounded Prescription, Promise Pharmacy 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 11052018 @4 BUD: 1/18/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Prednisolone and Gatifloxacin and Ketorolac Ophthalmic Solution 1%/0.5%/0.5%, Combo Drops: 3 mL Rx Only, Compounded Prescription, Promise Pharmacy 31818 US Hwy 19N, Palm Harbor FL 34684	Class II	Lots: 09262018 @5 BUD: 1/15/2019; 10092018 @1 BUD: 1/25/2019; 11052018 @1 BUD: 2/21/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Prednisolone and Gatifloxacin and Bromfenac Ophthalmic Solution, 1%/0.5%/0.09%, Combo Drops 6 mL, Rx Only, Compounded Prescription, Promise Pharmacy 31818 US Hwy 19N, Palm Harbor FL 34684	Class II	Lots: 09192018 @4 BUD: 12/18/2018; 10112018 @1 BUD: 12/24/2018; 10262018 @1 BUD: 1/8/2019; 10302018 @1 BUD: 1/12/2019; 11082018 @6 BUD: 1/21/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Prednisolone and Gatifloxacin and Bromfenac, Ophthalmic Solution, 1%/0.5%/0.09%, Combo Drops 3 mL, Rx Only, Compounded Prescription, Promise Pharmacy 31818 US Hwy 19N, Palm Harbor FL 34684	Class II	Lots: 11012018 @1 BUD: 1/14/2019; 11022018 @1 BUD: 1/15/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Prednisolone and Bromfenac Ophthalmic Solution, 1%/0.09% Combo Drops 3 mL, Rx Only, Compounded Prescription, Promise Pharmacy 31818 US Hwy 19N, Palm Harbor FL 34684	Class II	Lots: 09262018 @6 BUD: 12/25/2018; 11052018 @2 BUD: 2/3/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Vitamin B Complex, Dexpanthenol/Leucine/Niacinamide/Pyridoxine/Riboflavin/Thiamine 2 mg/2.5 mg/25 mg/ 25 mg/ 2 mg/ 25 mg/mL 10 mL vial, Rx Only, Compounded Prescription, Promise Pharmacy Compounding Specialists, 31818 US Hwy 19N, Palm Harbor FL 34684	Class II	Lots: 10092018 @4 BUD: 1/7/2019; 11122018 @7 BUD: 2/10/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Multi Trace, Zinc/Copper/Manganese/Selenium 5mg/1mg/0.5mg/60mcg/ml, injection 30 mL, Rx Only, Compounded Prescription, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 10312018 @5 BUD: 12/15/2018	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Infants' Ibuprofen, Concentrated Ibuprofen Oral Suspension, USP, (NSAID), 50 mg per 1.25 mL, Dye Free, Non-staining Berry Flavor, 0.5 FL OZ (15 mL) bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 39338 3, NDC 59779-925-23.	Class II	Lot#: 4718, Exp 12/19	Superpotent Drug: recalled lots may have higher concentration of ibuprofen than amount labeled	Tris Pharma Inc. 2033 US Highway 130 Monmouth Junction, NJ 08852-3003
Drugs	Vitamin D3 50,000iu/mL, injection 5 mL, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 09112018 @10 BUD: 1/2/2019; 09212018 @9 BUD: 1/12/2019; 11132018 @10 BUD: 2/27/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Trim Complete, Methlonine/Inositol/Choline/Thiamine/Riboflavin/Niacina mide Dexpanthenol/Pyridoxine/Methylcobalamin/Leucine/Chromium 25 mg/50 mg/50 mg/25 mg/2.5 mg/25 mg/2 mg/25 mg/0.5 mg2.5 mg/1.33 mcg/mL injection 10 mL, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 10022018 @6 BUD: 12/31/2018	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Methylcobalamin lyophilized 50,000 mcg Injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 08212018 @11 BUD: 12/19/2018; 10012018 @1 BUD: 1/29/2019	Lack of sterility assurance	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Methylcobalamin lyophilized, 10,000 mcg Injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 08032018 @3 BUD: 01/30/2019; 9; 08272018 @6 BUD: 2/23/2019; 09142018 @4 BUD: 3/13/2019; 10012018 @3 BUD: 3/30/2019	Lack of sterility assurance	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	infants* IBUPROFEN, Concentrated Ibuprofen Oral Suspension, USP (NSAID), 50 mg per 1.25 mL, Dye-Free Berry Flavor, 1 FL OZ (30 mL) bottle, Distributed by Wal-Mart Stores, Inc., Bentonville, AR 72716, NDC 49035-125-24.	Class II	Lot#: 00717006A , Exp 02/19	Superpotent Drug: recalled lots may have higher concentration of ibuprofen than amount labeled.	Tris Pharma Inc. 2033 US Highway 130 Monmouth Junction, NJ 08852-3003
Drugs	Infants' Ibuprofen, Concentrated Ibuprofen Oral Suspension, USP, (NSAID), 50 mg per 1.25 mL, Dye Free, Non-staining Berry Flavor, 1 FL OZ (30 mL) bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 39961 3, NDC 50428-1252-4.	Class II	Lot#: 00717006A , Exp 02/19	Superpotent Drug: recalled lots may have higher concentration of ibuprofen than amount labeled	Tris Pharma Inc. 2033 US Highway 130 Monmouth Junction, NJ 08852-3003
Drugs	Amino Blend Injection, Ornithine/Arginine/Lysine/Lidocaine 75 mg/75 mg/75 mg/10 mg/mL 10 mL, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 08302018 @12 BUD: 12/24/2018; 8; 10242018 @2 BUD: 2/17/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Glutathione Injection, 200 mg/mL, 10 mL, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 09172018 @7 BUD: 12/16/2018; 8; 10292018 @2 BUD: 1/27/2019	Lack of sterility assurance	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Ascorbic Acid, Compounded-Tapioca, 450 mg/mL Injection, 50 mL, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 10152018 @1 BUD: 1/13/2019; 10312018 @2 BUD: 1/29/2019	Lack of sterility assurance	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Thymosin Beta-4, 15 mg Injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 08302018 @8 BUD: 2/26/2019; 10012018 @2 BUD: 3/30/2019; 07052018 @2 BUD: 01/01/201	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Sermorelin Theanine/GHRP2, 15 mg/75 mg/5.4 mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 07202018 @4 BUD: 1/16/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Sermorelin 9 mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 06182018 @2 BUD: 12/15/2018; 08212018 @12 BUD: 2/17/2019; 09212018 @15 BUD: 3/20/2019; 11132018 @1 BUD: 5/12/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Sermorelin/GHRP2/GHRP6, 9 mg/9 mg/9 mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 07102018 @3 BUD: 1/6/2019 08302018 @9 BUD: 2/26/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Sermorelin/GHRP2/GHRP6 6mg/3mg/3mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 08302018 @13 BUD: 2/26/2019; 09212018 @14 BUD: 3/20/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Ipamorelin+Modified GRF 1-29, 9 mg/5mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 07052018 @1 BUD: 1/1/2019; 09182018 @6 BUD: 3/1/2019; 09212018 @10 BUD: 3/4/2019; 10052018 @1 BUD: 3/18/2019; 11062018 @2 BUD: 4/19/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Ipamorelin, 9 mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 07132018 @5 BUD: 1/9/2019; 07302018 @32 BUD: 1/26/2019; 09182018 @7 BUD: 3/17/2019; 10192018 @2 BUD: 4/17/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Ipamorelin+Sermorelin, 15mg/15mg, injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	09212018 @12 BUD: 12/20/2018; 11062018 @3 BUD: 6/4/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Ipamorelin, 15mg, injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 09182018 @4 BUD: 3/17/2019; 10052018 @3 BUD: 4/3/2019; 11132018 @3 BUD: 5/12/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	IGF-1 LR3, 620 mcg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 06282018 @3 BUD: 12/25/2018	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Epithalon, 15mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 09212018 @11 BUD: 12/20/2018; 11132018 @4 BUD: 2/11/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Bremelanotide (PT 141), 20mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 10192018 @4 BUD: 12/18/2019; 11132018 @5 BUD: 1/12/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	BPC 157, 10mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 11062018 @5 BUD: 2/4/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	HCG, Human chorionic gonadotropin 11,000 units, injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 11062018 @5 BUD: 2/4/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	HCG, Human chorionic gonadotropin 5,000 units, injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 06252018 @1 BUD: 12/22/2018; 07132018 @7 BUD: 1/9/2019; 07262018 @2 BUD: 1/22/2019; 08212018 @7 BUD: 2/17/2019; 08272018 @2 BUD: 2/23/2019; 09052018 @2 BUD: 2/28/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	HCG, Human chorionic gonadotropin 2,000 units, injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 07172018 @15 BUD: 1/13/2019; 08272018 @3 BUD: 2/23/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Sermorelin, 15mg, injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 07102018 @4 BUD: 1/6/2019; 09142018 @6 BUD: 3/13/2019; 10052018 @4 BUD: 4/3/2019; 11062018 @1 BUD: 5/5/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	IGF-1-LR3, 3 mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 06282018 @2 BUD: 12/25/2018	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Melanotan II, 10mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 07202018 @3 BUD: 1/13/2019; 09212018 @13 BUD: 2/28/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	ICB-Complex, injection, Inositol/Choline/B1/B2/B3/B5/B6/B12/Leucine/Carnitine/Chromium/Lidocaine :25mg/25mg/5mg/2.5mg/25mg/5mg/5mg/0.1mg/1.5mg/25mg/25mg/10mg/ML, 10ml, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 09262018 @1 BUD: 12/25/2018; 10232018 @5 BUD: 1/21/2019; 11012018 @3 BUD: 1/30/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	MIC B12+L-Carnitine+Chromium injection, Methionine Inositol Choline Methylcobalamin+L-Carnitine+Chromium, 25mg/50mg/50mg/1mg/100mg/0.4mcg/ml, 10mL, injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 10102018 @1 BUD: 1/8/2019	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Nicotinamide Adenine Dinucleotide, 0.5 mg, injection, 10mL vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 11062018 @13 BUD: 12/21/2018; 11072018 @24 BUD: 12/22/2018	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Niacinamide injection, 100mg/mL, 5mL vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 11022018 @9 BUD: 12/17/2018	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Myer's Cocktail, Pyridoxine/Dexpanthenol/Calcium Gluconate/Niacinamide/Vit B6/Vit B1/Leucine/Vit B5/Riboflavin/Ascorbic Acid/Hydroxycobalamin/Magnesium Chloride, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 11072018 @2 BUD: 12/14/2018	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Zinc Sulfate, 5mg/mL injection, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 11132018 @9 BUD: 12/28/2018;	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Folic Acid, Injection, 10 mg/mL, 10mL vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 11132018 @9 BUD: 12/28/2018;	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Trim Calm, GABA/Magnesium/Taurine/Theramine, 50mg/50mg/50mg/50mg/ml, 10mL vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 11052018 @7 BUD: 12/20/2018	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Procaine HCl, 2% injection, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lots: 11082018 @4 BUD: 12/23/2018; 10302018 @4 BUD: 12/14/2018	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Pyridoxine HCl, 100 mg/mL Injection, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 10302018 @3 BUD: 12/14/2018	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Leucine/Isoleucine/Valine injection, 10mg/10mg/5mg/mL/mL, 10mL vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 10312018 @3 BUD: 12/15/2018	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Lysine HCl, 100 mg/mL injection, 10ml, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 11132018 @8 BUD: 12/28/2018	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Dexpanthenol, 250mg/mL Injection, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 11052018 @5 BUD: 12/20/2018	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713
Drugs	Glycyrrhizic Acid, 8mg/mL Injection, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684	Class II	Lot: 11052018 @6 BUD: 12/20/2018	Lack of sterility assurance.	Promise Pharmacy, LLC 31818 Us Highway 19 N Palm Harbor, FL 34684-3713

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	LET Gel 4% (Lidocaine HCl 4% + EPINEPHrine HCl 0.05% + Tetracaine HCl 0.5%), 3mL Single Use Syringe, Rx only, US Compounding, 1270 Don's Lane, Conway, AR, 800-718-3588, Barcode 62295501303.	Class II	Labeled as Lot# YYYDDYY@ XX, Beyond Use Date: MM/DD/Y YYY.	Labeling: Incorrect or Missing Lot and/or Exp Date: Labels are missing lot and expiration date and are printed as Lot# YYYDDYY@XX with a Beyond Use Date: MM/DD/YYYY.	US Compounding Inc 1270 Dons Ln Conway, AR 72032-4753
Drugs	Moxifloxacin Ophthalmic Solution USP, 0.5%, 3 mL dropper bottle, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 Manufactured by: lupin Limited Pithampur (M.P.) 454 775 India. NDC 68180-422-01	Class III	Lot Numbers: H705562, H705563, EXP. 11/2019; H800616, EXP. 01/2020	Failed Impurities/Degradati on Specifications: Out of specification test results in related substance at three- month long term stability study was obtained.	Failed Impurities/De gradation Specifications: Out of specification test results in related substance at three-month long term stability study was obtained.
Drugs	Cardizem CD (diltiazem HCl) capsules, 120 mg, packaged in a) 30-count bottles (NDC 0187-0795-30); and b) 90-count bottles (NDC 0187-0795-42), Rx Only, Manufactured for: Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA; By: Valeant Pharmaceuticals International, Inc., Steinbach, MB R5G 1Z7, Canada.	Class III	Lots: a) 18J023P, Exp 08/2020; b) 18J021P, Exp 08/2020	Failed Dissolution Specifications: high out of specification results for dissolution when measuring the amount of drug released at certain time points.	Valeant Pharmaceutic als North America LLC 400 Somerset Corporate Blvd Bridgewater, NJ 08807- 2867

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Cardizem CD (diltiazem HCl) capsules, 180 mg, packaged in a) 30-count bottles (NDC 0187-0796-30); and b) 90-count bottles (NDC 0187-0796-42), Rx Only, Manufactured for: Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA; By: Valeant Pharmaceuticals International, Inc., Steinbach, MB R5G 1Z7, Canada.	Class III	Lots: a) 18J018P, Exp 08/2020; b) 18J029P, Exp 08/2020	Failed Dissolution Specifications: high out of specification results for dissolution when measuring the amount of drug released at certain time points.	Valeant Pharmaceuticals North America LLC 400 Somerset Corporate Blvd Bridgewater, NJ 08807-2867
Drugs	Cardizem CD (diltiazem HCl) capsules, 240 mg, packaged in a) 30-count bottles (NDC 0187-0797-30); and b) 90-count bottles (NDC 0187-0797-42), Rx Only, Manufactured for: Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA; By: Valeant Pharmaceuticals International, Inc., Steinbach, MB R5G 1Z7, Canada.	Class III	Lots: a) 18J019P, Exp 08/2020; b) 18J028P, Exp 08/2020	Failed Dissolution Specifications: high out of specification results for dissolution when measuring the amount of drug released at certain time points.	Valeant Pharmaceuticals North America LLC 400 Somerset Corporate Blvd Bridgewater, NJ 08807-2867
Drugs	Cardizem CD (diltiazem HCl) capsules, 300 mg, packaged in a) 30-count bottles (NDC 0187-0798-30); and b) 90-count bottles (NDC 0187-0798-42), Rx Only, Manufactured for: Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA; By: Valeant Pharmaceuticals International, Inc., Steinbach, MB R5G 1Z7, Canada.	Class III	Lots: a) 18J020P, Exp 08/2020; b) 18J034P, Exp 08/2020	Failed Dissolution Specifications: high out of specification results for dissolution when measuring the amount of drug released at certain time points.	Valeant Pharmaceuticals North America LLC 400 Somerset Corporate Blvd Bridgewater, NJ 08807-2867

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Diltiazem HCl CD capsules, 360 mg, 90-count bottles, Rx Only, Manufactured for: Oceanside Pharmaceuticals, a division of Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA; By: Valeant Pharmaceuticals International, Inc., Steinbach, MB R5G 1Z7 Canada; NDC 68682-521-01.	Class III	Lots: 18J035P, 18K094P, 18K093P, Exp 09/2020	Failed Dissolution Specifications: high out of specification results for dissolution when measuring the amount of drug released at certain time points.	Valeant Pharmaceuticals North America LLC 400 Somerset Corporate Blvd Bridgewater, NJ 08807-2867
Drug	LOPERAMIDE HCL TABLETS USP, 2 mg, ANTI-DIARRHEAL, 24 caplets per carton, OTC, Distributed by Drug Mart-Food Fair Medina Ohio 44256 Ohm Laboratories Inc. UPC 0 93351 11270 6 NDC#:53943-123-24	Class III	Lot: 2979325, EXP 5/5021	Labeling Not Elsewhere Classified: The front panel indicates 24 caplets whereas the side panel indicates 12 caplets. The drug product carton contains 24 caplets.	Sun Pharmaceutical Industries, Inc. 270 Prospect Plains Rd Cranbury, NJ 08512-3605
Drugs	Bimatoprost Ophthalmic Solution 0.03%, packaged in a) 5 mL (NDC 68180-429-02) and b) 7.5 mL (NDC 68180-429-03) bottles, Rx only, Manufactured by: Lupin Limited Pithampur (M.P.) 454 775, INDIA.	Class III	a) H804506 Exp. 06/2020; 803555 Exp. 04/2020; H805394, Exp. 08/2020 b) H804112 Exp. 05/2020; H803220 Exp. 03/2020	Failed Impurities/Degradation Specifications: OOS results observed in any other individual impurity and total impurities.	Lupin Pharmaceuticals Inc. 111 S Calvert St Fl 21ST Baltimore, MD 21202-6174

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	COSOPT Ophthalmic Solution, USP, (2% Dorzolamide Hydrochloride, 0.5% Timolol Maleate), 10 mL dropper bottle, Sterile, Rx only, Distributed by: Akorn, Inc., Lake Forest, IL, NDC: 17478-605-10	Class III	Lots: 426007 and 426008, exp 4/2020	Failed Stability Specifications: out of specification results for opalescence at 7 month stability study.	Akorn Inc 1925 W Field Ct Ste 300 Lake Forest, IL 60045-4862
Drugs	Clobetasol Propionate Topical Solution USP, 0.05% w/w, 50 mL bottle, Manufactured for: Macleods Pharma USA, Inc. Plainsboro, NJ 08536 Manufacturer: Macleods Pharmaceuticals Ltd Al Oxalis Labs Baddi Himachal Pradesh INDIA, UPC Code 33342032186 ---- NDC 33342-321-86	Class III	Lot Numbers: PCA801A, PCA802A, PCA803A, exp. date 12/2019; PCA804A, PCA805A, PCA806A, PCA807A, exp. date 04/2020	Defective Container; complaints of leakage.	Oxalis Labs Lodhimajra Tehsil - Baddi Theda

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

CURRENT DRUG SHORTAGES

Morphine Sulfate Immediate-Release Tablets

January 25, 2019

Reasons for Shortage:

- Hikma did not provide a reason for the shortage.

Estimated Resupply Date:

- Hikma has all morphine immediate-release tablets on allocation

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

Doxorubicin Injection

January 25, 2019

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

Estimated Resupply Date:

- Athenex has doxorubicin 2 mg/mL 25 mL vials available with short expiration dating of March 2019. The 100 mL vials also have short expiration dating of April 2019.9
- Fresenius Kabi has doxorubicin 25 mL vials available with short-expiration dating (< 9 months).
- Mylan Institutional has doxorubicin lyophilized powder 10 mg vials on back order and the company cannot estimate a release date. The 50 mg vials are on back order and the company estimates a release date of late-April 2019.
- Hikma has Adriamycin 2 mg/mL 5 mL vials on back order and the company estimates a release date of February to March 2019. The 2 mg/mL 25 mL and 100 mL vials are on back order and the company estimates a release date in February 2019. The 2 mg/mL 10 mL vials are available with an expiration date of June 2019. The 50 mg vials are on back order and the company cannot estimate a release date.

- Sagent has doxorubicin 2 mg/mL 5 mL, 10 mL, and 25 mL vials on back order and the company cannot estimate a release date.
- Teva has doxorubicin 2 mg/mL 10 mL vials available with short expiration dating

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

Cefotaxime Sodium Injection

January 25, 2019

Reasons for 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 Date:

- There are no marketed presentations available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=51>

Methadone Injection

January 28, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- All marketed presentations are available.

Lidocaine Injection

January 28, 2019

Reasons for 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 Date:

- 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% lidocaine 10 mL vials on back order and the company estimates a release date of early-February 2019. The 1% Xylocaine 20 mL and 50 mL vials are on back order and the company

estimates a release date of late-January to early-February 2019. The 1% Xylocaine-MPF 2 mL and 30 mL vials are on back order and the company estimates a release date of mid-March 2019 for the 2 mL vials, and late-February to early-March 2019 for the 30 mL vials. 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 1.5% Xylocaine-MPF 20 mL ampules are on back order and the company estimates a release date of mid-March 2019. The 2% Xylocaine 10 mL, 20 mL, and 50 mL vials are on back order and the company estimates a release date of late-January to early-February 2019 for the 10 mL and 20 mL vials and late-February to early-March 2019 for the 50 mL vials. The 2% Xylocaine-MPF 5 mL vials are on back order and the company estimates a release date of late-January to early-February 2019. Check wholesalers for inventory.

- Pfizer has 1% lidocaine 2 mL preservative-free ampules available in limited supply. The 1% lidocaine 5 mL preservative-free ampules are on back order and the company estimates a release date of 1st quarter 2020. The 1% lidocaine 20 mL vials preservative-free vials are on back order and the company estimates a release date of January 2019 for the 20 mL vials. The 1% lidocaine 30 mL preservative-free vials are available in limited supply. The 1% lidocaine 50 mL vials are on back order and the company estimates a release date of January 2019. The 1% lidocaine 5 mL Lifeshield syringes are on back order and the company estimates a release date of January 2019. The 1% lidocaine 5 mL Ansyf syringes are on back order and the company estimates a release date of January 2019. The 1.5% lidocaine 20 mL preservative-free ampules are on back order and the company estimates a release date of 4th quarter 2019. The 2% lidocaine 10 mL ampules are on back order and the company cannot estimate a release date. The 2% lidocaine 5 mL vials are on back order and the company estimates a release date of 4th quarter 2019. The 2% lidocaine 20 mL and 50 mL vials are on back order and the company estimates a release date of February 2019. The 2% lidocaine 5 mL Lifeshield syringes are on back order and the company estimates a release date of 1st quarter 2019. The 2% lidocaine 5 mL Ansyf syringes are available in limited supply. The 4% lidocaine 5 mL ampules are on back order and the company estimates a release date of February 2019.

- Hikma has 2% lidocaine 5 mL vials on allocation. The 1% lidocaine 50 mL vials are on back order and the company estimates a release date of late-January 2019.

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

Dexrazoxane Injection

January 28, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- Pfizer has Zinecard 500 mg vials on back order and the company estimates a release date of 2nd quarter 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=107>

Piperacillin and Tazobactam Injection

January 29, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- Apotex has temporarily discontinued all piperacillin/tazobactam presentations.
- Baxter has Zosyn 2.25 gram/50 mL and 3.375 gram/50 mL frozen premixed bags on allocation with intermittent delivery of product.
- Mylan has piperacillin/tazobactam 3.375 gram and 4.5 gram vials on back order and the company estimates a release date of late-January to early-February 2019.
- Pfizer has Zosyn 2.25 gram vials, 3.375 gram vials, 4.5 gram vials, and 40.5 gram vials on back order and the company estimates a release date of 2019.
- WG Critical Care has 2.25 gram vials on back order and the company estimates a release date of February 2019.

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

Yellow Fever Vaccine

January 30, 2019

Reasons for Shortage:

- Sanofi Pasteur states the shortage is due to production delays.
- There are no other suppliers of yellow fever vaccine.
- Additional information on the yellow fever shortage is available at <http://wwwnc.cdc.gov/travel/news-announcements/yellow-fever-vaccine-shortage-2015>.

Estimated Resupply Date:

- 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=>.

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

Sufentanil Injection

January 30, 2019

Reasons for 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 Date:

- Pfizer has sufentanil 0.5 mg/mL 2 mL vials on back order and the company estimates a release date of 2nd quarter 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=376>

Scopolamine Transdermal System

January 30, 2019

Reasons for 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 Date:

- Baxter has Transderm Scop 1.5 mg patches in 10 count on back order and the company cannot estimate a release date. The 24 count size is on back order and the company estimates a release date in mid- to late-February 2019.
- Perrigo has scopolamine patches on back order and the company cannot estimate a release date.

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

Remifentanil Injection

January 30, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- Mylan Institutional has Ultiva 1 mg vials on back order and the company cannot estimate a release date.

•Fresenius Kabi has remifentanyl 2 mg and 5 mg vials on back order and the company cannot estimate a release date. The 1 mg vials are on back order and the company estimates a release date of mid- to late-February 2019.

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

Ranitidine Injection

January 30, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- Teligent has Zantac 25 mg/mL 2 mL, 6 mL, and 40 mL vials on back order and the company estimates a release date of 2nd quarter 2019.

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

Polyvinyl Alcohol (Artificial Tears) Ophthalmic Solution

January 30, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

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

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=451>

Metronidazole Hydrochloride Injection

January 30, 2019

Reasons for Shortage:

- Pfizer has metronidazole injection on shortage due to manufacturing delay.
- BBraun has metronidazole injection available

Estimated Resupply Date:

- 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.

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

Methylphenidate Extended-Release Oral Suspension and Chewable Tablets

January 30, 2019

Reasons for Shortage:

- Tris Pharma did not provide a reason for Quillivant XR oral suspension shortage.
- Tris Pharma did not provide a reason for QuillChew ER chewable tablet shortage.

Estimated Resupply Date:

- Tris Pharma released QuilliChew ER 40 mg chewable tablets in mid-January 2019. Please check with your wholesaler.
- Tris Pharma released Quillivant XR oral suspension in 120 mL, 150 mL, and 180 mL bottles in mid-January 2019. Please check with your wholesaler

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

Methylene Blue

January 30, 2019

Reasons for Shortage:

- Akorn has methylene blue on shortage due to manufacturing delays.
- American Regent has recently launched an FDA approved presentation, ProveyBlue and product is available.

Estimated Resupply Date:

- Akorn has methylene blue 10 mg/mL 1 mL vials on back order and the company cannot estimate a release date. There are short-dated 10 mL vials available with an expiration date of August 2019

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=47>

Lorazepam Injection

January 30, 2019

Reasons for 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 Date:

- Akorn has lorazepam 2 mg/mL 1 mL vials on allocation.
- Hikma has lorazepam 4 mg/mL 1 mL vials on back order and the company estimates a release date of February 2019.
- Hikma has Ativan 2 mg/mL 1 mL vials on back order and the company estimates a release date of February 2019. Ativan 4 mg/mL 1 mL vials are on back order and the company cannot estimate a release date.

•Pfizer has lorazepam 2 mg/mL 10 mL vials on back order and the company estimates a release date of February 2019. The 2 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 2nd quarter 2019. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of 2nd quarter 2019. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 1st quarter 2020.

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

Iopamidol Injection

January 30, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

•Bracco Diagnostics has Isovue-370 (iopamidol 76%) in 125 mL bottles on back order and the company estimates a release date in mid- to late-February 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=495>

Hydroxyethyl Starch in Sodium Chloride Injection

January 30, 2019

Reasons for 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 Date:

•BBraun has Hespan injection on back order and the company cannot estimate a release date.

Daptomycin Injection

January 30, 2019

Reasons for 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 Date:

- Pfizer has daptomycin 500 mg vials on back order and the company cannot estimate a release date.
- Mylan Institutional has daptomycin 500 mg vials on back order and the company estimates a release date of mid-March 2019

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

Ceftazidime Injection

January 30, 2019

Reasons for Shortage:

- Pfizer has Tazicef available.
- Sagent has ceftazidime injection available.
- 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 Date:

- Pfizer has Tazicef 1 gram ADD-Vantage vials available with short expiration dating (June 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.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=63>

Atropine Ophthalmic Solution

January 30, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- Akorn has atropine ophthalmic solution in 5 mL, 10 mL, and 15 mL bottles on back order and the company estimates a release date of February 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=514>

Asparaginase Erwinia chrysanthemi

January 30, 2019

Reasons for Shortage:

- Jazz Pharmaceuticals did not provide a reason for the Erwinaze shortage.

Estimated Resupply Date:

- 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 early-March 2019. There is a new process for ordering Erwinaze. Additional information regarding the new ordering process is available at www.erwinazesupply.com.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=482>

Alcohol Dehydrated Injection (Ethanol)

January 30, 2019

Reasons for 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 Date:

- Akorn has dehydrated alcohol 5 mL vials on allocation.

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

Testosterone Enanthate Intramuscular Injection

January 31, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- Teva has testosterone enanthate 200 mg/mL 5 mL vials temporarily unavailable with no estimated release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=498>

RimabotulintoxinB Intramuscular Injection

January 31, 2019

Reasons for Shortage:

- Solstice Neurosciences, Inc. did not provide a reason for the shortage.

Estimated Resupply Date:

- Solstice Neurosciences, Inc. has Myobloc 5000 unit/mL 0.5 mL vials on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=526>

Olanzapine Intramuscular Injection

January 31, 2019

Reasons for Shortage:

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

- Sandoz has olanzapine injection available

Estimated Resupply Date:

- American Regent has olanzapine 10 mg vials for intramuscular injection on back order and the company cannot estimate a release date.

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

Octreotide Injection

January 31, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- Hikma has octreotide 1000 mcg/mL 5 mL vials on back order and the company estimates a release date of February 2019. The 100 mcg/mL 1 mL vials, 500 mcg/mL 1 mL vials, and 200 mcg/mL 5 mL vials are available with a short expiration date of March 2019.

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

Mycophenolate Mofetil Capsules and Tablets

January 31, 2019

Reasons for 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 Date:

- 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 500 count and 500 mg tablets in 100 count and 500 count on allocation. The 250 mg capsules in 100 count are on back order and the company estimates a release date of March to April 2019.
- Mylan has mycophenolate mofetil 250 mg capsules in 500 count on back order and the company estimates a release date of late-March 2019. The 500 mg tablets in 500 count are on back order and the company estimates a release date of mid-April 2019.

•Sandoz has mycophenolate mofetil 500 mg tablets in 500 count on back order and the company estimates a release date of early-February 2019. The 250 mg capsules in 100 count, 500 count, and 1440 count are on back order and the company estimates a release date of early-February 2019.

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

Leuprolide Acetate 14-Day Kit

January 31, 2019

Reasons for 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 Date:

- Sandoz has leuprolide acetate injection on back order and the company estimates a release date of early-February 2019.
- Sun Pharma has leuprolide acetate injection on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=81>

Fludrocortisone Acetate Tablets

January 31, 2019

Reasons for Shortage:

- Impax did not provide a reason for the shortage.
- Teva did not provide a reason for the shortage.

Estimated Resupply Date:

- Teva has fludrocortisone acetate 0.1 mg tablets temporarily unavailable and the company cannot estimate a release date.
- Impax has fludrocortisone acetate 0.1 mg tablets on back order and the company estimates a release date of March 2019.

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

Ceftriaxone Sodium Injection

January 31, 2019

Reasons for 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 has ceftriaxone available.
- Hikma states the reason for the shortage is manufacturing delay.
- Wockhardt has discontinued their ceftriaxone presentations.

Estimated Resupply Date:

- Baxter has ceftriaxone premixed bags on allocation.
- Lupin has all ceftriaxone presentations on allocation.
- Hikma has ceftriaxone 500 mg vials on back order and the company cannot estimate a release date. The 250 mg vials are on back order and the company estimates a release date of February 2019.
- Sagent has ceftriaxone 2 gram vials on allocation. The 500 mg vials are available with short expiration dating (April 2019).

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

Butorphanol Tartrate Injection

January 31, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

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

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=414>

Bisoprolol Fumarate Tablets

January 31, 2019

Reasons for Shortage:

- Mylan reports that product is on back order due to manufacturing delays.
- Unichem Pharmaceuticals had product available in limited supply due to market demand.

Estimated Resupply Date:

- 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.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=512>

PCA Sterile Empty Vials and Injector

February 1, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

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

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=493>

Morphine PCA Vials

February 1, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- ICU Medical has morphine PCA vials on allocation to contracted customers

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

Epinephrine Auto-Injectors

February 1, 2019

Reasons for Shortage:

- Impax was not able to provide a reason for the shortage.
- Mylan had EpiPen on shortage due to supply constraints.
- Sandoz launched Symjepi in January 2019 and product is available.
- Teva has FDA approval for generic epinephrine

Estimated Resupply Date:

- Amneal has Adrenaclick 0.3 mg/0.3 mL and 0.15 mg/0.15 mL auto-injectors on intermittent back order with regular releases.
- Impax has epinephrine 0.15 mg/0.15 mL and 0.3 mg/0.3 mL auto-injectors on intermittent back order and the company is releasing supplies as they become available.
- Teva has FDA approval of epinephrine 0.3 mg/0.3 mL auto injectors but they have not launched the product yet. They have an estimated launch date of 1st quarter 2019.

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

Atropine Sulfate Injection

February 1, 2019

Reasons for Shortage:

- American Regent had atropine injection on shortage due to market demand.
- Amphastar has atropine injection available.
- Pfizer has atropine injection on shortage due to manufacturing delays.
- Hikma has atropine injection available.

Estimated Resupply Date:

- Pfizer has atropine 0.1 mg/mL 10 mL LifeShield syringes on back order and the company estimates release dates of 1st quarter 2019. The 0.1 mg/mL 10 mL Ansyr syringes are on back order and the company estimates a release date of February 2019. The 0.1 mg/mL 5 mL LifeShield syringes are on back order and the company estimates release dates of 2nd quarter 2019. The 0.05 mg/mL 5 mL Ansyr syringes are available with an expiration date of 1st quarter 2019.

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

0.9% Sodium Chloride Large Volume Bags

February 1, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- ICU Medical has all 0.9% sodium chloride bags readily available except the 0.9% sodium chloride 250 mL 2-port bags are available to current customers only.

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

Sterile Water for Injection - Small Volume Vials

February 4, 2019

Reasons for 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 Date:

- Fresenius Kabi has sterile water for injection 50 mL vials on back order and the company estimates a release date of mid-February 2019. The 100 mL vials are on back order and the company cannot estimate a release date. Check wholesalers for inventory.
- Pfizer has sterile water for injection 50 mL vials on back order and the company estimates a release date of February 2019. The 20 mL and 100 mL vials are available in limited supply.

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

Morphine Injection

February 4, 2019

Reasons for 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 Date:

- Fresenius Kabi has morphine 2 mg/mL 1 mL syringes on back order and the company estimates a release date of mid-February 2019. The morphine 4 mg/mL 1 mL syringes are on back order and the company estimates a release date of 2nd quarter 2019. The morphine 5 mg/mL 1 mL syringes are on back order and the company estimates a release date of 2nd quarter 2019. The 2 mg/mL 1 mL vials are on back order and the company estimates a release date of late-February to early-March 2019. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of late-February to early-March 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 1 mg/mL 10 mL preservative-free vials are on back order and the company estimates a release date of March 2019. The 2 mg/mL 1 mL iSecure syringes, 4 mg/mL 1 mL iSecure syringes, 8 mg/mL 1 mL iSecure syringes, and 10 mg/mL 1 mL iSecure syringes are on back order and the company estimates a release date of 4th quarter 2019. The 4 mg/mL 1 mL Carpuject syringes, 8 mg/mL 1 mL Carpuject syringes, and 10 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date in 2nd quarter 2019. The 25 mg/mL 1 mL preservative-free vials are on back order and the company estimates a release date of 2nd quarter 2019. The 50 mg/mL 20 mL vials are on back order and the company estimates a release date of 2nd quarter 2019. The 50 mg/mL 50 mL vials are on back order and the company estimates a release date of 2nd quarter 2019. The 0.5 mg/mL 10 mL preservative-free vials are available in limited supply

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

Methyldopa Tablets

February 4, 2019

Reasons for Shortage:

- Accord did not provide a reason for the shortage.
- Mylan did not provide a reason for the shortage.
- Teva did not provide a reason for the shortage.

Estimated Resupply Date:

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

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

Mannitol Injection

February 4, 2019

Reasons for 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 Date:

- Fresenius Kabi has mannitol 250 mg/mL 50 mL vials on back order and the company estimates a release date of early-March 2019.
- Pfizer has mannitol 250 mg/mL 50 mL vials available in limited supply.

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

Labetalol Injection

February 4, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- Akorn has labetalol 5 mg/mL 20 mL and 40 mL vials on back order and the company cannot estimate a release date.
- Alvogen has labetalol 5 mg/mL 20 mL and 40 mL vials on back order and the company cannot estimate a release date.
- Hikma has labetalol 5 mg/mL 40 mL vials on back order and the company estimates a release date of March to April 2019. The 20 mL vials are on allocation.
- Pfizer has labetalol 5 mg/mL 20 mL and 40 mL vials on back order and the company estimates a release date of 4th quarter 2019 for the 20 mL vials and 2nd quarter 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 March 2019

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

Flumazenil Injection

February 4, 2019

Reasons for 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 Date:

•Mylan Institutional has flumazenil 0.1 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of mid-March 2019 for the 5 mL vials and cannot estimate a release date for the 10 mL vials.

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

Epinephrine Injection

February 4, 2019

Reasons for 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 Date:

- 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 February 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>

Dobutamine Injection

February 4, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- Pfizer has dobutamine 12.5 mg/mL 20 mL and 40 mL latex-free vials on back order with an estimated release date of 1st quarter 2020 for the 20 mL vials and 2019 for the 40 mL vials.
- Pfizer has dobutamine 1 mg/mL in 250 mL bags on back order and the company estimates a release date of 2nd quarter 2019. The dobutamine 2 mg/mL 250 mL bags are on back order and the company estimates a release date of February 2019. The dobutamine 4 mg/mL 250 mL bags are available in limited supply.

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

Diphenhydramine Injection

February 4, 2019

Reasons for Shortage:

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

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

Estimated Resupply Date:

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

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

Dexmedetomidine Hydrochloride 4 mcg/mL Premix for Injection February 4, 2019

Reasons for 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 Date:

- Pfizer has Precedex 4 mcg/mL 20 mL glass vials on back order and the company estimates a release date of February 2019. The 4 mcg/mL 50 mL and 100 mL premixed bottles are available in limited supply.

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

Cefoxitin Sodium Injection February 4, 2019

Reasons for 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 Date:

- Apotex has temporarily discontinued cefoxitin 1 gram, 2 gram, and 10 gram vials and the company cannot estimate when product will be available again.
- BBraun has cefoxitin 1 gram and 2 gram vials on allocation.
- Fresenius Kabi has cefoxitin 1 gram and 2 gram vials on back order and the company estimates a release date of mid-April 2019 for the 1 gram vials and late-February to early-March 2019 for the 2 gram vials.

- Sagent has cefoxitin 1 gram and 2 gram vials on back order and the company estimates a release date of March 2019. The 10 gram vials are on allocation.
- WG Critical Care has cefoxitin 2 gram vials on back order and the company estimates a release date of March 2019. The 10 gram vials are on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=271>

Cefazolin Injection

February 4, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- Baxter has cefazolin 2 gram/100 mL premixed bags on allocation.
- BBraun has 1 gram/50 mL and 2 gram/50 mL premixed bags on allocation.
- Fresenius Kabi has cefazolin 500 mg vials on back order and the company estimates a release date of mid- to late-February 2019. The 1 gram vials are on back order and the company estimates a release date of mid- to late-February 2019. The 10 gram vials are on back order and the company estimates a release date of 2nd quarter 2019.
- Pfizer has 1 gram and 10 gram vials on back order and the company estimates a release date of 3rd quarter 2019. The 1 gram ADD-Vantage vials are on back order and the company estimates a release date of 1st quarter 2019.
- Sagent has cefazolin 500 mg, 1 gram, and 10 gram vials on back order and the company estimates a release date of March 2019.
- Sandoz has cefazolin 500 mg, 1 gram, and 10 gram vials on back order and the company estimates a release date of late-February to early-March 2019 for the 500 mg vials and mid-February 2019 for the 1 gram and 10 gram vials.
- Hikma has cefazolin 500 mg vials on back order and the company estimates a release date of March to April 2019. The 1 gram and 10 gram vials are on allocation.
- WG Critical Care has cefazolin 500 mg, 1 gram, and 10 gram vials on back order and the company estimates a release date of March 2019.

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

Carbidopa and Levodopa Extended-Release Tablets

February 4, 2019

Reasons for 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 Date:

- Accord has carbidopa and levodopa 50 mg/200 mg extended-release tablets on allocation.
- Mylan has carbidopa and levodopa 25 mg/100 mg extended-release tablets in 100 count unit-dose packs on back order and the company cannot estimate a release date. The carbidopa and levodopa 50 mg/200 mg extended-release tablets in 100 count unit-dose packs are on back order and the company estimates a release date of early-April 2018. The 50 mg/200 mg extended release tablets in 100 count bottles are on back order and the company estimates a release date of early-March 2019. The 25 mg/100 mg extended release tablets in 100 count bottles are on back order and the company estimates a release date of late-May 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.

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

Calcium Gluconate Injection

February 4, 2019

Reasons for Shortage:

- American Regent is not currently marketing calcium gluconate.
- Fresenius Kabi has calcium gluconate available.
- WG Critical Care launched calcium gluconate premixed bags in January 2019.

Estimated Resupply Date:

- All marketed presentations are available

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

Bacteriostatic 0.9% Sodium Chloride Vials

February 4, 2019

Reasons for 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 Date:

- Pfizer has bacteriostatic 0.9% sodium chloride 30 mL vials on back order and the company estimates a release date of March 2019. The 10 mL vials are available in limited supply.

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

14.6% Sodium Chloride Concentrated Solution for Injection

February 4, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

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

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

Proparacaine Hydrochloride Ophthalmic Solution

February 5, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- Akorn has proparacaine 0.5% ophthalmic drops on allocation.
- Bausch Health has proparacaine 0.5% ophthalmic drops on back order and the company estimates a release date of early-March 2019.

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

Indocyanine Green

February 5, 2019

Reasons for Shortage:

- Akorn had IC-Green on shortage due to manufacturing delays.
- Hub has indocyanine green available.

Estimated Resupply Date:

- Akorn has IC-Green 25 mg kits on allocation.

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

2% Lidocaine Hydrochloride Topical Jelly

February 5, 2019

Reasons for 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 Date:

- Akorn has 2% lidocaine jelly 5 mL and 30 mL tubes on back order and the company estimates a release date of February to March 2019.

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

Sodium Polystyrene Sulfonate Powder

February 6, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- CMP Pharma has sodium polystyrene sulfonate in 454 gram bottles on back order and the company estimates a release date of March 2019.
- ECI Pharmaceuticals has sodium polystyrene sulfonate in 454 gram bottles on back order and the company estimates a release date of mid-February 2019.
- KVK-Tech has sodium polystyrene sulfonate in 15 gram and 454 gram bottles on back order and the company estimates a release date of late-February 2019.
- Sunrise Pharmaceuticals has sodium polystyrene sulfonate in 15 gram and 454 gram bottles on back order and the company estimates a release date of mid-February 2019.
- Trigen has sodium polystyrene sulfonate in 454 gram bottles on back order and the company estimates a release date of mid-February 2019.

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

Sodium Polystyrene Sulfonate Oral or Rectal Suspension

February 6, 2019

Reasons for Shortage:

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

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

Pentamidine Isethionate

February 6, 2019

Reasons for Shortage:

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

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

Meropenem Injection

February 6, 2019

Reasons for 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 Date:

- 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 cannot estimate a release date. Pfizer has Merrem 1 gram vials (NDC 00069-0314-10) available in limited supply. Pfizer has generic meropenem 500 mg and 1 gram vials on back order and the company estimates a release date of 2019.

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

Valsartan Tablets

February 7, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- 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.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=444>

Valsartan and Hydrochlorothiazide Tablets

February 7, 2019

Reasons for Shortage:

- Several drug products containing valsartan were recalled due to an unexpected impurity found in the active pharmaceutical ingredient manufactured by a third party. The impurity is N-nitrosodimethylamine (NDMA) and is classified as a probably human carcinogen. 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 Date:

- Mylan has all valsartan/hydrochlorothiazide presentations on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=445>

Thrombin Topical Powder (Recombinant)

February 7, 2019

Reasons for Shortage:

- Baxter did not provide a reason for the shortage.

Estimated Resupply Date:

- Baxter has all Recothrom presentations on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=499>

Spironolactone Tablets

February 7, 2019

Reasons for 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 Date:

- Accord has spironolactone 25 mg tablets in 500 and 1,000 count bottles and 100 mg tablets in 100 count bottles on intermittent back order and the company is releasing supplies as they become available.
- Amneal has all spironolactone presentations on back order and the company cannot estimate a release date.

- Cadista has spironolactone presentations on allocation.
- Mylan has spironolactone 50 mg tablets in 100 and 500 count bottles and 100 mg tablets in 100 count bottles are on back order and the company estimates release dates of mid-February 2019 for the 50 mg tablets in 100 count and 500 count bottles and mid- to late-February 2019 for the 100 mg tablets in 100 count bottles. The 25 mg tablets in 100 count bottles are on back order and the company cannot estimate a release date.
- Par has most presentations on back order and the company cannot estimate a release date.
- Pfizer has Aldactone 25 mg tablets in 100 count bottles on back order and the company cannot estimate a release date. The 50 mg tablets in 100 count bottles are on back order and the company estimates a release date in mid-February 2019.
- Sun Pharma has spironolactone 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.

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

Sincalide Injection

February 7, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Bracco has Kinevac on backorder and the company cannot estimate a release date.

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

Nystatin Oral Suspension

February 7, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Akorn has nystatin 100,000 unit/mL suspension 60 mL and 473 mL bottles on back order and the company cannot estimate a release date.
- Pharmaceutical Associates, Inc. has nystatin suspension in 473 mL bottles on allocation. All other presentations are on back order and the company cannot estimate a release date.
- Precision Dose has all nystatin suspension presentations on back order and the company estimates a release date in early- to mid-March 2019.
- Vista Pharma has nystatin 100,000 units/mL suspension 60 mL bottles, 480 mL bottles, and 5 mL unit-dose cups in 100 count on back order and the company cannot estimate release dates.
- Wockhardt USA has nystatin 100,000 units/mL suspension 60 mL and 473 mL bottles on back order and the company estimates a release date of mid-February 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=500>

Midodrine Tablets

February 7, 2019

Reasons for 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-May 2019.
- Upsher-Smith has midodrine 2.5 mg, 5 mg, and 10 mg tablets on allocation.

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

Methotrexate Injection

February 7, 2019

Reasons for 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 did not provide a reason for the shortage.
- Teva has methotrexate injection on shortage due to increased demand.
- Hikma has methotrexate injection available

Estimated Resupply Dates:

- Accord has methotrexate 25 mg/mL 2 mL and 40 mL preservative-free vials on back order and the company estimates a release date of mid-February 2019.
- Teva has methotrexate 25 mg/mL 40 mL preservative-free vials on allocation. Check wholesaler for inventory.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=282>

Isocarboxazid Tablets

February 7, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

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

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

Immune Globulin, Intravenous or Subcutaneous (Human)

February 7, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Grifols is releasing Gamunex-C on a regular basis, however production cannot keep up with demand in market.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=527>

Ethiodized Oil

February 7, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Guerbet is shipping supplies of Lipiodol Ultra-Fluide. Lipiodol Ultra-Fluide is not FDA approved. In order to prevent a drug shortage, FDA is allowing Guerbet to import Lipiodol Ultra-Fluide, a product manufactured for Guerbet in France by Delpharm Tours.
- Customers must order Lipiodol Ultra-Fluide directly from Guerbet by calling 1-877-729-6679. Lipiodol Ultra-Fluide is non-refundable and may not be resold.

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

Calcium Chloride Injection

February 7, 2019

Reasons for 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 LifeShield syringes available in limited supply.\

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

Argatroban Injection

February 7, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Chiesi has argatroban 1 mg/mL 50 mL vials on back order and the company cannot estimate a release date.
- Hikma has argatroban 1 mg/mL 50 mL vials on allocation.
- Par has argatroban 100 mg/mL 2.5 mL vials on back order and the company cannot estimate a release date.
- Pfizer has argatroban 100 mg/mL 2.5 mL vials on back order and the company estimates a release date in February 2019.
- Novartis has argatroban 100 mg/mL 2.5 mL vials available with short expiration dating (November 2019).
- Sandoz has argatroban 1 mg/mL 50 mL vials on back order and the company estimates a release date of mid-February 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=494>

Vancomycin Hydrochloride Injection

February 8, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Pfizer has 500 mg ADD-Vantage vials, 750 mg vials, 750 mg ADD-Vantage vials, 1 gram vials, 5 gram, and 10 gram vials available in limited supply. The 1 gram ADD-Vantage vials are on back order and the company estimates a release date of March 2018.
- Sagent has vancomycin 5 gram and 10 gram vials on allocation.

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

Thiamine Injection

February 8, 2019

Reasons for 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 early-March 2019.
- Mylan Institutional has thiamine 100 mg/mL 2 mL vials on back order and the company estimates a release date of mid-February 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=502>

Temazepam Capsules

February 8, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Ascend has temazepam 15 mg capsules in 100 count on allocation. The 7.5 mg capsules in 100 count and 30 mg capsules in 500 count are on back order and the company cannot estimate a release date.
- Major has temazepam 7.5 mg capsules in 100 count bottles on back order and the company cannot estimate a release date.
- Mylan has temazepam 15 mg capsules in 100 and 500 count, 22.5 mg capsules in 30 count, and 30 mg capsules in 100 and 500 count on back order and the company estimates a release date of August 2019.
- Mylan Institutional has temazepam 30 mg capsules in 100 count unit-dose packs on back order and the company estimates a release date of early-September 2019.
- Teva has temazepam 30 mg capsules in 100 count and 500 count on intermittent back order and the company is releasing supplies as they become available. The 15 mg capsules in 100 count are on back order. The company estimates release dates of early-March 2019 for all products on back order.

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

Sodium Acetate Injection

February 8, 2019

Reasons for 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:

- All marketed presentations are available.

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

Progesterone Injection

February 8, 2019

Reasons for Shortage:

- American Regent is not currently marketing progesterone injection.
- Fresenius Kabi has progesterone on shortage due to increased demand and manufacturing delays.

Estimated Resupply Dates:

- Fresenius Kabi has progesterone in oil 50 mg/mL 10 mL vials for intramuscular injection on back order and the company estimates a release date of mid- to late-March 2019.
- Hikma has progesterone in oil 50 mg/mL 10 mL vials for intramuscular injection on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=381>

Phenytoin Sodium Injection

February 8, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

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

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

Ondansetron Hydrochloride Injection

February 8, 2019

Reasons for Shortage:

- Apotex did not provide a reason for the shortage.
- Athenex had ondansetron injection on shortage due to increased demand.
- AuroMedics did not provide a reason for the shortage.
- Fresenius Kabi has ondansetron injection available.

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

Estimated Resupply Dates:

- AuroMedics has ondansetron 2 mg/mL 2 mL vials and 20 mL vials on intermittent back order and the company is releasing supplies as they become available.
- Fresenius Kabi has ondansetron 2 mg/mL 20 mL vials with a short-expiration date (< 4 months).
- Hikma has ondansetron 2 mg/mL 20 mL vials in 10 count on back order and the company estimates a release date of March or April 2019.
- Pfizer has ondansetron 2 mg/mL 2 mL iSecure syringes on back order and the company estimates a release date of 4th quarter 2019.
- Sagent has ondansetron 2 mg/mL 2 mL vials and 20 mL vials on back order and the company cannot estimate a release date.

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

Multiple Vitamins for Infusion

February 8, 2019

Reasons for 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. There is limited short-dated product available for the 50 mL adult vials and 5 mL pediatric vials.

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

Mineral Oil and Petrolatum Ophthalmic Ointment

February 8, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Allergan has Refresh PM and Lacri-Lube SOP ointment 3.5 gram tubes on back order and the company cannot estimate a release date. Lacri-Lube SOP 7 gram tubes are also on back order and the company cannot estimate a release date.
- Rugby has Artificial Tears 3.5 gram tubes on back order and the company cannot estimate a release date.
- Alcon has Systane Lubricating Night ointment and Genteal Tears Night-Time ointment on back order and the company estimates a release date in March 2019.
- Perrigo has Puralube ointment in 3.5 gram tubes on back order and the company estimates a release date in February 2019.

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

Metoclopramide Injection

February 8, 2019

Reasons for Shortage:

- Pfizer had metoclopramide injection on shortage due to increased demand.
- Teva had metoclopramide injection on shortage due to increased demand.
- Fresenius Kabi has metoclopramide injection on shortage due to increased demand.

Estimated Resupply Dates:

- Fresenius Kabi has metoclopramide 5 mg/mL 2 mL syringes on back order and the company estimates a release date of mid-March 2019.

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

Methocarbamol Tablets

February 8, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Bayshore has all methocarbamol presentations on allocation.
- Hikma has methocarbamol 750 mg tablets in 500 count on back order and the company estimates a release date of February 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.

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

Melphalan Injection

February 8, 2019

Reasons for 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.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=525>

Magnesium Sulfate Injection

February 8, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

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

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

Lorazepam Tablets

February 8, 2019

Reasons for Shortage:

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

- Teva did not provide a reason for the shortage.

Estimated Resupply Dates:

- Leading has all lorazepam tablets on allocation.
- Major has lorazepam 0.5 mg tablets in 100-count unit-dose packs, 1 mg tablets in 100-count bottles and 100-count unit-dose packs, and 2 mg tablets in 100-count bottles and 100-count unit-dose packs on back order and the company cannot estimate a release date. Lorazepam 0.5 mg tablets in 100-count bottles are available in limited supply.
- Mylan Institutional has lorazepam 0.5 mg, 1 mg, and 2 mg tablets in 100-count unit-dose packs on back order and the company estimates release dates of late-April to early-May 2019.
- Teva has lorazepam 2 mg tablet in 500 count bottles on back order and the company estimates a release date of late-May 2019. All other lorazepam tablet presentations are on back order and the company estimates a release date in early-April 2019.

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

Latanoprost Ophthalmic Solution

February 8, 2019

Reasons for 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 has latanoprost ophthalmic solution available.
- Sandoz (Falcon) has latanoprost ophthalmic solution available

Estimated Resupply Dates:

- Greenstone has latanoprost ophthalmic solution on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=507>

Ketorolac Injection

February 8, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Alvogen has 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 are 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 mid-March 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. The 30 mg/mL 1 mL vials are on back order and the company estimates a release date of early-March 2019. The 30 mg/mL 2 mL vials for intramuscular use are on back order and the company estimates a release date in early-March 2019.
- Hikma has ketorolac 15 mg/mL 1 mL vials on back order and the company estimates a release date of February 2019. The 30 mg/mL 1 mL vials are on back order and the company estimates a release date of March or April 2019
- Pfizer has ketorolac 30 mg/mL 1 mL Carpuject syringes, 30 mg/mL 2 mL Carpuject syringes for intramuscular injection, and 30 mg/mL 1 mL iSecure syringes on back order and the company estimates a release date of 1st quarter 2020. The 15 mg/mL 1 mL vials are on back order and the company estimates a release date of February 2019.
- Sagent has ketorolac 30 mg/mL 1 mL vials on back order and the company cannot estimate a release date.

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

Iron Dextran Injection

February 8, 2019

Reasons for 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.

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

Heparin Injection

February 8, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Fresenius Kabi has heparin 10,000 unit/mL 4 mL vials available as short-dated product (<1 months expiration date). The 1,000 unit/mL 2 mL vials are on back order and the company estimates a release date of mid- to late-March 2019. The 10,000 unit/mL 5 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 5,000 unit/mL 2 mL vials are on back order and the company estimates a release date of March to April 2019.
- Pfizer has 5,000 unit/mL 1 mL Carpuject syringes on back order and the company estimates a release date of December 2019. The 1,000 unit/mL 10 mL and 5,000 unit/mL 10 mL vials are on back order and the company cannot estimate a release date. The 5,000 unit/mL 1 mL glass vials and 10,000 unit/mL 1 mL glass vials are on back order and the company estimates a release date of June 2019. The 1,000 unit/mL 1 mL glass vials and 10,000 unit/mL 0.5 mL carpuject syringes are available in limited supply. The 1,000 unit/mL 30 mL glass vials are on back order and the company estimates a release date in March 2019.
- Sagent has 1,000 unit/mL 1 mL vials, 1,000 unit/mL 2 mL vials, 5,000 unit/mL 1 mL vials, and 10,000 unit/mL 4 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.

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

Folic Acid Injection

February 8, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Fresenius Kabi has folic acid available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=518>

Fluconazole Injection

February 8, 2019

Reasons for Shortage:

- Hikma discontinued fluconazole injection in August 2018.
- Pfizer has fluconazole injection on shortage due to manufacturing delays. The 200 mg/100 mL fluconazole in dextrose bags were discontinued in August 2018.
- Renaissance Lakewood Pharmaceuticals bought fluconazole in sodium chloride premixed bags from Claris Lifescience.
- Sagent has fluconazole injection on shortage due to increased demand and manufacturing delays.

Estimated Resupply Dates:

- Pfizer has fluconazole 200 mg/100 mL and 400 mg/200 mL in 0.9% sodium chloride on back order and the company estimates a release date of February 2019 for the 200 mg/100 mL bags and 1st quarter 2019 for the 400 mg/200 mL bags.
- Renaissance Lakewood has fluconazole 400 mg/200 mL in 0.9% sodium chloride in 6 and 10 count on back order and the company cannot estimate a release date.

- Sagent has fluconazole injection 200 mg/100 mL in 0.9% sodium chloride on allocation.

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

Famotidine Injection

February 8, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Fresenius Kabi has famotidine 20 mL vials on back order and the company estimates a release date of late-February to early-March 2019. Check wholesalers for inventory.
- Hikma has famotidine 2 mL and 4 mL vials on back order and the company estimates a release date of to late-February to early-March 2019 for the 4 mL vials.
- Mylan Institutional has famotidine 2 mL vials on back order and the company estimates a release date of mid- to late-February 2019.

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

Dexamethasone Sodium Phosphate Injection

February 8, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- AuroMedics has dexamethasone sodium phosphate 4 mg/mL 1 mL, 5mL, and 30 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has dexamethasone sodium phosphate 4 mg/mL 1 mL prefilled syringes on back order and the company estimates a release date of 2nd quarter 2019. The 10 mg/mL 1 mL preservative-free vials are on back order and the company estimates a release date of late-February to early-March 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 mid-February 2019 for the 1 mL vials and 5 mL vials and mid- to late-February 2019 for the 30 mL vials. The 10 mg/mL 10 mL vials are on back order and the company estimates a release date of mid- to late-February 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 back order and the company estimates a release date of late-February to early-March 2019.

- Mylan Institutional has dexamethasone 40 mg/mL 30 mL vial on back order and the company estimates a release date of mid- to late-March 2019.

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

0.9% Sodium Chloride 10 mL, 20 mL, and 50 mL Preservative Free Vials and Syringes February 8, 2019

Reasons for 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 and 50 mL vials on back order and the company estimates a release date of March 2019 for the 20 mL vials and February 2019 for the 50 mL vials. The 10 mL LifeShield syringes are on back order and the company estimates a release date of March 2019.

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

Vecuronium Bromide Injection February 11, 2019

Reasons for 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-April 2019.
- Pfizer has vecuronium 10 mg and 20 mg vials on back order and the company estimates a release date of September 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=167>

Valganciclovir HCl Oral Powder for Solution February 11, 2019

Reasons for 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-March 2019.

Thrombin Topical Solution (Bovine)

February 11, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Pfizer has Thrombin-JMI 20,000 unit syringe spray kits on back order and the company estimates a release date of March 2020. The 5,000 unit epistaxis kits are on back order and the company estimates a release date of February 2019. The 20,000 unit pump spray kits are on back order and the company estimates a release date of June 2019. The 5,000 unit vials and 5,000 unit syringe spray kits are available in limited supply.

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

Norepinephrine Bitartrate Injection

February 11, 2019

Reasons for 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.

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

Losartan and Hydrochlorothiazide Tablets

February 11, 2019

Reasons for Shortage:

- 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 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 50 mg/ 12.5 mg in 90 and 1000 count bottles and 100mg/ 12.5 mg in 90 and 1000 count bottles in December 2018 and January 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>.

- Torrent has losartan and hydrochlorothiazide tablets available in all presentations (from lots unaffected by the recall).

Estimated Resupply Dates:

- Cadista has losartan and hydrochlorothiazide tablets on back order and the company cannot estimate a release date.
- 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 most losartan and hydrochlorothiazide tablet presentations on back order and the company estimates a release date in mid-February 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=529>

Levetiracetam Injection

February 11, 2019

Reasons for 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. The 100 mg/mL 5 mL vials are on intermittent back order and the company is releasing supplies as they become available.
- Sun Pharma has levetiracetam 100 mg/mL 5 mL vials on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=84>

Letemovir Injection

February 11, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

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

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=487>

Indomethacin Capsules

February 11, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Camber has indomethacin 25 mg and 50 mg capsules on intermittent back order and the company is releasing product weekly.
- Glenmark has indomethacin 25 mg capsules in 100 count and 50 mg capsules in 500 count on back order and the company estimates a release date of mid-February 2019. Indomethacin 25 mg capsules in 1000 count and 50 mg capsules in 100 count are on back order and the company estimates a release date of late-April 2019.

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

Immune Globulin, Subcutaneous (Human)

February 11, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Baxalta is reviewing all Cuvitru orders and the company cannot estimate a release date.
- Baxalta is reviewing all HyQvia orders and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=515>

Hydralazine injection

February 11, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Akorn has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of February 2019.
- Fresenius Kabi has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of mid- to late-February 2019. Check wholesalers for inventory.
- X-Gen has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of mid-March 2019.

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

Heparin Sodium Premixed Bags February 11, 2019

Reasons for Shortage:

- Baxter has heparin on shortage due to manufacturing delays.
- BBraun has heparin premixes available.
- Fresenius Kabi has heparin premixes on shortage due to increased demand.
- Pfizer has heparin on shortage due to manufacturing delays.

Estimated Resupply Dates:

- Baxter has heparin 2000 units/1000 mL premixed bags on back order and the company estimates a release date of 1st quarter 2019.
- Fresenius Kabi has heparin 25,000 units/500 mL 5% dextrose premixed bags on back order and the company estimates a release date of mid-February 2019. The 25,000 units/250 mL in 5% dextrose are on back order and the company estimates a release date of early-March 2019.
- Pfizer has heparin 2000 units/1000 mL 0.9% sodium chloride premixed bags on back order and the company estimates a release date of February 2019. Heparin 1000 units/500 mL 0.9% sodium chloride premixed bags, 12,000 unit/250 mL in 0.45% sodium chloride premixed bags, and 25,000 units/250 mL 0.45% sodium chloride premixed bags are available in limited supply. Heparin 25,000 units/250 mL 5% dextrose premixed bags are on back order and the company estimates a release date of March 2019.

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

Furosemide Tablets February 11, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Hikma has furosemide 20 mg tablets in 100 count unit dose packs, 40 mg tablets in 100 count unit dose packs, 40 mg tablets in 100 count bottles, 40 mg tablets in 1000 count bottles, and 80 mg tablets in 100 count unit dose packs on allocation.
- Mylan has furosemide 40 mg tablets in 100 count and 1000 count on back order and the company estimates a release date of mid-February 2019.

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

Diazepam Injection

February 11, 2019

Reasons for Shortage:

- Pfizer has diazepam on shortage due manufacturing delays.

Estimated Resupply Dates:

- Pfizer has diazepam 5 mg/mL 2 mL Carpuject syringes on back order and the company estimates a release date of April 2019.

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

Dexmedetomidine Hydrochloride 100 mcg/mL Vials for Injection

February 11, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Hikma has dexmedetomidine 100 mcg/mL 2 mL vials on allocation.
- Mylan has dexmedetomidine 100 mcg/mL 2 mL vials on back order and the company cannot estimate a release date.
- Sandoz has short dated dexmedetomidine 100 mcg/mL 2 mL vials available with an expiration date of July 2019.
- Teva has short dated dexmedetomidine 100 mcg/mL 2 mL vials available.
- WG Critical Care has dexmedetomidine 100 mcg/mL 10 mL on back order and the company cannot estimate a release date.

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

Aminophylline Injection

February 11, 2019

Reasons for 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 March 2019.

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

Albuterol Inhalation Solution

February 11, 2019

Reasons for Shortage:

- Akorn has albuterol inhalation solution on shortage due to manufacturing delays.

Estimated Resupply Dates:

- Akorn has albuterol 0.5% inhalation solution 20 mL bottles on allocation

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

Acetazolamide Injection

February 11, 2019

Reasons for Shortage:

- Hikma did not provide a reason for the shortage.
- X-Gen has 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 mid-February 2019.
- X-Gen has acetazolamide 500 mg vials on back order and the company estimates a release date of mid-March 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=528>

Abciximab Injection

February 11, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

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

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

Penicillamine

February 13, 2019

Reasons for 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-June 2019.

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

Fluorescein Sodium Ophthalmic Strips

February 13, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Akorn has Ful-Glo 0.6 mg strips on back order and the company estimates a release date of mid-March 2019. The 1 mg strips are on allocation.
- Hub has Bio-Glo 1 mg strips on intermittent back order and the company is releasing supplies as they become available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=362>

Dorzolamide 2% and Timolol 0.5% Ophthalmic Solution

February 13, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Akorn has Cosopt 2%/0.5% ophthalmic solution in 10 mL bottles on back order and the company cannot estimate a release date. Dorzolamide 2% and timolol 0.5% ophthalmic solution in 10 mL bottles are available on allocation.
- Bausch Health has dorzolamide 2% and timolol 0.5% ophthalmic solution in 10 mL bottles on back order and the company estimates a release date of mid-February 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 February 2019.

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

Amphotericin B Injection

February 13, 2019

Reasons for Shortage:

- X-Gen has amphotericin B on shortage due to manufacturing delays. They are the sole suppliers of amphotericin B lyophilized powder for injection.[1]
- 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-March 2019

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=524>

Buprenorphine Hydrochloride Injection

February 14, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

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

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

Betamethasone Acetate/Betamethasone Sodium Phosphate Suspension for Injection

February 14, 2019

Reasons for 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 launched betamethasone acetate/betamethasone sodium phosphate in early-2019.

Estimated Resupply Dates:

- American Regent 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 mid-February 2019.

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

Ampicillin Sodium and Sulbactam Sodium Injection

February 14, 2019

Reasons for 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 15 gram vials on back order and the company estimates a release date of mid-March to mid-April 2019. The 1.5 gram and 3 gram vials are on allocation.
- Mylan Institutional has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on back order and the company estimates a release date of early-April 2019 for the 1.5 gram vials and mid-March 2019 for the 3 gram and 15 gram vials.
- Pfizer has Unasyn 1.5 gram vials and 3 gram vials on back order and the company estimates a release date of June 2019 for the 1.5 gram vials and March 2019 for the 3 gram vials. Unasyn 15 gram bulk vials are on back order and the company estimates a release date of March 2020.
- 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 15 gram bulk vials on back order and the company estimates a release date of March 2019. The 1.5 gram and 3 gram vials are on allocation.
- WG Critical Care has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on back order and the company estimates a release date of March 2019.

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

Albuterol Sulfate Extended-Release Tablets

February 14, 2019

Reasons for Shortage:

- Mylan did not provide a reason for the shortage. They are the sole suppliers of albuterol sulfate extended-release tablets.

Estimated Resupply Dates:

- Mylan has albuterol sulfate 4 mg and 8 mg extended-release tablets on back order and the company estimates a release date of mid-May 2019 for the 4 mg tablets and late-May 2019 for the 8 mg tablets.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=530>

Thiothixene Capsules

February 15, 2019

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

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

Sodium Fluoride Chewable Tablets

February 15, 2019

Reasons for Shortage:

- Kirkman has discontinued sodium fluoride chewable tablets because their supplier, Medical Product Laboratory, has stopped manufacturing sodium fluoride tablets. Kirkman is looking for a new supplier.
- PureTek has sodium fluoride chewable tablets available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=481>

Promethazine Injection

February 15, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

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

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

Physostigmine Salicylate Injection

February 15, 2019

Reasons for 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 on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=532>

Nelarabine Injection

February 15, 2019

Reasons for Shortage:

- Novartis did not provide a reason for the shortage

Estimated Resupply Dates:

- Novartis has Arranon 5 mg/mL 50 mL vials on a limited allocation.

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

Ketamine Injection

February 15, 2019

Reasons for 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 March to April 2019.
- Mylan Institutional has ketamine 100 mg/mL 10 mL vials on back order and the company estimates a release date of mid-March 2019.
- Pfizer has ketamine 50 mg/mL 10 mL vials on back order and the company estimates a release date of March 2021. The 100 mg/mL 5 mL vials are on back order and the company estimates a release date of June 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

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

Hydroxocobalamin Injection

February 15, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Meridian Medical Technologies has Cyanokit injection 5 gram vials on back order and the company estimates a release date in early-April 2019. Check with your wholesaler for inventory

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

Haloperidol Tablets

February 15, 2019

Reasons for Shortage:

- Mylan did not provide a reason for the shortage.
- Sandoz has discontinued haloperidol 0.5 mg and 1 mg tablets.

Estimated Resupply Dates:

- Mylan has haloperidol 0.5 mg and 1 mg tablets in 100 count unit-dose packs on back order and the company estimates a release date of early-May 2019. The 2 mg and 5 mg tablets are on back order and the company estimates a release date of mid-May 2019. The 10 mg tablets in 100 count unit-dose packs are on back order and the company estimates a release date of early-June 2019. The 0.5 mg tablets in 100 count and 1000 count, 1 mg tablets in 100 count and 1000 count, 2 mg tablets in 100 count and 1000 count, and 5 mg tablets in 100 count and 1000 count are on back order and the company estimates a release date of mid-April 2019. The 10 mg tablets in 100 count and 20 mg tablets in 100 count are on back order and the company estimates a release date of mid-May 2019.
- Zydus has all haloperidol tablet presentations on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=459>

Enalaprilat Injection

February 15, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Hikma has enalaprilat 1.25 mg/mL 1 mL vials on back order and the company estimates a release date of mid-February 2019. The 2 mL vials are 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.

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

Diltiazem Extended-Release Capsules (Twice-Daily Dosing)

February 15, 2019

Reasons for Shortage:

- Mylan did not provide a reason for the shortage

Estimated Resupply Dates:

- Mylan has diltiazem extended-release 60 mg, 90 mg, and 120 mg capsules in 100 count bottles on back order and the company estimates a release date of mid-February 2019.
- Mylan Institutional has diltiazem extended-release 60 mg, 90 mg, and 120 mg capsules in 100 count unit-dose packs on back order and the company estimates a release date of mid- to late-March 2019 for the 60 mg and 120 mg tablets and early-April 2019 for the 90 mg tablets.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=496>

Clindamycin Phosphate Injection

February 15, 2019

Reasons for 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 clindamycin 600 mg/50 mL in 5% dextrose premixes on back order and the company estimates a release date of February or March 2019. The 900 mg/50 mL in 5% dextrose premixes are on back order and the company estimates a release date of mid-February 2019.
- Alvogen has clindamycin 150 mg/mL 2 mL, 4 mL, and 6 mL ADD-Vantage vials on back order and the company estimates a release date of 2nd quarter 2019.
- Baxter has clindamycin 600 mg/50 mL in 5% dextrose on back order and the company cannot estimate a release date.
- Fresenius Kabi has clindamycin 150 mg/mL 6 mL vials on allocation. There are some product available with short expiry of < 6 to 8 months.
- 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 3rd quarter 2019. The 150 mg/mL 2 mL and 4 mL single-dose vials are on back order and the company estimates a release date of February 2019.

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

Buspirone Tablets

February 15, 2019

Reasons for Shortage:

- Accord did not provide a reason for the shortage.
- Mylan did not provide a reason for the shortage.
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates:

- Accord has all buspirone on back order and the company estimates a release date of late-March 2019.
- Mylan Institutional has buspirone 5 mg, 10 mg, 15 mg, and 30 mg tablets in 100 count unit-dose packs on back order and the company cannot estimate a release date.
- Mylan has all buspirone presentations in bottles on long-term back order and the company cannot estimate a release date.
- Par Pharmaceuticals has 7.5 mg tablets in 100 count on back order and the company estimates a release date of late-February 2018.
- Teva has buspirone 5 mg, 10 mg, and 15 mg tablets in 100 and 500 count on back order and the company estimates a release date of mid-March 2019. However, there are 15 mg tablets in 100 count available with a short expiry of November 2019. The 30 mg tablets in 60 and 180 count are on back order and the company estimates a release date of mid-March 2019.
- Zydus has all buspirone presentations on allocation.

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

Ascorbic Acid Injection

February 15, 2019

Reasons for 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 mid-March 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=531>

Amiodarone Injection

February 15, 2019

Reasons for 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 mid-February 2019. There are short-dated 4 mL vials available with an expiration date of <3 months.
- Mylan Institutional has amiodarone 50 mg/mL 3 mL vials on back order and the company estimates a release date of mid-February 2019. The 9 mL vials are on back order and the company cannot estimate a release date.
- Sagent has amiodarone 50 mg/mL 3 mL vials available with a short expiry of February 2019.

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

Amino Acid Products

February 15, 2019

Reasons for Shortage:

- Baxter discontinued Premasol in late-2018. The remaining amino acid products are available.
- BBraun discontinued FreAmine HBC, Nephramine, and Trophamine 6% in mid-2018. The remaining amino acid presentations are available.
- ICU Medical discontinued several Aminosyn products in September 2018. The remaining amino acid presentations are available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=297>

Sodium Phosphate Injection

February 18, 2019

Reasons for 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 early-March 2019 for the 5 mL vials and late-February to early-March 2019 for the 15 mL vials.
- Pfizer has sodium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of September 2019

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

Secobarbital Capsules

February 18, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

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

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=517>

Potassium Phosphate Injection

February 18, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Fresenius Kabi has potassium phosphate 3 mmol/mL 50 mL vials on back order and the company estimates a release date of mid- to late-February 2019 for the 50 mL vials.
- Pfizer has potassium phosphate 3 mmol/mL 15 mL vials available in limited supply.

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

Mitoxantrone Hydrochloride Injection

February 18, 2019

Reasons for Shortage:

- Fresenius Kabi has mitoxantrone available.
- Pfizer had mitoxantrone injection on shortage due to manufacturing delays.
- Teva has mitoxantrone injection available except for the 10 mL vials which are temporarily discontinued.

Estimated Resupply Dates:

- Fresenius Kabi has short-dated mitoxantrone 2 mg/mL 15 mL vials available with an expiration date of <8 months.
- Teva has temporarily discontinued mitoxantrone 10 mL vials and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=189>

Mepivacaine Injection:

February 18, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Fresenius Kabi has 1.5% Polocaine-MPF 30 mL vials on back order and the company estimates a release date of mid- to late-February 2019. The 1% Polocaine 50 mL vials are on back order and the company

estimates a release date of late-February to early-March 2019. The 2% Polocaine 50 mL vials are on back order and the company estimates a release date of late-February to early-March 2019. The 1% Polocaine-MPF 30 mL vials are on back order and the company estimates a release date of late-February to early-March 2019. The 2% Polocaine-MPF 20 mL vials are on back order and the company estimates a release date of early- to mid-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.

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

Lidocaine with Epinephrine Injection

February 18, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Fresenius Kabi has 0.5% Xylocaine with epinephrine (1:200,000) 50 mL vials on back order and the company estimates a release date of late-February to early-March 2019. The 1% Xylocaine with epinephrine (1:200,000) 10 mL vials are on back order and the company estimates a release date of early-March 2019. The 1% Xylocaine with epinephrine (1:200,000) 20 mL vials are on back order and the company estimates release dates of mid- to late-February 2019. The 1% Xylocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates release dates of late-February to early-March 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 are on back order and the company estimates a release date of mid- to late-March 2019. 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 mid- to late-February 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 February 2019. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are on back order and the company estimates a release date of February 2019. The 1% lidocaine with epinephrine (1:100,000) 50 mL vials are on back order and the company estimates a release date of March 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 March 2019. The 2% lidocaine with epinephrine (1:100,000) 20 mL vials are on back order and the company estimates a release date of March 2019. The 2% lidocaine with epinephrine (1:100,000) 30 mL and 50 mL vials are on back order and the company estimates a release date of March 2019 for the 30 mL vials and June 2019 for the 50 mL vials.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=98>

Levothyroxine Sodium Injection

February 18, 2019

Reasons for Shortage:

- Athenex started marketing levothyroxine sodium in January 2019
- Fresenius Kabi has levothyroxine sodium available.
- Par had levothyroxine sodium on shortage due to increased demand.
- Piramal Critical Care has levothyroxine sodium available.

Estimated Resupply Dates:

- Fresenius Kabi has levothyroxine 100 mcg vials on back order and the company estimates a release date of mid- to late-February 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=506>

Leucovorin Calcium Injection

February 18, 2019

Reasons for Shortage:

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

Estimated Resupply Dates:

- Fresenius Kabi has leucovorin 500 mg vials on back order and the company estimates a release date of early-March 2019.
- Hikma has leucovorin 200 mg and 350 mg vials on back order and the company estimates a release date of March to April 2019 for the 350 mg vials and cannot estimate a release date for the 200 mg vials.
- Sagent has leucovorin 200 mg vials on back order and the company estimates a release date of February 2019.

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

Furosemide Injection

February 18, 2019

Reasons for 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 early-April 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=323>

Fluorouracil Injection

February 18, 2019

Reasons for 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:

- Accord has fluorouracil 50 mg/mL 100 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has fluorouracil 50 mg/mL 100 mL vials on back order and the company estimates a release date of mid- to late-February 2019.
- Sagent has fluorouracil 50 mg/mL 100 mL vials on back order and the company estimates a release date of March 2019.

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

Dicyclomine Injection

February 18, 2019

Reasons for 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

- American Regent has dicyclomine 10 mg/mL 2 mL vials on back order and the company estimates a release date of mid-February 2019.
- Hikma has short-dated dicyclomine 10 mg/mL 2 mL vials available with an expiration date of May 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=520>

Cefuroxime Sodium Injection

February 18, 2019

Reasons for 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 and 1.5 gram vials on back order and the company estimates a release date of late-February to mid-March 2019.

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

50% Dextrose Injection

February 18, 2019

Reasons for Shortage:

- Amphastar has 50% dextrose injection on allocation due to increased demand.
- Pfizer has 50% dextrose injection on shortage due to manufacturing delays.

Estimated Resupply Dates:

- Pfizer has 50% dextrose 50 mL LifeShield syringes on back order and the company estimates a release date of June 2019. The 50% dextrose 50 mL Ansyf syringes are on back order and the company estimates a release date of April 2019. The 50% dextrose 50 mL vials are on back order and the company estimates a release date of April 2019.
- Amphastar has 50% dextrose 50 mL Luer-Jet syringes on allocation with regular releases

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

23.4% Sodium Chloride Injection

February 18, 2019

Reasons for Shortage:

- Fresenius Kabi has 23.4% sodium chloride injection on shortage due to increased demand.
- Pfizer has 23.4% sodium chloride injection on shortage due to increased demand.

Estimated Resupply Dates:

- Fresenius Kabi has 23.4% sodium chloride 30 mL, 100, and 200 mL vials on back order and the company estimates a release date of mid-to late-February 2019 for the 30 mL and 100 mL vials and late-March 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.

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

Sodium Bicarbonate Injection

February 19, 2019

Reasons for 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 Date:

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

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

Ropivacaine Injection

February 19, 2019

Reasons for 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 Date:

- Akorn has ropivacaine 5 mg/mL 30 mL vials on back order and the company estimates a release date of early-March 2019.
- AuroMedics has ropivacaine 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 cannot estimate a release date. The 5 mg/mL 30 mL vials are on back order and the company estimates a release date of mid- to late-February 2019. The 5 mg/mL 100 mL bottles are on back order and the company estimates a release date of late-February to early-March 2019. Check wholesalers for inventory.

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

Meperidine Hydrochloride Injection

February 19, 2019

Reasons for Shortage:

- Pfizer has Demerol injection on shortage due to manufacturing delays.
- ICU Medical discontinued meperidine 30 mL PCA vials.

Estimated Resupply Date:

- Hikma has meperidine 50 mg/mL 1 mL vials on back order and the company estimates a release date of March to April 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 and 50 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of December 2019. The 75 mg/mL 1 mL

Carpujet syringes and 100 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of December 2019. The 50 mg/mL 30 mL vials are on back order and the company estimates a release date of June 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=347>

Ketamine Injection

February 19, 2019

Reasons for 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 Date:

- 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 March to April 2019.
- Mylan Institutional has ketamine 100 mg/mL 10 mL vials on back order and the company estimates a release date of mid-March 2019.
- Pfizer has ketamine 50 mg/mL 10 mL vials on back order and the company estimates a release date of March 2021. The 100 mg/mL 5 mL vials are on back order and the company estimates a release date of June 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.

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

Deferoxamine Injection

February 19, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- Fresenius Kabi has deferoxamine 2 gram vials on back order and the company estimates a release date of late-February to early-March 2019.
- Pfizer has deferoxamine 500 mg vials on back order and the company estimates a release date of December 2019.

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

Cefepime Injection

February 19, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- Baxter has cefepime 2 gram premixed bags on allocation.
- BBraun has cefepime 1 gram and 2 gram premixed bags on allocation.
- Fresenius Kabi has cefepime 2 gram vials on back order and the company estimates a release date of mid-March 2019.
- Pfizer has Maxipime 1 gram and 2 gram ADD-Vantage vials on back order and the company estimates a release date of September 2019. The 1 gram and 2 gram vials are on back order and the company estimates a release date of December 2019.
- Sagent has cefepime 2 gram vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=59>

Bupivacaine with Epinephrine Injection

February 19, 2019

Reasons for 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 Date:

- Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 10 mL vials on back order and the company estimates a release date of late-March 2019. The 0.25% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of mid- to late-February 2019. The 0.25% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of mid- to late-February 2019. The 0.5% Sensorcaine-MPF with epinephrine 30 mL sterile packs are on back order and the company cannot estimate a release date.
- Pfizer has 0.25% bupivacaine with epinephrine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of September 2019. The 0.25% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of September 2019. The 0.5% bupivacaine with epinephrine 10 mL preservative-free vials are on back order and the company estimates a release date of September 2019. The 0.5% bupivacaine with epinephrine 30 mL preservative-free vials are on back order and the company estimates a release date of February 2019. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of September 2019.

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

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

Bupivacaine Injection

February 19, 2019

Reasons for 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 Date:

- AuroMedics has 0.25% bupivacaine 10 mL and 30 mL preservative-free vials on intermittent back order and the company is releasing product as it becomes available. The 0.5% bupivacaine 10 mL and 30 mL preservative-free vials are on intermittent back order and the company is releasing product as it becomes available. The 0.75% bupivacaine 10 mL and 30 mL preservative-free vials are on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has 0.25% Sensorcaine 10 mL preservative-free vials on back order and the company estimates a release date of mid- to late-February 2019. The 0.25% 30 mL preservative-free vials are on back order and the company estimates a release date of late-February to early-March 2019. The 0.25% 50 mL vials are on back order and the company estimates a release date of mid- to late-March 2019. The 0.5% Sensorcaine 10 mL preservative-free vials are on back order and the company estimates release dates of late-February to early-March 2019. The 0.5% Sensorcaine 50 mL vials are on back order and the company estimates a release date of early-March 2019. The 0.25% and 0.5% Sensorcaine 30 mL preservative-free vials in sterile packs are on back order and the company cannot estimate release dates.
- Pfizer has 0.25% bupivacaine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of March 2019 for the 10 mL vials and February 2019 for the 30 mL vials. The 0.25% bupivacaine 50 mL vials are on back order and the company estimates release dates of February 2019. The 0.5% bupivacaine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of March 2019. The 0.5% bupivacaine 50 mL vials are on back order and the company estimates a release date of February 2019. The 0.75% bupivacaine 10 mL preservative-free vials are on back order and the company estimates a release date of March 2019. The 0.75% bupivacaine 30 mL preservative-free vials are available in limited supply.
- Pfizer has all Marcaine vials on back order and the company estimates a release date of March 2020. The 0.75% Marcaine Spinal in 8.25% dextrose 2 mL ampules are available.

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

Bumetanide Injection

February 19, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- 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.

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

Benzotropine Mesylate Injection

February 19, 2019

Reasons for 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 Date:

- Akorn has benztropine 1 mg/mL 2 mL ampules and Cogentin 1 mg/mL 2 mL ampules on back order and the company cannot estimate a release date.
- Fresenius Kabi has benztropine 1 mg/mL 2 mL vials on back order and the company estimates a release date of late-February to early-March 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=497>

25% Dextrose Injection

February 19, 2019

Reasons for Shortage:

- Pfizer has 25% dextrose on shortage due to manufacturing delays.

Estimated Resupply Date:

- Pfizer has 25% dextrose 10 mL Ansyr syringes on back order and the company estimates a release date of March 2019.

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

Hepatitis B Vaccine (Recombinant)

February 20, 2019

Reasons for Shortage:

- Merck has Recombivax HB on shortage due to increase in global demand.
- GlaxoSmithKline has Engerix B available.
- GlaxoSmithKline discontinued Engerix B pediatric vials in October 2017.

Estimated Resupply Date:

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

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

Hepatitis A Virus Vaccine Inactivated

February 20, 2019

Reasons for Shortage:

- Merck did not provide a reason for the Vaqta shortage.
- Merck discontinued Vaqta adult formulation 50 U/1 mL vials in 1 count in January 2019.
- GlaxoSmithKline did not provide a reason for the Havrix shortage.
- GlaxoSmithKline discontinued the Havrix pediatric vials in late-2018. The Havrix adult vials were discontinued in November 2017

Estimated Resupply Date:

- GlaxoSmithKline has Havrix adult prefilled syringes on back order and the company cannot estimate a release date.

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

Fluphenazine Tablets

February 20, 2019

Reasons for Shortage:

- Lannett has fluphenazine tablets available.
- Mylan did not provide a reason for the shortage

Estimated Resupply Date:

- Mylan has all fluphenazine tablet presentations in 100 count and 500 count bottles on back order and the company estimates a release date in late-May 2019. The unit dose presentations are on back order and the company estimates a release date of mid- to late-June 2019.

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

Enoxaparin Sodium Injection

February 20, 2019

Reasons for 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 Date:

- Amphastar has enoxaparin 120 mg/0.8 mL prefilled syringes available in limited supply.
- Fresenius Kabi has enoxaparin 120 mg/0.8 mL prefilled syringes on back order and the company estimates a release date in mid- to late-March 2019.
- Sandoz has discontinued enoxaparin prefilled syringes. They continue to supply product to customers according to forecast until their supply is depleted.
- Sanofi-Aventis has all Lovenox prefilled syringes on allocation.
- Teva has enoxaparin 150 mg/1 mL, 120 mg/0.8 mL, 100 mg/1 mL, and 80 mg/0.8 mL prefilled syringes on allocation.
- Winthrop has all enoxaparin prefilled syringes on allocation.

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

Cyclosporine Injection

February 20, 2019

Reasons for Shortage:

- Novartis has Sandimmune available.
- Perrigo did not provide a reason for the shortage.

Estimated Resupply Date:

- Perrigo has cyclosporine 50 mg/mL ampules on back order and the company estimates a release date of late-February 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=534>

Ciprofloxacin Ophthalmic Solution

February 20, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

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

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

Ciprofloxacin Injection

February 20, 2019

Reasons for Shortage:

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

Estimated Resupply Date:

- All marketed presentations are available.

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

Amyl Nitrite Inhalation

February 20, 2019

Reasons for Shortage:

- James Alexander has amyl nitrite inhalation on shortage because they are in the process of serializing the product.

Estimated Resupply Date:

- James Alexander has amyl nitrite inhalation on back order and the company estimates a release date in April 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=505>

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

February 20, 2019

Reasons for 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.
- 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 Date:

- ICU Medical has 0.9% sodium chloride 100 mL VisIV bags on allocation to current customers. The 100 mL bags in 48 count and 80 count are available to current customers. The 0.9% sodium chloride 50 mL VisIV bags, 50 mL bags, 25 mL bags, and 50 mL preservative-free bags are fully available.
- Pfizer has 0.9% sodium chloride 100 mL Add-Vantage bags available in limited supply. The 50 mL preservative-free vials are on back order and the company estimates a release date of February 2019.

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

Amphetamine Mixed Salts, Immediate-Release Tablets

February 21, 2019

Reasons for Shortage:

- Aurobindo did not provide a reason for the shortage.
- Mallinckrodt has amphetamine mixed salts available.
- Mylan did not provide a reason for the shortage.
- Sun Pharma did not provide a reason for the shortage.
- Teva did not provide a reason for the shortage of generic amphetamine mixed salts. Teva has Adderall available.
- Zydus has amphetamine mixed salts available.

Estimated Resupply Date:

- Aurobindo has amphetamine mixed salts, immediate-release 10 mg tablets on back order and the company cannot estimate a release date.
- Mylan has all amphetamine mixed salts, immediate-release tablets on back order and the company estimates a release date of late-June 2019.
- Teva has all amphetamine mixed salts, immediate-release tablets on back order and the company estimates a release date of early-March 2019.
- Sun Pharma has amphetamine mixed salts, immediate-release 10 mg tablets available in limited supply. The 15 mg tablets are available in limited supply as short-dated product (June 2019). All other strengths are on back order and the company cannot estimate a release date.
- Zydus has all amphetamine mixed salts, immediate-release tablets available on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=535>

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