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# Drug Information Update

August 2019

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## NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
PREGABALIN	25 MG, 50 MG, 75 MG, 100 MG, 150 MG, 200 MG, 300 MG, 225 MG CAPSULE; 20 MG/ML SOLUTION	ASCEND LABORATORIES, AMNEAL PHARMACEUTICALS, GREENSTONE LLC, RISING PHARMACEUTICALS, EXELAN PHARMACEUTICALS, DR. REDDY'S LAB, SCIEGEN PHARMACEUTICALS, ALEMBIC PHARMACEUTICALS, TEVA USA, CIPLA USA, INC, NOVADOS PHARMACEUTICALS.	LYRICA
RAMELTEON	8 MG TABLET	TEVA, USA, DR. REDDY'S LAB, ZYDUS PHARMACEUTICALS	ROZEREM
ERYTHROMYCIN BASE	250 MG, 333 MG, 500 MG TABLET	WILSHIRE PHARMACEUTICALS, AMNEAL PHARMACEUTICALS.	ERY-TAB
PHENOBARB/HYOSC/ATROPINE/SCOP	16.2-0.1037-0.0194-0.0065 MG/5 ML ORAL ELIXIR	LAZARUS PHARMACEUTICALS	DONNATAL
POSACONAZOLE	200 MG/5 ML ORAL SUSPENSION 100 MG TABLET	PAR PHARMACEUTICALS	NOXAFIL

## NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTISPSORIATIS AGENTS	NUDERMRX PAK	CALCIPOTRIENE/ DIMETHICONE	0.005%-5% CREAM	RX + OTC
AGENTS TO TREAT HYPOGLYCEMIA (HYPERGLYCEMICS)	BAQSIMI	GLUCAGON	3 MG NASAL SPRAY	NEW ROUTE (NASAL), DOSAGE FORM AND STRENGTH
OPHTHALMIC PREPARATIONS, MISCELLANEOUS	HYALURONIDASE	HYALURONIDASE IN NACL, ISO/PF	175 UNITS/ML VIAL	NEW COMBINATION
EYE ANTI-INFLAMMATORY AGENTS	KLARITY-L	LOTEPREDNOL/ CHONDROITIN (PF)	0.2%-0.25%, 0.5%-0.25% DROPS	NEW COMBINATION
OPHTHALMIC ANTIBIOTICS	KLARITY-A	AZITHROMYCIN/ CHONDROITIN (PF)	1%-0.25% DROPS	NEW COMBINATION
ANTINEOPLASTIC-ANTIANDROGENIC AGENTS	NUBEQA	DAROLUTAMIDE	300 MG TABLET	NEW ENTITY
CALCIUM CHANNEL BLOCKING AGENTS	KATERZIA	AMLODIPINE BENZOATE	1 MG/ML ORAL SUSPENSION	NEW FORMULATION/ DOSAGE FORM
SEDATIVE-HYPNOTIC, NON-BARBITURATE	KETAMINE HCL	KETAMINE HCL	100 MG SL TROCHE	NEW DOSAGE FORM
ANTINEOPLASTIC EGFR RECEPTOR BLOCKER	KANJINTI	TRASTUZUMAB-ANNS	420 MG IV VIAL	NEW ENTITY
ANTINEOPLASTIC HUM VEGF INHIBITOR RECOMBINANT MC ANTIBODY	MVASI	BEVACIZUMAB-AWWB	25 MG/ML IV VIAL	NEW ENTITY
HYPOACTIVE SEXUAL DESIRE DISORDER (HSDD) TX AGENTS	VYLEESI	BREMELANOTIDE ACETATE	1.75MG/0.3 SQ SOLUTION AUTO- INJECTOR	NEW ENTITY
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	TURALIO	PEXIDARTINIB HCL	200 MG CAPSULE	NEW ENTITY
EYE ANTI-BIOTIC, GLUCOCORTICOID AND NSAID COMBINATION	PREDNISOLONE PHOSPHATE- MOXIFLOXACIN BROMFEN	PREDNISOLN SP/ MOXIFLOX/BROMFEN	1 %-0.5 %- 0.075% EYE DROPS	NEW COMBINATION

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
HEART RATE REDUCING, SELECTIVE I(F) CURRENT INHIB.	CORLANOR	IVABRADINE HCL	5 MG/5 ML ORAL SOLUTION	NEW DOSAGE FORM
METALLIC POISON, AGENTS TO TREAT	FERRIPROX	DEFERIPRONE	1000 MG TABLET	NEW STRENGTH
TOPICAL ANTI-INFLAMMATORY, NSAIDS	VAROPHEN	DICLOFENAC/MET SALICYL/MENTHOL	1.5 % SOLUTION-15 % CREAM	RX + OTC
TOPICAL LOCAL ANESTHETICS	LMR PLUS	LIDOCAINE/MENTHOL	5 % PATCH-6 % GEL	RX + OTC
TOPICAL ANTI-INFLAMMATORY STEROIDAL	QUINIXIL	MOMETASONE FUROATE/DIMETHICONE	0.1% CREAM-5 % SKIN PROTECTANT	RX + OTC
EYE ANTI-INFLAMMATORY AGENTS	KLARITY-B (BETAMETHASONE-CHOND)	BETAMETHASONE/CHONDROITIN (PF)	0.1%-0.25% EYE DROPS	NEW COMBINATION

## NEW INDICATIONS (EXISTING DRUGS)

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### OTEZLA<sup>®</sup>

July 19, 2019

SUMMIT, N.J.- July 19, 2019-(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) today announced that the U.S. Food and Drug Administration (FDA) has approved OTEZLA<sup>®</sup> (apremilast) 30 mg twice daily (BID) for the treatment of adult patients with oral ulcers associated with Behçet's Disease. OTEZLA, an oral, selective inhibitor of phosphodiesterase 4 (PDE4), is the first and only approved treatment option for oral ulcers associated with Behçet's Disease, a rare, chronic, multisystem inflammatory disease that is difficult to treat.

Source: Celgene Corporation

### GADAVIST<sup>®</sup>

July 15, 2019

WHIPPANY, N.J., July 15, 2019 /PRNewswire/ -- Bayer announced today the U.S. Food and Drug Administration (FDA) has approved Gadavist<sup>®</sup> (gadobutrol) injection for use in cardiac magnetic resonance (MR) imaging to assess myocardial perfusion (stress, rest) and late gadolinium enhancement in adult patients with known or suspected coronary artery disease (CAD). Gadavist is now the first and only contrast agent FDA approved for use in cardiac MR – an important diagnostic tool for patients with CAD.

Source: dotmed.com

### KEYTRUDA<sup>®</sup>

July 31, 2019

KENILWORTH, N.J.- July 31, 2019-(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved KEYTRUDA, Merck's anti-PD-1 therapy, as monotherapy for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 (Combined Positive Score [CPS]  $\geq 10$ ) as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy.

Source: Merck

## FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

### Bayer Statement on Voluntary Recall of Two Lots of Kogenate® FS Antihemophilic Factor (Recombinant) in the United States

[July 19, 2019]

Bayer is voluntarily recalling two lots of Kogenate® FS antihemophilic factor (recombinant) 2000 IU vials in the United States to the patient level. Certain vials from these two lots that were labeled as Kogenate FS actually contain the FVIII hemophilia A treatment, Jivi® antihemophilic factor (recombinant) PEGylated-aucl 3000 IU. The U.S. is the only country where affected products were distributed. We are working closely with the U.S. Food and Drug Administration to manage the recall and to minimize disruption to supply and inconvenience to patients. The affected lots, distributed from February 5, 2019 to July 15, 2019 from Bayer's distribution sites in Berkeley, CA and Shawnee, KS, are listed below:

Product name	NDC Number	Product Code	Lot Number	Expiration Date
Kogenate FS antihemophilic factor (recombinant) 2000 IU	0026-3786-65	DR03	27118RK	06/12/2021
	0026-3786-65	DR03	27119CG	06/12/2021

While the majority of the mislabeled vials in the affected lots were recovered, approximately 990 of these vials were released in the U.S. The associated Jivi batch was expired as of August 2018. However, all stability specifications of this expired Jivi batch had continued to be met, as of April 2019. We have voluntarily recalled both lots in the interest of patient safety, and to ensure that any potentially impacted product is removed from pharmacy shelves, and that patients and their healthcare providers are alerted. Importantly, vials of Kogenate FS that are not associated with the affected lot numbers (27118RK and 27119CG) are not impacted and can continue to be used without interruption. There are no lots of Jivi or Kovaltry® antihemophilic factor (recombinant) product affected by this recall. Patient safety is Bayer's highest priority. We are carefully monitoring for any complaints or adverse event reports that may be related to this recall. The company is issuing this notification after discovering the issue earlier this week. Following an immediate internal assessment, Bayer contacted the FDA to inform the agency of the situation.

Kogenate FS and Jivi are both medicines used to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A. Kogenate FS is approved to treat or control bleeding in adults and children with hemophilia A. Jivi is approved to treat and control bleeding in previously treated adults and adolescents (12 years of age and older) with hemophilia A.

Patients in possession of vials from the affected lot numbers should immediately stop using the product and contact their physician. In addition, patients should contact their pharmacy to return the affected product. Bayer is notifying its distributors in writing to check their stock immediately and to discontinue the distribution and use of any affected product. For distributors with questions regarding the recall process, please contact the Bayer Recall Coordinator, Inmar, at 855-707-7518.

Bayer is committed to providing our patients safe and effective therapy. We encourage healthcare providers and patients with questions to call our medical communications hotline with questions: 1-888-84-BAYER (1-888-842-2937).

We understand that this news may be concerning for patients with hemophilia A who depend on these medicines. Bayer is committed to providing the most up-to-date and accurate information to those who may be affected by this issue. Bayer takes its 30-year partnership with the hemophilia community very

seriously, and we remain deeply dedicated to meeting the needs of patients living with this life-long disease.

Patients and healthcare providers are encouraged to report side effects or quality complaints of products to the FDA by visiting [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or calling 1-800-FDA-1088. For Bayer products, you can report these directly to Bayer at [www.adversereactions.bayer.com](http://www.adversereactions.bayer.com) External Link Disclaimer

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

### **Jubilant Cadista Pharmaceuticals Inc. Issues Voluntary Nationwide Recall of Drospirenone and Ethinyl Estradiol Tablets, USP, Due to Out-of-Specification Dissolution Test Results**

[July 23, 2019]

Salisbury, Maryland, Jubilant Cadista Pharmaceuticals Inc. is voluntarily recalling one lot of Drospirenone and Ethinyl Estradiol Tablets, USP, 3 mg/ 0.02mg, 28x3 Blister Pack/Carton to the consumer level. The affected product is being recalled due to out-of-specification (OOS) dissolution results at the 3-month stability time point. The affected product is manufactured by Cyndea Pharma, S.L., Olvega (Soria), 42110 Spain under contract from Jubilant Cadista Pharmaceuticals Inc., 207 Kiley Drive Salisbury, Maryland 21801.

As a result of the OOS dissolution results, product efficacy may be decreased due to incomplete absorption of the active ingredients. To date, Jubilant Cadista Pharmaceuticals Inc. has not received any reports of adverse events related to this recall.

Product Description: Drospirenone and Ethinyl Estradiol tablets are an estrogen/progestin combination oral contraceptive, indicated for use by women to:

- Prevent pregnancy
- Treat symptoms of premenstrual dysphoric disorder (PMDD) for women who choose to use an oral contraceptive for contraception
- Treat moderate acne for women at least 14 years old and/or if the patient desires an oral contraceptive for birth control

Drospirenone and Ethinyl Estradiol tablets are packaged into a carton containing 3 blister cards. Each blister card contains 28-film coated, biconvex tablets, in the following order: 24 active pink-color round, unscored, film-coated tablets debossed with a "20" on one side, each containing 3 mg Drospirenone and 0.02 mg Ethinyl Estradiol, and four (4) inert white-color round, unscored, film-coated tablets debossed with a "PL".

The affected Drospirenone and Ethinyl Estradiol Tablets, USP, has been identified as Lot number 183222, with NDC number 59746-763-43 and expiration date of 11/2020.

Drospirenone and Ethinyl Estradiol Tablets, USP, 3 mg/0.02 mg, lot 183222 was distributed Nationwide to wholesalers, distributors, and retailers.

Jubilant Cadista Pharmaceuticals Inc. is notifying its customers by emailing a recall notification letter and response form and is arranging for return of all recalled product.

Patients that have used the affected lot of Drospirenone and Ethinyl Estradiol Tablets, USP, 3 mg/0.02 mg should consult their healthcare provider. Patients may return the affected lot to their place of purchase.

Wholesalers, distributors, and retailers should immediately examine their inventory for the affected lot. All inventory of the affected lot should be quarantined to prevent further distribution to patients.

Customers who purchased the impacted product directly from Jubilant Cadista Pharmaceuticals Inc. can call Inmar at 1-855-205-9246 (9:00 a.m. – 5:00 p.m. EDT, Monday – Friday) to arrange for their return.



Consumers with additional questions regarding the recall may contact Jubilant Cadista by phone at 1-800-308-3985 (9:00 a.m. – 6:00 p.m. EDT, Monday – Friday). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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

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

Complete and submit the report online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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

### **Xeljanz, Xeljanz XR (tofacitinib): Drug Safety Communication - Due to an Increased Risk of Blood Clots and Death with Higher Dose**

[Posted 07/26/2019]

**ISSUE:** FDA has approved new warnings about an increased risk of blood clots and of death with the 10 mg twice daily dose of Xeljanz, Xeljanz XR (tofacitinib), which is used in patients with ulcerative colitis. In addition, the approved use of tofacitinib for ulcerative colitis will be limited to certain patients who are not treated effectively or who experience severe side effects with certain other medicines. We approved these changes, including adding our most prominent Boxed Warning, after reviewing interim data from an ongoing safety clinical trial of tofacitinib in patients with rheumatoid arthritis (RA) that examined a lower and this higher dose of the medicine.

#### **BACKGROUND:**

Tofacitinib works by decreasing the activity of the immune system; an overactive immune system contributes to RA, PsA, and ulcerative colitis. Tofacitinib was first approved in 2012 to treat adult patients with RA who did not respond well to the medicine methotrexate. When FDA first approved tofacitinib in 2012, FDA required a post-marketing clinical trial in patients with RA on background methotrexate, to evaluate the risk of heart-related events, cancer, and infections. The trial is studying two different doses of tofacitinib (5 mg twice daily, which is the currently approved dose for RA, and a higher, 10 mg twice daily dosage) in comparison to a TNF blocker. In RA, the body attacks its own joints, causing pain, swelling, and loss of function. An interim analysis of the trial's results found an increased occurrence of blood clots and of death in patients treated with tofacitinib 10 mg twice daily compared to patients treated with tofacitinib 5 mg twice daily or a TNF blocker. In 2017, we approved the medicine to treat patients with a second condition that causes joint pain and swelling, PsA, who did not respond well to methotrexate or other similar medicines. In 2018, we approved tofacitinib to treat ulcerative colitis, which is a chronic, inflammatory disease affecting the colon.

#### **RECOMMENDATION:**

Patients should tell your health care professionals if you have a history of blood clots or heart problems, and talk to them about any questions or concerns. Stop taking tofacitinib and seek emergency medical attention right away if you experience any unusual symptoms, including those that may signal a blood clot such as:

- Sudden shortness of breath
- Chest pain that worsens with breathing
- Swelling of a leg or arm
- Leg pain or tenderness, or red or discolored skin in the painful or swollen leg or arm

Do not stop taking tofacitinib without first talking to your health care professional, as doing so can worsen your condition.

Healthcare professionals should discontinue tofacitinib and promptly evaluate patients with symptoms of thrombosis. Counsel patients about the risks and advise them to seek medical attention immediately if they experience any unusual symptoms, including those of thrombosis listed above. Reserve tofacitinib to treat ulcerative colitis for patients who have failed or do not tolerate tumor necrosis factor (TNF) blockers. Avoid tofacitinib in patients who may have a higher risk of thrombosis. When treating ulcerative colitis, use tofacitinib at the lowest effective dose and limit the use of the 10 mg twice daily dosage to the shortest duration needed (See Additional Information for Health Care Professionals for more recommendations).

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

- Complete and submit the report Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form, or submit by fax to 1-800-FDA-0178

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

## Comtan, Stalevo (entacapone): Drug Safety Communication - Ongoing Safety Review of Stalevo (entacapone/carbidopa/levodopa) and Possible Development of Prostate Cancer

[Posted 08/13/2019]

**ISSUE:** FDA review finds no increased risk of prostate cancer with Parkinson's disease medicines, Comtan (entacapone) and Stalevo (a combination of entacapone, carbidopa, and levodopa).

**BACKGROUND:** FDA alerted the public of a clinical trial in March 2010 suggesting a possible increased risk of prostate cancer with the entacapone component of Stalevo. FDA subsequently required the Stalevo manufacturer, Novartis, to conduct a study to further evaluate this potential risk. FDA also studied this issue independently using data from the Department of Veterans Affairs Health Care System. Based on these additional studies, FDA concluded that entacapone use is not associated with an increased risk of prostate cancer (see Data Summary).

**RECOMMENDATION:** As a result, FDA's recommendations for using Comtan (entacapone) and Stalevo (a combination of entacapone, carbidopa, and levodopa) will remain the same in the prescribing information.

Health care professionals should follow standard prostate cancer screening recommendations for patients.

Patients should continue to take their medicine as prescribed. Talk to your health care professionals if you have any questions or concerns.

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

- Complete and submit the report online.

- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form, or submit by fax to 1-800-FDA-0178.

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

### RELPAK (eletriptan hydrobromide) 40 mg tablets by Pfizer: Recall - Due to Potential Microbiological Contamination of Non-Sterile Product

[Posted 08/15/2019]

**ISSUE:** Pfizer Inc. is voluntarily recalling two lots of RELPAK® (eletriptan hydrobromide) 40 mg tablets, lots AR5407 and CD4565, to the patient level. Pfizer Inc. initiated this recall because these product lots may not meet Pfizer's in-house microbiological specification for the potential presence of Genus Pseudomonas and Burkholderia.

Individuals who consume oral products contaminated with microorganisms are at risk of bacterial dissemination from the gut to the bloodstream potentially resulting in serious, life-threatening infections. In addition, there is risk of temporary gastrointestinal distress without serious infection. For the general population these risks are low; for certain vulnerable patient populations (such as patients with compromised immune systems, cystic fibrosis and chronic granulomatous disease) there may be the potential for serious adverse events including life-threatening infections. To date, Pfizer has not received any customer complaints or reports of adverse events related to this issue.

Health care professionals should follow standard prostate cancer screening recommendations for patients.

Patients should continue to take their medicine as prescribed. Talk to your health care professionals if you have any questions or concerns.

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

- Complete and submit the report online.
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form, or submit by fax to 1-800-FDA-0178.

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

## STUDIES AND RECENT TOPICS

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### Vaccinations in the Pipeline

July 11, 2019

The drug approval process is infamous for its complexity and the length of time it takes. But as complicated as standard drugs are to develop, biologics—such as vaccines—are more complicated. On average, vaccines take about 10 to 15 years to develop, compared to the average six to seven years for a standard drug. In addition to the longer development period, vaccines also have a lower success rate—fewer than 10% of vaccine candidates ever reach the market, compared to about a 12% success rate for drug candidates overall.

Source: [drugtopics.com](http://drugtopics.com)

### Pharmacist Coalition Urges Immunization against Preventable Diseases

July 12, 2019

A coalition of pharmacy organizations has asserted its commitment to vaccinations for preventing and eliminating communicable diseases. Pharmacists for Healthier Lives aims to raise awareness around the full range of health care services that pharmacists provide to consumers and patients. In a public statement, the organization is urging every eligible person to receive vaccinations to protect themselves and their communities.

Source: [pharmacytimes.com](http://pharmacytimes.com)

### Research Brief: Partnering with a pharmacist may decrease burnout among primary care providers

July 15, 2019

More than 50 percent of physicians experience burnout, which can lead to increased depression and higher rates of suicide; poor patient outcomes; and increases in medical errors. One suggested path toward reducing the rate of burnout has been to examine how teamwork can improve satisfaction on primary care teams.

Source: [twin-cities.umn.edu](http://twin-cities.umn.edu)

### Fetal Isotretinoin Exposure Remains Steady, Despite iPLEDGE

July 17, 2019

Isotretinoin, the life-changing drug for people with severe acne, can pose a serious threat for pregnant individuals. Since isotretinoin's approval in 1982, there has been 4 different Risk Evaluation and Mitigation Strategy (REMS) systems set to ensure its proper use. The drug carries risks for spontaneous abortion and fetal defects.

Source: [mdmag.com](http://mdmag.com)

### **Ubrogепant Efficacious in Acute Migraine Treatment for Those in Whom Triptans Not Effective**

July 17, 2019

Ubrogепant has demonstrated efficacy in treating acute migraine among individuals for whom triptan has not been effective. This research was recently presented at the American Headache Society 61st Annual Scientific Meeting, held July 11 to 14, 2019, in Philadelphia, Pennsylvania.

Source: neurologyadvisor.com

### **Common Medications Can Masquerade As Dementia in Seniors**

July 18, 2019

By all accounts the woman, in her late 60s, appeared to have severe dementia. She was largely incoherent. Her short-term memory was terrible. She couldn't focus on questions that medical professionals asked her. But Dr. Malaz Boustani, a professor of aging research at Indiana University School of Medicine, suspected something else might be going on. The patient was taking Benadryl for seasonal allergies, another antihistamine for itching, Seroquel (an antipsychotic medication) for mood fluctuations, as well as medications for urinary incontinence and gastrointestinal upset.

Source: khn.org

### **The Impact of Community Pharmacies on Immunization**

July 21, 2019

The community pharmacist wears multiple hats in the daily delivery of health care to patients, one of which might be providing immunization services. Certainly, the patient who walks in for an immunization benefits from the convenience provided by the community pharmacy.

Source: pharmacytimes.com

### **Revamped OxyContin was supposed to reduce abuse, but has it?**

July 22, 2019

Dr. Raeford Brown was uniquely positioned to help the U.S. government answer a critical question: Is a new version of the painkiller OxyContin helping fight the national opioid epidemic?

Source: apnews.com

### **FDA grants breakthrough therapy designation to Keytruda-Lenvima combination for hepatocellular carcinoma**

July 23, 2019

The FDA granted breakthrough therapy designation to pembrolizumab in combination with lenvatinib as first-line treatment for patients with advanced unresectable hepatocellular carcinoma who are not able to receive locoregional treatment.

Source: healio.com

### **Sanofi expects one-month delay of vaccine shipments for fall flu season**

July 24 2019

Sanofi's flu vaccine shipments will be delayed by roughly one month this upcoming flu season, according to the French drug maker. Sanofi said Wednesday that shipment of its vaccines will begin in mid-August, with all shipments expected to be completed by the end of November. The company said the delay is due to the World Health Organization taking a bit longer to select vaccine virus strains. The extra time allowed health officials to improve the match of strains of H3N2 viruses expected to circulate during the 2019-2020 season, Sanofi said.

Source: cnbc.com

### **Advocates face tough path to OTC birth control**

July 25, 2019

Drug companies are facing increasing pressure to make birth control pills available for over-the-counter sale, but that situation is still years away from reality. Leading medical organizations and experts have said for years that the birth control pill is safe enough to sell without a prescription requirement in the U.S. And supporters of the idea say it could make the pills more accessible and potentially lower costs.

Source: thehill.com

### **Dermatologists can limit skin, hair, nail side effects from cancer therapy**

July 29, 2019

While new drugs for cancer are helping patients fight the disease, they also produce side effects that can affect the hair, skin and nails and can significantly affect quality of life and, potentially, the ability to continue treatment, according to a press release issued here at the American Academy of Dermatology Summer Meeting.

Source: healio.com

### **Congress seeks briefing on potential threat to U.S. heparin supply**

July 30, 2019

Leaders of the U.S. House Energy and Commerce Committee on Tuesday asked the Food and Drug Administration about the potential threat to the U.S. heparin supply due to the outbreak of African swine fever in China.

Source: reuters.com

### **Boom in overdose-reversing drug is tied to fewer drug deaths**

August 6, 2019

Prescriptions of the overdose-reversing drug naloxone are soaring, and experts say that could be a reason overdose deaths have stopped rising for the first time in nearly three decades. The number of



naloxone prescriptions dispensed by U.S. retail pharmacies doubled from 2017 to last year, rising from 271,000 to 557,000, health officials reported Tuesday.

Source: apnews.com

### **Study Finds Increase in Pharmacy Dispensing of Naloxone, More Efforts Needed to Improve Access**

August 07, 2019

Drug overdoses involving opioids have increased, and naloxone can be a life-saving drug to prevent deaths. In April 2018, the U.S. Surgeon General issued a public health advisory emphasizing the importance of naloxone and increasing access and awareness among patients, family, friends, and healthcare professionals.

Source: pharmacytimes.com

### **FDA panel backs Gilead's HIV prevention drug Descovy, except in women**

August 7, 2019

An FDA advisory panel on Wednesday voted in favor of Gilead's combination drug to reduce the risk of sexually acquired HIV infection in men and transgender women who have sex with men.

Source: reuters.com

### **Senator Grassley seeks info on Novartis's Zolgensma data issues**

August 12, 2019

U.S. Senate Finance Committee Chairman Chuck Grassley has asked Swiss drugmaker Novartis AG to provide details on data manipulation related to its \$2 million gene therapy, Zolgensma, by Aug. 23.

Source: reuters.com

### **Counsel Patients as They Head into the Fall**

August 15, 2019

Brown bag consults can be essential educational and safety tools to measure and ensure quality care. By asking patients to bring in all their current medications, including OTC, mail-order, specialty, and herbal products, pharmacists can guarantee appropriate and up-to-date care.

Source: pharmacytimes.com

### **Trump health official: Controversial drug pricing move is 'top priority'**

August 15, 2019

A top Trump administration health official on Thursday indicated that the administration is pushing forward with a controversial proposal to lower drug prices, despite opposition from some fellow Republicans. Centers for Medicare and Medicaid Services Administrator Seema Verma told reporters



that the proposal to lower certain drug prices in Medicare by tying them to lower prices in other countries, known as the International Price Index, is a “top priority.”

Source: thehill.com

### **Scientists Develop Vaccine that Prevents Cats from Making you Allergic to hem**

August 15, 2019

A Swiss pharmaceutical company announced the development of a vaccine that makes cats less able to produce allergens, thereby lessening the likelihood of an owner developing an allergy. In April, scientists at Hypo Pet published a study in the Journal of Allergy and Clinical Immunology suggesting that an early version of its injectable vaccine performed well in clinical trials.

Source: newsweek.com

### **Roche cancer treatment priced at \$17,050 a month, lower than rival Vitakvi**

August 16, 2019

Roche Holding AG has priced its personalized cancer treatment, Rozlytrek, at about \$17,050 per month, nearly half of the monthly price of a rival drug from Bayer AG and Eli Lilly and Co that was approved last year. Roche’s drug and Bayer/Lilly’s Vitakvi target tumors with rare genetic anomalies called NTRK fusions, irrespective of where in the body the disease started.

Source: reuters.com

### **Canada plots response to U.S. import plan after meeting with stakeholders**

August 16, 2019

Canadian health officials are expected to meet soon with their U.S. counterparts to detail major concerns over a proposal to set up drug importation. Canadian Health Minister Pettipas Taylor had a roundtable meeting of stakeholders across the healthcare spectrum Monday to hear out how to respond to the U.S. import plan. The Department of Health and Human Services (HHS) released a plan last month to create a pilot project for states, wholesalers and pharmacists to import drugs from Canada offered at a cheaper price than in the U.S.

Source: fiercehealthcare.com

### **Reversal Agents for Commonly Used DOACs**

August 19, 2019

Recently, it seems like more and more of our patients are on anticoagulation, with direct acting oral anticoagulants (DOACs) being used more often. DOACs have significant advantages over the older anticoagulants, and they are associated with lower risks of bleeding. However, bleeding episodes do occur, and clinicians need to have tools to deal with them. Fortunately, new reversal agents are available for DOACs.

Source: pharmacytimes.com



## **AstraZeneca diabetes drug shows promise in heart failure**

August 20, 2019

AstraZeneca made strides on Tuesday toward its goal of adding heart failure to the conditions that can be treated by its diabetes drug Farxiga, putting it ahead of a rival medicine from Eli Lilly. The British drugmaker said Farxiga was successful in reducing the risk of deadly heart attacks or disease progression in patients with a common form of heart failure in a clinical trial that could help win regulatory approval for its wider use.

Source: reuters.com

## **Teva to launch generic version of EpiPen for young children**

August 20, 2019

Teva Pharmaceutical Industries Ltd on Tuesday made its generic version of Mylan's EpiPen for young children available in most retail pharmacies at \$300 for a 2-pack.

Source: reuters.com

## **Study finds about 1 in 7 people with diabetes ration medicine due to cost**

August 21, 2019

Almost 1 in 7 adults with diabetes did not take their medication as prescribed because of its cost, according to new data released by the Centers for Disease Control and Prevention (CDC) on Wednesday. The survey found that 13.2 percent of adults with diabetes either skipped a dose, took less medicine or delayed filling a prescription because of cost. That can be deadly for people with diabetes who need insulin to survive.

Source: thehill.com

## **Prescriptions for Opioid Addiction Treatments Increase, but Access Is Uneven**

August 21, 2019

MILLIONS OF prescriptions have been filled in recent years for buprenorphine, but not all patients have equal access to the opioid addiction treatment drug, a new analysis indicates. Buprenorphine, commonly sold as Suboxone, is one of three drugs approved by the Food and Drug Administration to treat opioid addiction – along with methadone and naltrexone – but the only medication covered by all state Medicaid programs. The drugs blunt opioid cravings and are commonly paired with counseling, an approach called medication-assisted treatment.

Source: usnews.com

## **More Antibiotics, Higher Odds for Colon Cancer?**

August 21, 2019

Taking certain antibiotics -- especially multiple times or for long courses -- may put you at risk for colon cancer, a large new study suggests.



Source: usnews.com

**Trump administration appeals drug price disclosure ruling**

August 21, 2019

The Trump administration announced Wednesday that it is appealing a federal judge's ruling that blocked the implementation of a policy requiring prescription drug manufacturers to disclose their list prices in TV ads.

Source: thehill.com

## RECALLS

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Fluorouracil Injection, USP, 5 g / 100 mL (50 mg / mL), 100 mL fill in a 100 mL vial, Rx Only, Mfd. by: Fresenius Kabi, Lake Zurich, IL 60047. 63323-117-61 [Fresenius Kabi brand] and NDC 63323-117-69 [NOVAPLUS brand]	Class I	Lot 6120420 NDC 63323-117-61, Product Code 101761 and Lot 6120341 NDC 63323-117-69, Product Code NP101761	Presence of Particulate Matter; glass particulates	Fresenius Kabi USA, LLC
Drugs	Milrinone Lactate Injection 200 mcg (0.2 mg)/mL* in 5% Dextrose Injection 40 mg/200 mL, 200 mL bag, Rx Only, Hospira, Inc., Lake Forest, IL 60045 USA, NDC 0409-2776-02, Barcode (01)0030409277602 8	Class II	Lot #: 86-615-KL, Exp. 1FEB2020; 87-701-KL, Exp. 1MAR2020; 90-114-KL, Exp. 1JUN2020	Lack of Assurance of Sterility: Bags have the potential to leak	Pfizer Inc.
Drugs	Milrinone Lactate Injection 200 mcg (0.2 mg)/mL* in 5% Dextrose Injection, 20 mg/100 mL, 100 mL bag, Rx Only, Hospira, Inc., Lake Forest, IL 60045 USA, NDC 0409-2776-23, Barcode (01)0030409277623 3	Class II	Lot #: 85-516-KL; 85-517-KL, Exp. 1JAN2020; 86-601-KL; 86-603-KL; 86-618-KL, Exp. 1FEB2020; 87-707-KL, Exp. 1MAR2020; 91-205-KL, Exp. 1JUL2020; 92-306-KL, Exp. 1AUG2020.	Lack of Assurance of Sterility: Bags have the potential to leak	Pfizer Inc.
Drugs	LA FRESH travel lite Sunnyside Lotion Wipe silky, non-greasy formula smooth, soft & moisturizing featuring titanium	Class II	All lots beginning with 453091	Marketed without an Approved NDA/ANDA: The product may be construed a sunscreen due	La Fresh Group, Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	dioxide, 1 wipe individually wrapped packet, 4.75" x 5.75" (12.0 cm x 14.6 cm) Ingredients: Water, Dimethicone, Dimethiconol, Titanium Dioxide, Benzophenone-3, Octinoxate, Ethylhexylglycerine, Phenoxyethanol, Distributed by La Fresh Group, Inc. Chino, CA 91710 www.LaFreshGroup.com			to labeling of the product and comments about the product found on e-commerce websites	
Drugs	Oliver's Harvest CBD+Capsaicin 0.2% Pain Relief (Capsaicin 0.2%) Topical Analgesic Cream, 4 OZ (113.4 g) bottle with pump, Distributed by: Coast to Coast Natural, Inc., Wellington, FL 33414, NDC 63788-120-04	Class II	All lots remaining within expiry	CGMP Deviations: products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing practice violations	Pharma-Natural Inc.
Drugs	Diphenhydramine Oral Liquid Alcohol Free, 12.5 mg/5 mL, 4 fl oz (118 mL), RIJ Pharmaceutical Corporation 40 Commercial Avenue Middletown, NY 10941, NDC 53807-204-04	Class II	Lot #: 70606, Exp 6/19	cGMP Deviations: Products may have microbial contamination	Geritrex, LLC
Drugs	Ritussin DM Children & Adults, 4 Fl. Oz. (118 mL), RIJ	Class II	Lot #: 70602, Exp 6/19	cGMP Deviations: Products may	Geritrex, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Pharmaceutical Corporation 40 Commercial Avenue Middletown, NY 10941, NDC 53807-409-04			have microbial contamination	
Drugs	Gericare Diocto Liquid Docusate Sodium Stool Softener, 50 mg/5mL, 16 FL OZ (473 ml), Dist. BY: Gericare Pharmaceuticals corp. 1650 63rd Street Brooklyn, NY 11204, NDC 57896-403-16	Class II	Lot #: 70612, Exp 6/19	cGMP Deviations: Products may have microbial contamination.	Geritrex, LLC
Drugs	Gericare Iron Supplement Elixir Ferrous Sulfate, 220 mg, 16 fl oz. (473 mL), Distributed by: Geri-care Pharmaceuticals Corp. 1650 63rd Street Brooklyn, NY 11204, NDC 57896-709-16	Class II	Lot #: 70601, Exp 6/19	cGMP Deviations: Products may have microbial contamination	Geritrex, LLC
Drugs	Preferred Plus Pharmacy Iron Elixir Ferrous Sulfate, 220 mg, 16 fl oz. (473 mL), Distributed by: Geri-care Pharmaceuticals Corp. 1650 63rd Street Brooklyn, NY 11204, NDC 52807-177-16	Class II	Lot #: 70601, Exp 6/19	cGMP Deviations: Products may have microbial contamination.	Geritrex, LLC
Drugs	Ritussin DM Double Strength, 4 FL. OZ. (118 mL), RIJ Pharmaceutical Corporation 40	Class II	Lot #: 70611, Exp 6/19	cGMP Deviations: Products may have microbial contamination.	Geritrex, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Commercial Avenue Middletown, NY 10941				
Drugs	Gericare Geri-Tussin DM, 16 FL OZ (473 mL), Geri-care Pharmaceuticals Corp. 1650 63rd Street Brooklyn, NY, NDC 57896-660-16	Class II	Lot #: 70602, Exp 6/19	cGMP Deviations: Products may have microbial contamination.	Geritrex, LLC
Drugs	AbeeMed cream (Menthol 1.48% and Histamine DHCL 0.05%), 2 OZ jar, Manufactured exclusively for: Cas, P.O. Box 520248, Miami, FL 33152, UPC 8 50993 00402 4.	Class II	All lots remaining within expiry.	CGMP Deviations: products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing practice violations	Pharma-Natural Inc.
Drugs	ARMY HEALTH With CURCUMIN (Menthol 3.00%) Pain Reliever Roll-On, 2.5 FL OZ (73ML) roll on bottle, Manufactured exclusively for: Crossover Telecom, LLC., P.O. Box 520248, Miami, FL 33122, UPC 8 50993 00408 6.	Class II	All lots remaining within expiry.	CGMP Deviations: products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing practice violations	Pharma-Natural Inc.
Drugs	Oliver's Harvest CBD+Lidocaine HCL 4% Pain Relief (Lidocaine HCL 4%) Topical Analgesic	Class II	All lots remaining within expiry	CGMP Deviations: products were manufactured with lack of	Pharma-Natural Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Cream, 4 OZ (113.4 g) bottle with pump, Distributed by: Coast to Coast Natural, Inc., Wellington, FL 33414, NDC 63766-119-04.			process validation, cleaning validation, stability studies, and other current good manufacturing practice violations	
Drugs	ARMY HEALTH Pain Reliever Gel With CURCUMIN (Menthol 3.00%), 0.5 OZ jar, Manufactured exclusively for: Manufactured exclusively for: Crossover Telecom, LLC., P.O. Box 520248, Miami, FL 33122, UPC 8 50993 00461 1.	Class II	All lots remaining within expiry	CGMP Deviations: products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing practice violations	Pharma-Natural Inc.
Drugs	GENCONTUSS (Chlorpheniramine Maleate, 2mg; Dextromethorphan HBr, 10 mg; Phenylephrine HCl, 5 mg) in each 5 mL tsp, Cherry Flavor, 16 fl oz (474 mL) bottle, Manufactured in the USA for Kramer Novis, San Juan, PR 00917, NDC 52083-650-16.	Class II	All lots remaining within expiry	CGMP Deviations: products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing practice violations	Pharma-Natural Inc.
Drugs	DOUBLE TUSSIN DM (Dextromethorphan HBr 20 mg, Guaifenesin 300 mg) in each 5ml teaspoon, 4 FL OZ	Class II	All lots remaining within expiry	CGMP Deviations: products were manufactured with lack of process	Pharma-Natural Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	(120 mL) bottle, Distributed by: Pamby Dist., Miami, FL 33414, NDC 63708-121-04.			validation, cleaning validation, stability studies, and other current good manufacturing practice violations	
Drugs	LidoAID (Lidocaine HCL 4%) portable pain relieving TOPICAL ANALGESIC GEL, 0.17 Oz (4 g) roll on bottle, Distributed by: Diabetic Supply of Suncoast, Inc., dba Advocate Diabetes, PO Box 2102, Vega Alta, PR 00692, NDC 63788-114-04.	Class II	All lots remaining within expiry	CGMP Deviations: products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing practice violations	Pharma- Natural Inc.
Drugs	Dermanak original crema blanqueador (Hydroquinone 2%) Skin Fade Cream, 2 OZ. (56.7 g) jar, Manufactured by: Pamby Distributors, Inc., Miami, FL 33126, NDC 63788- 108-02.	Class II	All lots remaining within expiry	CGMP Deviations: products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing practice violations	Pharma- Natural Inc.
Drugs	Lido E.R. (Lidocaine HCL 4%) Pain Relieving Topical Analgesic Cream, 4 oz (113 g) jar, Distributed by Diabetic Supply of	Class II	All lots remaining within expiry	CGMP Deviations: products were manufactured with lack of process validation,	Pharma- Natural Inc.



Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Suncoast, Inc., P.O. Box 2102, Vega Alta, PR 00692, NDC 63788-115-04			cleaning validation, stability studies, and other current good manufacturing practice violations	
Drugs	Lid O Creme (Lidocaine HCL 4% and Menthol 1%) Topical Analgesic Cream, 2.5 Oz (71 g) roll on bottle, Manufactured & Distributed by: Pharma Natural, Inc. Hialeah, FL 33016, NDC 63788-111-25	Class II	All lots remaining within expiry	CGMP Deviations: products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing practice violations	Pharma-Natural Inc.
Drugs	Dayma SUPER FORTE XL10 (Camphor 0.5%, Menthol 2%, Methyl Salicylate 2%) Pain Relieving Topical Analgesic Gel, 4 Oz (113.4 g) jar, Distributed by: Biosfera International Distribution, LLC., Miami Lakes, FL 33016, NDC 63788-118-04.	Class II	All lots remaining within expiry	CGMP Deviations: products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing practice violations.	Pharma-Natural Inc.
Drugs	TUSSLIN (Dextromethorphan HBr, 28 mg; Guaifenesin, 388 mg; Phenylephrine HCl, 10 mg) in each 5 mL tsp, Grape Flavor, 16 fl. oz.	Class II	All lots remaining within expiry	CGMP Deviations: products were manufactured with lack of process validation, cleaning	Pharma-Natural Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	(474 mL) bottle, Kramer Novis, San Juan, PR 00917, NDC 52083-622-16			validation, stability studies, and other current good manufacturing practice violations.	
Drugs	SORBUGEN NR (Dextromethorphan HBr, 15 mg; Glyceryl Guaiacolate (Guaifenesin), 150 mg) in each 7.5 mL 1 1/2 tsp), GRAPE FLAVOR, 16 fl. oz. (473 mL) bottle, Manufactured in the USA for Kramer Novis, San Juan, PR 00917, NDC 52083-660-16.	Class II	All lots remaining within expiry	CGMP Deviations: products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing practice violations.	Pharma-Natural Inc.
Drugs	NEOGEN-D (Dextromethorphan HBr, 30 mg; Guaifenesin, 200 mg; Phenylephrine HCl, 7.5 mg) in each 5 mL tsp, Raspberry Flavor, 16 fl oz (473 mL) bottle, Manufactured in the USA for Kramer Novis, San Juan, PR 00917, NDC 52083-699-16	Class II	All lots remaining within expiry	CGMP Deviations: products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing practice violations.	Pharma-Natural Inc.
Drugs	Workvie Instant Pain Relieving Roll On (Lidocaine HCL 4% + Menthol 1% & Arnica), 2.5oz (71 g) roll on bottle, Exclusively Distributed by: Marketite, LLC.,	Class II	All lots remaining within expiry	CGMP Deviations: products were manufactured with lack of process validation, cleaning validation,	Pharma-Natural Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Coral Gables, FL 33134, NDC 72393-201-25			stability studies, and other current good manufacturing practice violations.	
Drugs	<p>Temozolomide Capsules, 5 mg, packaged in a) 5-count bottle (NDC 67877-537-07), b) 14-count bottle (NDC 67877-537-14), Rx only, Manufactured by: Deva Holding A.S., 1 Merkez Mahallesi, Istanbul, Turkey 34303, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054</p>	Class II	<p>Lot #: a) A062238, A062118, A062115, A062112, A062100, Exp 08/31/2019; A068946, Exp 04/30/2020; A071733, Exp 09/30/2020; b) A062194, A062181, A62275, A062218, Exp 08/31/2019; A069154, Exp 04/30/2020; A071734, A071783, A071735, Exp 09/30/2020</p>	<p>CGMP Deviations: product was manufactured that did not prevent possible cross contamination with beta lactam products.</p>	Deva Holding AS - Cerkezkoy Subesi
Drugs	<p>Temozolomide Capsules, 20 mg, packaged in a) 5-count bottle (NDC 67877-538-07), b) 14-count bottle (NDC 67877-538-14), Rx only, Manufactured by: Deva Holding A.S., 1 Merkez Mahallesi, Istanbul, Turkey 34303, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054.</p>	Class II	<p>Lot #: a) A061688, A061687, A061685, Exp 07/31/2019; A068994, Exp 04/30/2020; A071853, Exp 09/30/20; b) A061794, A061833, A061822, Exp 07/31/2019; A069115, Exp 04/30/2020; A071855, A071854, Exp 09/30/2020</p>	<p>CGMP Deviations: product was manufactured that did not prevent possible cross contamination with beta lactam products.</p>	Deva Holding AS - Cerkezkoy Subesi
Drugs	<p>Temozolomide Capsules, 100 mg, packaged in a) 5-count bottle (NDC 67877-539-07), b) 14-count bottle</p>	Class II	<p>Lot #: a) A061783, A061782, A061781, Exp 07/31/2019; A069128, Exp 05/31/2020; A071923, Exp</p>	<p>CGMP Deviations: product was manufactured that did not prevent possible</p>	Deva Holding AS - Cerkezkoy Subesi

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	(NDC 67877-539-14), Rx only, Manufactured by: Deva Holding A.S., 1 Merkez Mahallesi, Istanbul, Turkey 34303, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054		09/30/20; b) A061874, A061861, A061896, Exp 07/31/2019; A069326, Exp 05/31/2020; A071924, A071977, A071925, Exp 09/30/2020	cross contamination with beta lactam products	
Drugs	Temozolomide Capsules, 140 mg, packaged in a) 5-count bottle (NDC 67877-540-07), b) 14-count bottle (NDC 67877-540-14), Rx only, Manufactured by: Deva Holding A.S., 1 Merkez Mahallesi, Istanbul, Turkey 34303, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054	Class II	Lot #: a) A063581, A063462, A063460, Exp 09/30/2019; A063582, Exp 10/31/2019; A069129, Exp 05/31/2020; A071801, Exp 09/30/2020; b) A063639, A063624, A063609, Exp 09/30/2019; A063657, Exp 10/31/2019; A069366, Exp 05/31/2020; A071817, A071819, A071818, Exp 09/30/2020	CGMP Deviations: product was manufactured that did not prevent possible cross contamination with beta lactam products	Deva Holding AS - Cerkez koy Subesi
Drugs	Temozolomide Capsules, 180 mg, packaged in a) 5-count bottle (NDC 67877-541-07), b) 14-count bottle (NDC 67877-541-14), Rx only, Manufactured by: Deva Holding A.S., 1 Merkez Mahallesi, Istanbul, Turkey 34303, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ	Class II	Lot #: a) A061858, A061857, A061856, A061860, A061859, Exp 07/31/2019; A069401, A069402, Exp 05/31/2020; A071978, Exp 09/30/2020; A076736, A076735, Exp 04/30/2021; b) A062031. A062015, A062014, A062050, A062038, Exp 07/31/2019; A069521, A069470, Exp 05/31/2020;	CGMP Deviations: product was manufactured that did not prevent possible cross contamination with beta lactam products	Deva Holding AS - Cerkez koy Subesi

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	07054		A071979, A072014, A072013, Exp 09/30/2020; A076739, A076738, A076737, Exp 04/30/2021		
Drugs	<p>Temozolomide Capsules, 250 mg, 5-count bottle, Rx only, Manufactured by: Deva Holding A.S., 1 Merkez Mahallesi, Istanbul, Turkey 34303, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054, NDC 67877-542-07</p>	Class II	<p>Lot #: A062228, A062227, A062226, A062295, A062294, Exp 08/31/2019; A069325, A069323, Exp 05/31/2020; A072015, Exp 10/31/2020; A076611, A076609, A076608, A076607, Exp 04/30/2021</p>	<p>CGMP Deviations: product was manufactured that did not prevent possible cross contamination with beta lactam products</p>	Deva Holding AS - Cerkezkoj Subesi
Drugs	<p>0.9% Sodium Chloride Injection USP, 100 mL Viaflex Container, Rx Only, Baxter Healthcare Corporation, Deerfield, IL 60015, USA, NDC 0338-0049-38</p>	Class II	<p>Lot #: P389684; P389742, Exp. 8/31/2020</p>	<p>Lack of Assurance of Sterility: Bags have potential to leak</p>	Baxter Healthcare Corporation
Drugs	<p>Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension, (equivalent to 10 mg hydrocodone bitartrate and 8 mg chlorpheniramine maleate per 5 mL), 16 fl. oz. (473 mL) bottle, Rx only, Manufactured by: Tris Pharma, Inc., Monmouth Junction, NJ 08852,</p>	Class II	<p>Lot#: 14079, Exp 10/2021</p>	<p>Superpotent Drug and Failed Stability Specifications: High out-of-specification results for the active ingredients, hydrocodone and chlorpheniramine, as well as high out-of-specification results for the</p>	Tris Pharma Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	NDC 27808-086-02.			preservatives.	
Drugs	Preferred Plus Dioctyl Liquid Stool Softener (Docusate Sodium), 50mg/5mL, 16 FL. Oz. (1 PT.) 473 mL, Manufactured by RIJ Pharmaceutical Corp. 40 Commercial Avenue Middletown, NY 10941, Distributed by Kinray Inc. Whitestone, NY 11357, NDC 53807-216-16	Class II	Lot #: 70603, 70604, 70612, Exp 6/19	cGMP Deviations: Products may have microbial contamination.	Geritrex, LLC
Drugs	Clobazam Oral Suspension, 2.5 mg/mL, 120 mL bottle, Rx only, Distributed by: Bionpharma Inc., 600 Alexander Road, Princeton, NJ 08540, NDC 69452-116-45.	Class II	Lot #: 18246, Exp 09/2020	Microbial Contamination of Non-Sterile Products: Out-of-specification results for Microbial Enumeration Tests USP <61> was observed.	Bionpharma Inc.
Drugs	Lisinopril and Hydrochlorothiazide Tablets USP, 20 mg/12.5 mg, 500-count bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, Manufactured by: Lupin Limited Pithampur (M.P.) 454 775, INDIA, NDC 68180-519-02	Class II	Lot #:H801815, Exp. March 2021	Presence of Foreign Tablets/Capsules: Product complaint received of one Fenofibrate tablet 145mg observed in 500 s count product bottle	Lupin Pharmaceuticals Inc.
Drugs	Neomycin Sulfate 3.5 mg/Polymyxin B Sulfate 10,000	Class II	Lot #: L2117Q, Batch: 12211717, Exp. 09/2019; F2818H,	CGMPs Deviations: Insufficient	Preferred Pharmaceuticals, Inc

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	units/Dexamethasone 1 mg Ophthalmic Ointment, Pkg Size 3 g Tube, Generic for: Maxitrol, For External Use Only, Rx only, Mfg: Paddock Laboratories, LLC, Preferred Pharmaceuticals, Inc., The Physicians Solutions, Anaheim, CA, NDC 68788-9373-03		Batch: 06281808, Exp. 11/2019; B1819T, Batch: B1819T001 to B1819T048 (Inclusive), Exp. 05/2020.	Quality Assurance controls over critical systems in the manufacturing facility.	
Drugs	Atorvastatin Calcium Tablet USP 80 mg, a) 90 count (NDC 67877-0514-90) and b) 500 count (NDC 67877-0514-05) bottles, Rx only, Manufactured by: Alkem Laboratories, Ltd, Mumbai INDIA, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ	Class II	a) Lot# 19140443, exp. date 12/2020, Lot# 19140525, 19140535, exp. date 01/2021 and b) Lot# 19140756, exp. date 12/2020, Lot# 19140757, Lot# 19140758, exp. date 01/2021, Lot# 19141696, Lot# 19141793, exp. date 03/2021	Failed Dissolution Specifications	Ascend Laboratories LLC
Drugs	MONSEL'S (Ferric Sub sulfate) Solution, 8 mL amber glass bottle, packaged as one dozen bottles with applicators per box, Rx only, Gordon Laboratories, Upper Darby, PA 19082, NDC 10481-0112-8.	Class II	Batch #: 579634, 579635, Exp 5/2020	Microbial Contamination of Non-Sterile Products and Superpotent Drug: FDA analysis revealed microbial contamination in addition to high out of specification results for iron content.	Dercher Enterprises, Inc., DBA
Drugs	Gablofen (baclofen	Class II	Lot #: 2155-111,	Failed	Piramal



Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	injection), 50 mcg/mL, Single Use Syringe, Rx only, packaged in a box containing one 1 mL syringe, Distributed by: Primal Critical Care, Inc., 3950 Schelden Circle Bethlehem, PA, 18017, NDC 66794-151-01		2155-111A, Exp 6/20	Impurities/Degradation Specification - This recall is being initiated as a precaution due to the presence of an unknown impurity observed during shelf life of the product.	Critical Care, Inc.
Drugs	Kaitlib Fe norethindrone and ethinyl estradiol chewable tablets (0.8 mg/0.025 mg) and Ferrous Fumarate, Chewable Tablets, Rx Only, Distributed by: Lupin Pharmaceuticals, Inc. Baltimore, MD - 21202 Manufactured by: Lupin Limited Pathampur -454775 India. NDC 68180-903-11 (wallet of 28 tablets) NDC 68180-903-13 (carton of 3 wallets)	Class II	Lot L800050	Failed Impurities/Degradation Specifications: Kaitlib Fe Tablets has an out of specification result observed in long term stability study.	Lupin Pharmaceuticals Inc.
Drugs	Equate Night-time Sleep Aide (Diphenhydramine HCl), 50 mg, Alcohol Free, Berry Flavor, 12 Fl. Oz. (354 mL), OTC, Distributed by: Walmart Stores, Inc., Bentonville, AR 72716, NDC 49035-330-02, UPC 6 8113117595 1	Class II	Lot #: P300456, P300475, P300482, P300489, Exp 09/30/2020	Microbial contamination of non-sterile product	LNK International, Inc.



Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Neomycin 3.5 mg/g / Polymyxin B10000 USP Units/g / Dexamethasone 1 mg/g Ophthalmic Ointment, 3.5 g tube, Rx only, Manufactured for H.J. Harkins Company, Inc. dba Pharma Pac by Perrigo Co, Allegan, MI 49010, NDC 52959-0407-01	Class II	Lot #: NPD10RP, Exp 08/19; NPD11RP, Exp 09/19; NPD12RP, Exp 11/19; NPD13RP, Exp 02/20; NPD14RP, Exp 02/20; NPD15RP, Exp 05/20; NPD16RP, Exp 06/20; NPD17RP, Exp 01/21; NPD18RP, Exp 02/21	CGMPs Deviations: Insufficient Quality Assurance controls over critical systems in the manufacturing facility.	H J Harkins Company Inc dba Pharma Pac
Drugs	Timolol-Latanoprost P-F (0.5/0.005%) ophthalmic drops, packaged in 5mL bottles, Rx only, ImprimisRX NJ 1705 Route 46 West, Suite 4, Ledgewood, NJ 07852 (844) 446-6979	Class II	Lot #:01252019@1, Exp. 07/21/2019; 03182019@7, Exp. 09/7/2019; 05092019@2, Exp. 11/2/2019	Subpotent Drug	ImprimisRx NJ 1705 Us
Drugs	Timolol-Dorzolamide-Latanoprost P-F (0.5/2.0/0.005%) ophthalmic drops, packaged in 5mL bottles, Rx only, ImprimisRx NJ 1705 Route 46 West, Suite 4, Ledgewood, NJ 07852 (844) 446-6979	Class II	Lot #: 03132019@2, Exp. 09/17/2019; 05102019@2, Exp. 11/02/2019	Subpotent Drug	ImprimisRx NJ 1705 Us
Drugs	Acetylcysteine 2% Otic Drop, 15 mL bottle, Rx only, Refrigerate, Compounded by Wise Pharmacy, Littleton, CO 80123.	Class II	Lot #: 7131N, Exp 7/11/19	Lack of Processing Controls	Wise Pharmacy
Drugs	Alprostadil 100 mcg/mL Injectable,	Class II	Lot #: 6981N, Exp 10/17/2019	Lack of Processing	Wise Pharmacy

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	2.5 mL vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.			Controls	
Drugs	Dexamethasone Sodium Phosphate PF 24 mg/mL Injection, Refrigerate, Single Use Vial, 1 mL vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.	Class II	Lots #: 5506N, Exp 9/21/2019; 7180N, Exp 12/29/2019	Lack of Processing Controls	Wise Pharmacy
Drugs	Gentamicin (GU) Irrigation 240 mg/500 mL Solution, 250 mL Container, Shake well and Refrigerate, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.	Class II	Lot #: 7179N, Exp 7/16/2019	Lack of Processing Controls	Wise Pharmacy
Drugs	Tobramycin Irrigation 80 mg/1000 mL Solution, 1000 mL Container, Refrigerate, Nasal,, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123	Class II	Lot #: 7270N, Exp 7/22/2019	Lack of Processing Controls	Wise Pharmacy
Drugs	Papaverine/Phentolamine 30 mg/1 mg/mL Injectable, 2.5 mL Vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.	Class II	Lot #: 5978N, Exp 8/20/2019; 7266N, Exp 11/5/2019	Lack of Processing Controls	Wise Pharmacy
Drugs	Papaverine/Phentolamine/Alprostadil 30 mg/0.2 mg/10 mcg/mL Injectable,	Class II	Lot #: 6054N; 4796N, Exp 7/16/2019; 7049N, Exp 11/24/2019	Lack of Processing Controls	Wise Pharmacy

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	2.5 mL Vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.				
Drugs	Papaverine/Phentolamine/Alprostadil - 30 mg/1 mg/10 mcg/mL Injectable, 2.5 mL Vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123	Class II	Lot #: 5333N, Exp 7/12/2019; 7000N, Exp 10/18/2019	Lack of Processing Controls	Wise Pharmacy
Drugs	Papaverine/Phentolamine/Alprostadil 30 mg/2 mg/30 mcg/mL Injectable, 2.5 mL Vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123	Class II	Lot #: 5620N, Exp 7/16/2019; 6221N, Exp 8/31/2019; 6952N, Exp 10/16/2019	Lack of Processing Controls	Wise Pharmacy
Drugs	Papaverine/Phentolamine/Alprostadil 30 mg/2 mg/50 mcg/mL Injectable, 2.5 mL Vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.	Class II	Lot #: 5620N, Exp 7/16/2019; 6221N, Exp 8/31/2019; 6952N, Exp 10/16/2019	Lack of Processing Controls	Wise Pharmacy
Drugs	Papaverine/Phentolamine/Alprostadil/A tropine 30 mg/2 mg/50 mcg/0.15 mg/mL Injectable, 2.5 mL Vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.	Class II	Lot #: 6153N, Exp 8/29/2019	Lack of Processing Controls	Wise Pharmacy
Drugs	DIVALPROEX SODIUM EXTENDED-RELEASE TABLETS, USP Tablets, 250 mg, 100 count-unit dose carton, RX only, Manufactured by Dr. Reddy's	Class II	Lot# M02250 EXP 10/2020	cGMP deviations: Product was exposed above 50% relative humidity levels during packaging	MAJOR PHARMACEUTICALS

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Laboratories Ltd. Bachupally - 500 090 India. Distributed by: Major Pharmaceuticals 17177 N Laurel Park Dr., Suite 233 Livonia, MI 48152. NDC # 0904-6363- 61.			operations.	
Drugs	Doxycycline Hyclate Tablets, USP, 100 mg, 30 Tablets per carton (3 x 10 Unit Dose Blisters), Rx Only, Distributed by: American Health Packaging, Columbus, Ohio, 43217, NDC Carton: 62584-693-21; NDC Unit Dose: 62584- 693-11	Class II	Lot 172569, Exp 7/31/2019	Failed Dissolution Specifications: Out of specification result for the dissolution test.	American Health Packaging
Drugs	Ascorbic Acid 500 MG/ML (Non-Corn) Injection (PFV), 50 mL per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731- 0173-10	Class II	All lots within expiry	Crystallization	RXQ Compounding LLC
Drugs	Ascorbic Acid 400 MG/ML (Non-Corn) Injection Solution, 65 mL per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731- 0914-65	Class II	All lots within expiry	Crystallization	RXQ Compounding LLC
Drugs	Ascorbic Acid 500 MG/ML (Non-Corn) INJ (MDV), 50 mL	Class II	All lots within expiry	Crystallization	RXQ Compounding LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0975-50				
Drugs	Avastin, 25MG/ML Syringe, [a) 0.1 mL NDC 70731-0197-91; b) 0.12 mL NDC 70731-0197-92; c) 0.15 mL NDC 70731-0197-93] per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701.	Class II	All lots within expiry	Crystallization	RXQ Compounding LLC
Drugs	BUFFERED LIDOCAINE 1%+EPI 1:100,000 INJ SOL, [3ML NDC: 70731-0137-03 and 30ML NDC: 70731-0137-30] per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0137-03	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	BUFFERED LIDOCAINE HCL 1% INJECTION SOLUTION (PF), 10ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0139-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	BUFFERED LIDOCAINE HCL 1% INJECTION SOL (PF) SYR, 0.5 ML per vial, RXQ Compounding, 340 West State	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Street, Unit 9, Athens, OH 45701. NDC: 70731-0139-84				
Drugs	CALCIUM CHLORIDE 100MG/ML (PFV) INJ SOLN, 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0920-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	CALCIUM GLUCONATE 5% INJECTION SOLUTION (MDV), 20 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0903-20	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	Copper 0.4MG/ML (PVF) INJECTION SOLUTION, 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0925-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	CYANCOBALAMIN 1200MCG/ML MDV INJECTION, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0946-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	DEXPANTHENOL 250MG/ML (MDV) INJECTION SOLN, 30ML per vial, RXQ	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0932-30				
Drugs	DEXTROSE 50% INJECTION SOLUTION (PF) VIAL, 50 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0969-89	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	diazePAM 5 MG/ML INJECTION SOLUTION (C-IV) SYR, 2 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0929-02	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	DIMERCAPTO-PROPANESULFONIC 5% (DMPS)( PFV) INJ SOL, 5 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0904-05	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	EDETATE CALCIUM DISODIUM 150MG/ML INJECTABLE, 100 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0934-11	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	EDETATE DISODIUM	Class II	All lots within expiry	Lack of	RXQ

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	30% INJECTABLE, 100 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0931-11			Assurance of Sterility	Compounding LLC
Drugs	EDETATE DISODIUM 15% INJECTABLE, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0922-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	EDETATE DISODIUM 15% INJECTABLE, 100 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0922-11	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	EDETATE DISODIUM 150mg/mL PFV, 10 ML per Vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0934-11	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	EPHEDRINE 5MG/ML (PF) SYRINGE, 5 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0201-85	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	EPINEPHrine 4MG ADDED TO D5W 5%, 250 ML per bag,	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC



Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0113- 22				
Drugs	EPINEPHrine 1:1000 INJECTION SOLUTION (PF) Syringe, 1 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731- 0947-01	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	fentaNYL 0.05MG/ML INJ SOL (PF), 55ML per syringe (C-II) RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731- 0118-55	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	FENTANYL 2MCG/ML BUPIVACAINE 0.125% IN NAACL 0.9% SRY C-II, 50ML per syringe (C-II) RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0207- 89	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	FOLIC ACID 10MG/ML INJECTION SOLUTION (MDV), 5 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	45701. NDC: 70731-0921-05				
Drugs	FOLIC ACID 5MG/ML INJECTION SOLUTION (MDV), 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0924-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	GLUTATHIONE 200MG/ML (PFV) INJECTION SOLN, 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0971-81	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	GLUTATHIONE 200MG/ML (MDV) INJECTION SOLN, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0906-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	HYDROGEN PEROXIDE 3% INJECTABLE PFV, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0907-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	HYDROMORPHONE 0.2MG/ML IN NAACL 0.9% SYR (C-II) , [a] 50 ML NDC 70731-0114-89; b) 55 ML NDC 70731-0114-95] per syringe, RXQ	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Compounding, 340 West State Street, Unit 9, Athens, OH 45701.				
Drugs	HYDROXOCOBALAM IN 1000 MCG/ML (PFV), 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0949-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	HYDROXOCOBALAM IN 1000 MCG/ML (MDV), 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0926-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	Inositol/Choline B12:B6, 50/50/1/0.175 MG/ML INJ SOLN(Sulfa Free Lipostat), 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0999-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	KETAMINE 50 MG/ML (NPV) INJECTION SOLUTION (C-III), 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0173-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	KETAMINE 10	Class II	All lots within expiry	Lack of	RXQ

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	MG/ML INJ SOL SYR (C-III), [a] 2 ML NDC: 70731-0132-02; b) 5 ML NDC: 70731-0132-05] per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701			Assurance of Sterility	Compounding LLC
Drugs	LIDOCAINE HCL 1% INJECTION SOLUTION (NPV), 20ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0174-20	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	LIDOCAINE HCL 2% INJECTION SOLUTION (NPV), 20ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0172-20	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	MAGNESIUM 200 MG/ML/ CALCIUM GLUC 6MG/ML/ ZINC 1MG/ML, 5ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0176-05	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	MAGNESIUM 200 MG/ML/ CALCIUM GLUC 6MG/ML/ ZINC 1MG/ML, 5ML per vial, RXQ Compounding, 340 West State Street,	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Unit 9, Athens, OH 45701. NDC: 70731-0176-05				
Drugs	MAGNESIUM CHLORIDE HEXAHYDRATE (PFV) 20% INJ SOLN, 50 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0951-50	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	MANGANESE SULFATE MONOHYDRATE (PFV) 0.1MG/ML INJ, 10 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0952-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	METHYLCOBALAMIN 10MG/ML INJECTABLE SOLUTION (MDV), 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0130-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	METHYLCOBALAMIN 1 MG/ML (MDV) INJECTABLE SOLUTION, 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0915-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	METHYLCOBALAMI	Class II	All lots within expiry	Lack of	RXQ

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	N (PFV) 10 MG/ML INJECTABLE, 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0902-10			Assurance of Sterility	Compounding LLC
Drugs	MIC (METHIONINE/INOSITOL/CHOLINE CHLORIDE) 25/50/50 MG/ML INJ, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0100-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	MIC B12 W/B6 (LIPOSTAT PLUS) 25/50/50/1/.175 MG/ML, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0978-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	MIDAZOLAM 1MG/ML IN NAACL 0.9% INJ SOL SYR (C-IV), 10 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0135-86	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	MIDAZOLAM 1MG/ML IN NAACL 0.9% INJ SYR C-IV, 55 ML per syringe, RXQ Compounding,	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0135-55				
Drugs	MITOMYCIN 0.04% (PF) OPH SOLN, 1ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0917-01	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	MOLYBDENUM 0.025MG/ML INJECTION SOLUTION, 10ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0964-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	MORPHINE 1MG/ML IN NAACL 0.9% 55ML SYR (C-II), 55 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0138-89	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	MOXIFLOXACIN 0.5% OPHTH SOLUTION SYRINGE, 1 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0973-81	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	NEOSTIGMINE METHYL SULFATE	Class II	All lots within expiry	Lack of Assurance of	RXQ Compounding

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	1MG/ML INJ SOL SYR, 5 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0143-05			Sterility	LLC
Drugs	NIACINAMIDE 100MG/ML, 10ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0938-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	ONDANSETRON 2 MG/ML INJECTION SOLUTION (NPF), 20ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0157-20	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	ONDANSETRON 2 MG/ML INJECTION SOLUTION (PFV), 2 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0158-02	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	PHENYLEPHRINE HCL 100 MCG/ML IN NACL 0.9% SYR, 10 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0136-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	PHO-TID-CHOL 50MG/	Class II	All lots within expiry	Lack of Assurance of	RXQ Compounding



Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	DEOXYCHOLIC 42 MG/ML INJ, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0953-30			Sterility	LLC
Drugs	POTASSIUM CHLORIDE 15% (2MEQ/ML) INJ SOLN, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0954-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	PREDNISOLONE 1%, MOXIFLOXACIN 0.5% OPHTH SOL, 5ML per dropper bottle, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0109-05	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	PROCAINE HCL 20 MG/ML (MDV) INJECTABLE SOLUTION, 30 ML per vial. RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0987-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	PROCAINE HCL (PFV) 20 MG/ML INJECTABLE SOLUTION, 30 ML per vial, RXQ Compounding, 340 West State Street,	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Unit 9, Athens, OH 45701. NDC: 70731-0900-30				
Drugs	PROCAINE HCL 8% (PFV) INJECTABLE, 10ML PER VIAL, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0970-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	PYRIDOXINE (MDV) 100MG/ML, 30ML PER VIAL, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0956-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	PYRIDOXINE (PFV) 100MG/ML, 30ML PER VIAL. RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0955-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	RIBOFLAVIN 0.1% OPHTHALMIC SOLUTION SYRINGE, 2 ML per syringe. RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0923-02	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	ROPIVICAIN 0.2%, INJ SOLN, 550 ML ON-Q PUMP. RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0238-55	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	RXQ CAIN (PHENYLEP 1.5%/LIDO 1% OPHTH SOL (PF), 1 ML PER VIAL, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0918-01	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	SODIUM BICARBONATE 8.4% (1 MEQ/ML) INJ SOLN (PFV), 50 ML PER VIAL, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0957-50	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	LIDOCAINE 0.75%/Epinephrine 0.025%/BSS 0.56ML SYR, 1 ML PER Syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0919-01	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	SOD-PHOS (PHOS 3MMOL/ML-SOD 4MEQ/ML) PFV INJ SOLN, 10 ML PER VIAL, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0905-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	Mometasone Furoate Cream USP, 0.1%, packaged in a) 15gram tubes (NDC 68462-192-17) and	Class II	a) 05171238, 05171248, 05171249, Exp. Jul-2019; 05171582, 05171612, Exp. Aug-	GMP Deviations: Glenmark received complaints stating that	Glenmark Pharmaceuticals Inc., USA

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	<p>b) 45 gram tubes (NDC 68462-192-55), Rx Only, Manufactured by; Glenmark Pharmaceuticals Ltd At: Village: Kishanpura, Baddi Nalagari Road, District: Solan, Himachal Pradesh - 173205, India Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430</p>		<p>2019; 05171674, 05171675, 05171682, Exp. Sep 2019; 05180065, 05180066, Exp. Dec 2019; 05180264, 05180264, 05180265, 05180275, 0518276, Exp. Jan 2020; 05180411, 05180412, 05180422, Exp. Jan 2020; 05180556, 05180568 Exp. Feb-2020; 05180889, 05180890, 05180896, 05180896, 05180897 Exp. Apr 2020; 05181123, 05181129, 05181134, 05181135, Exp. May 2020; 05181415, 05181425, 05181429, 05181433, Exp. Jun 2020; 05181528, Exp. Jul 2020; 05181747, 05181748, Exp. Aug 2020. b) 05171207, 05171212, 05171213, 05171232, 05171233, Exp. Jul-2019; 05171476, 05171478, 05171479, Exp. Aug 2019; 05171596 , 05171597, 05171602, 05171603, Exp. Aug 2019; 05171683, 05171697,</p>	<p>mometasone fuorate cream was gritty</p>	

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			05171698, 05171703, 05171718, 05171783, 05171788, 05171789, 05171790, 05171791, Exp. Sep 2019; 05180092, 05180093, 05180119, 05180219, 05180220, Exp. Dec 2019; 05180289, 05180291, 05180434,05180435, Exp. Jan-2020; 05180438, 05180439, 05180443, 05180444, 05180450, 05180462, 05180572, 05180646, Exp. Feb 2020 05180648, 05180649, 05180659, 05180660, 05180671, Mar 2020; 05180870, 05180871, 05180874, 05180877, 05180900, 05180901, Exp. Apr 2020; 05181073, 05181074, 05181086, 05181087, 05181091, 05181092, 05181101, 05181102, 05181111, 05181146,		

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			05181147, 05181148, 05181240 Exp. May 2020; 05181241, 05181248, 05181252, 05181253, 05181257, 05181265, 05181266, 05181267, 05181272, 05181309, 05181316, 05181317, 05181332 Exp. Jun 2020; 05181588, 05181602, 05181603, 05181618, 05181619, 05181621, 05181622, 05181633, 05181634 Exp. Jul 2020; 05181754, 05181772, 05181773, 05181781 Exp. Aug 2020		
Drugs	STERILE WATER FOR INJECTION USP, [10, 30, or 50 ML] per Vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 10 ML vial: 70731-Class II0188-10; NDC 30 ML vial: 70731- 0188-30; NDC 50 ML vial: 70731-0188-50	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	SUCCINYLCOLINE CHLORIDE 20MG/ML INJ SOL, 10 ML per Vial, RXQ	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0129-10				
Drugs	TAURINE 50 MG/ML (MDV) INJECTABLE, 30 ML per Vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0958-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	THIAMINE HCL 100MG/ML (MDV) INJECTION, 10 ML per Vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0950-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	THIAMINE HCL 100MG/ML (MDV) INJECTION, 10 ML per Vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0950-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	TURBO CAINE 2.5 (PHEN2.5/CYCLO1/TROP1/TETRA 0.5), 0.4 ML per Syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0193-81	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	TURBO DROPS (PHEN 0.625%/CYCLO 0.25%/TROP 0.25%/KETO	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	0.125%) OPHTH SOLN, 0.4 ML per Syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0192-81				
Drugs	TURBO DROPS (PHEN 10% / CYCLO 1%/ TROP 1%/ KETO 0.5%) OPHTH SOLN, 5 ML per dropper bottle, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0206-05	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	TURBO DROPS (PHEN 2.5% / CYCLO 1%/ TROP 1%/ KETO 0.5%) OPHTH SOLN, 5 ML per dropper bottle, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0205-05	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	VITAMIN B COMPLEX 100 (MDV), 30 ML per Vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0976-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	VITAMIN B COMPLEX 100 (PFV), [2 or 30 ML] per Vial, RXQ Compounding, 340 West State Street,	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC



Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Unit 9, Athens, OH 45701. NDC 2 ML Vial: 70731-0961-02; NDC 30 ML Vial: 70731-0961-30				
Drugs	ZINC SULFATE 1MG/ML INJECTION SOLUTION (PFV), 10ML per VIAL, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0963-10	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	ZINC SULFATE 1MG/ML INJECTION SOLUTION, 30ML per VIAL, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0152-30	Class II	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	CVS Health Children's Allergy Relief Liquid Medication Diphenhydramine HCl 12.5 mg/5 mL Oral Solution, Antihistamine, Mixed Berry Flavor, 20 Single-Use Vials per Carton, 0.17 fl. oz. (5 mL) Each, 3.4 fl. oz. (100 mL) Total Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895, NDC 69842-261-01 UPC 050428597156	Class II	Lot: 80060 Exp. 11/30/20	CGMP Deviations: Recall as a precautionary measure due to potential risk of product contamination with the bacteria B. cepacia.	Unipharma, LLC
Drugs	DrKids Children's Allergy Relief	Class II	Lot: 90003 Exp. 01/31/21	CGMP Deviations:	Unipharma, LLC

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Diphenhydramine HCl 12.5 mg/5 mL Antihistamine, Mixed berry Flavor, 20 Pre-measured Single-Use vials per Carton, Manufactured in USA by: Unipharma, LLC. Tamarac, FL 33321, UPC 370302255010			Recall as a precautionary measure due to potential risk of product contamination with the bacteria B. cepacia.	
Drugs	CVS Health Children's Nasal Saline Drops with Himalayan Salt Saline Nasal Moisturizer, 30 single-use vials per Carton, 0.05 fl. oz. (1.5 mL) each 1.5 fl. oz. (45 mL) total, Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895, UPC 050428598207	Class II	Lot: 90008 Exp. 02/28/21	CGMP Deviations: Recall as a precautionary measure due to potential risk of product contamination with the bacteria B. cepacia.	Unipharma, LLC.
Drugs	Lovastatin Tablets USP, 40 mg, packaged in a) 100-count bottles (NDC 68001-316-00) and b) 1000-count bottles (NDC 68001-316-08), Rx Only, Manufactured by: Lupin Limited, Goa 403 722 INDIA For BluePoint Laboratories.	Class III	Lot #: a) G702705 and b) G702706, Exp. 3/31/2020	CGMP Deviations: Finished product made with lovastatin drug substance that was out of specification for individual impurity results.	American Health Packaging
Drugs	Smart Sense Regular Strength Aspirin Tablets, 325 mg packed in a) 100 count UPC 8-8397-	Class III	a) P136370, exp 9/2022 b) P136366, exp 9/2022	Labeling; Incorrect or Missing Lot Number and/or Exp Date;	AAA Pharmaceutical, Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	38781-6 and b) 500 count UPC 8-83967-38786-1 bottles, Distributed by: Kmart Corporation Hoffman Estates, IL 60179			Product has an incorrect expiration date of 9/2022 applied to the labeling, where the actual expiration date is 10/2021.	
Drugs	DEXTROSE 50% INJECTION SOLUTION (PF) SYRINGE, 50 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0969-89	Class III	All lots within expiry	Lack of Assurance of Sterility	RXQ Compounding LLC
Drugs	Nystatin and Triamcinolone Acetonide Cream USP100,000 units/g, 0.1%, 15 g tube, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, Manufactured by: Lupin Limited Pithampur (M.P.) 454 775 INDIA, NDC 68180-545-01	Class III	Lot #: K800245, Exp. Dec 2019; K900036 Exp. Sep 20; K900153, Exp. 09/2020	Failed Content Uniformity Specifications: Out-of-specification result observed in uniformity of containers test at 9 month long term stability condition for upright orientation	Lupin Pharmaceuticals Inc.
Drugs	Gatifloxacin Ophthalmic Solution 0.5%, For Use in the Eyes Only, Rx Only, Sterile, 2.5 mL Bottle, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, United States,	Class III	Lot #: H805157, Exp. 05/2020	Labeling: Missing label; Product complaints reported missing bottle label.	Lupin Pharmaceuticals Inc.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Manufactured by: Lupin Limited, Pithampur (M.P.) 454 775, India, NDC 68180-435-01				
Drugs	Methylergonovine Maleate USP 0.2 mg Tablets a) 12 count (NDC 69238-1605-02) and b) 28 count bottles (NDC 69238-1605-08)	Class III	a) Lot # BA10619A, b) Lot # BA10619B, exp. date 07/2020	Presence of Foreign Tablet/Capsule; one Promethazine tablet was found in a bottle of Methylergonovine Maleate tablets	Amneal Pharmaceutical, Inc.
Drugs	Accent Care of New York Home Care Nursing Personal Care Hand Sanitizer (Ethyl Alcohol 62%), 0.33 oz/10 mL, OTC, Made in China	Class III	Lot #: 20170619, Exp 6/18/2019; 20170620, Exp 6/19/2019; 20170621, Exp 6/20/2019	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products	NingBo Huize Commodity Co. Ltd.
Drugs	Good to Go Hand Sanitizer (Ethyl Alcohol 62%), 1 FL OZ (30 mL), OTC, Made in China for Cashco Distributors Inc. 6430 N. E. Columbia Blvd Portland OR 97218	Class III	Lot #: 20180601 Exp 5/31/2020, 20180604 Exp 6/3/2020, 20180820 Exp 8/19/2020, 20180821 Exp 8/20/2020, 20180822 Exp 8/21/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products	NingBo Huize Commodity Co. Ltd.
Drugs	Tootsie Roll POP GRAPE SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed By: JFL Enterprises, Inc. Cleveland, Ohio 44102, Made in China	Class III	Lot #: 20181018, Exp 10/17/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products	NingBo Huize Commodity Co. Ltd.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	AIR HEADS BLUE RASPBERRY SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181120, Exp 11/19/2020; 20181121, Exp 11/20/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	festpak clearly fun SPF30 sunscreen lotion SPF 30 SUNSCREEN LOTION Active Ingredients Octinoxate 7.5%, Octisalate 2.0%, Oxybenzone 4.0% Titanium Dioxide 2.5% Sunscreen Distributed by: festpak - Austin, TX 78732 Made in China	Class III	Lot #: 20181008, Exp 10/07/2020; 20181009, Exp 10/08/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	SPF 30 SUNSCREEN LOTION Active Ingredients Octinoxate 7.5%, Octisalate 2.0%, Oxybenzone 4.0% Titanium Dioxide 2.5% Sunscreen, 53mL/1.8fl.oz., OTC, Distributed by: EVANS, Made in China	Class III	Lot #: 20180709, Exp 07/08/2020; 20180710, Exp 07/09/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products	NingBo Huize Commodity Co. Ltd.
Drugs	Texas Home Health Home Care Hospice Personal Care Hand Sanitizer (Ethyl Alcohol 62%), 0.33 oz/10 mL, OTC, Made in China	Class III	Lot #: 20180410, Exp 4/9/2020; 20180411, Exp 4/10/2020; 20180830, Exp 8/29/2020; 20180831, Exp 8/30/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	Tootsie Roll POP ORANGE SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102	Class III	Lot #: 20181015, Exp 10/14/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	Tootsie Roll POP CHOCOLATE SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181016, Exp 10/16/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	Tootsie Roll POP RASPBERRY SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102	Class III	Lot #: 20181017, Exp 10/16/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products	NingBo Huize Commodity Co. Ltd.
Drugs	DOTS SCENTED ANTIBACTERIAL HAND GEL ORANGE (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102	Class III	Lot #: 20181019, Exp 10/18/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products	NingBo Huize Commodity Co. Ltd.
Drugs	DOTS SCENTED ANTIBACTERIAL HAND GEL STRAWBERRY (Ethyl	Class III	Lot #: 20181023, Exp 10/22/2020	CGMP deviations: Stability testing was not	NingBo Huize Commodity Co. Ltd.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.			conducted on manufactured sunscreen and hand sanitizer OTC products	
Drugs	DOTS SCENTED ANTIBACTERIAL HAND GEL LIME (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181022, Exp 10/21/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products	NingBo Huize Commodity Co. Ltd.
Drugs	AIR HEADS STRAWBERRY SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181116, Exp 11/15/2020; 20181119, Exp 11/18/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	DOTS SCENTED ANTIBACTERIAL HAND GEL LEMON (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181024, Exp 10/23/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products	NingBo Huize Commodity Co. Ltd.
Drugs	CHARMS BLOW POP CHERRY SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181025, Exp 10/24/2020; 20181026, Exp 10/25/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.



Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
Drugs	TOOTSIE ROLL FRUIT CHEWS LEMON SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181112, Exp 11/11/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	CHARMS BLOW POP WATERMELON SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181029, Exp 10/28/2020; 20181030, Exp 10/29/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	DIPPIN' DOTS SCENTED BIRTHDAY CAKE ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181211, Exp 12/10/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	CHARMS BLOW POP BLUE RAZZ BERRY SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181031, Exp 10/28/2020; 20181101, Exp 10/31/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	ICEE LEMON LIME	Class III	Lot #: 20181128, Exp	CGMP	NingBo Huize



Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.		11/27/2020; 20181129, Exp 11/28/2020	deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	Commodity Co. Ltd.
Drugs	CHARMS BLOW POP SOUR APPLE SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181102, Exp 11/1/2020; 20181105, Exp 11/4/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	ICEE BLUE RASPBERRY SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181206, Exp 12/5/2020; 20181207, Exp 12/6/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	TOOTSIE ROLL FRUIT CHEWS LIME SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181114, Exp 11/13/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	DIPPIN' DOTS SCENTED BANANA SPLIT	Class III	Lot #: 20181210, Exp 12/09/2020	CGMP deviations: Stability testing	NingBo Huize Commodity Co. Ltd.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.			was not conducted on manufactured sunscreen and hand sanitizer OTC products.	
Drugs	DIPPIN' DOTS SCENTED COOKIES 'N CREAM ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181212, Exp 12/11/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	AMERICA'S ORIGINAL DUBBLE BUBBLE Pink Lemonade SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181108, Exp 11/7/2020; 20181109, Exp 11/8/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	TOOTSIE ROLL SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181115, Exp 11/14/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	DIPPIN' DOTS SCENTED COTTON CANDY ANTIBACTERIAL	Class III	Lot #: 20181213, Exp 12/12/2020	CGMP deviations: Stability testing was not	NingBo Huize Commodity Co. Ltd.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.			conducted on manufactured sunscreen and hand sanitizer OTC products.	
Drugs	ICEE PEACH SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181130, Exp 11/29/2020; 20181203, Exp 12/2/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	ICEE CHERRY SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181204, Exp 12/3/2020; 20181205, Exp 12/4/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	TOOTSIE ROLL FRUIT CHEWS VANILLA SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181113, Exp 11/12/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.
Drugs	AMERICA'S ORIGINAL DUBBLE BUBBLE SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC,	Class III	Lot #: 20181106, Exp 11/5/2020; 20181107, Exp 11/6/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and	NingBo Huize Commodity Co. Ltd.

Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
	Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.			hand sanitizer OTC products.	
Drugs	AIR HEADS ORANGE SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181126, Exp 11/25/2020; 20181127, Exp 11/26/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products	NingBo Huize Commodity Co. Ltd.
Drugs	AIR HEADS PINK LEMONADE SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.	Class III	Lot #: 20181122, Exp 11/21/2020; 20181123, Exp 11/22/2020	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products	NingBo Huize Commodity Co. Ltd.
Drugs	Lemon Hand Sanitizer (Alcohol 62%), 30 mL / 1.0 fl. Oz., OTC, Made in China	Class III	Lot #: 20170410, Exp 04/09/2019; 20170515, Exp 05/14/2019; 20170516, Exp 05/15/2019; 20170517, Exp 05/16/2019; 20170518, Exp 05/17/2019; 20170519, Exp 05/18/2019; 20170522, Exp 05/21/2019; 20170523, Exp 05/22/2019; 20170524, Exp 05/23/2019; 20170525, Exp 05/24/2019; 20170526, Exp	CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.	NingBo Huize Commodity Co. Ltd.



Product Type	Product Description	Classification	Code Info	Reason for Recall	Recalling Firm
			05/25/2019; 20180615, Exp 06/14/2020		

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

## CURRENT DRUG SHORTAGES

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### Albuterol Sulfate inhalation solution, 0.5% 5 mg/mL, 20 mL bottle

**July 25, 2019**

Reason for the Shortage

- Akorn did not provide a reason for the shortage

Estimated Resupply Dates

- Akorn has albuterol sulfate 0.5% 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=470>

### Aspirin suppository, Perrigo, 600 mg, 12 count

**July 25, 2019**

Reason for the Shortage

- Perrigo did not provide a reason for the shortage

Estimated Resupply Dates

- Perrigo has aspirin 600 mg suppositories on back order and the company estimates a release date of August 2019

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=568>

### Ketamine Injection

**July 25, 2019**

Reason for the Shortage

- Hikma did not provide a reason for the shortage.
- Mylan Institutional refuses to provide availability information.
- Pae had 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 allocation.
- Pfizer has ketamine 50 mg/mL 10 mL vials on back order and the company estimates a release date of January 2020. The 100 mg/mL 5 mL vials are on back order and the company estimates a release date of November 2019.

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

### Vinblastine Sulfate Injection

**July 25, 2019**

Reason for the Shortage

- Fresenius Kabi has vinblastine on shortage due to a short-term manufacturing delay. They are the sole suppliers of vinblastine.

Estimated Resupply Dates

- Fresenius Kabi has released vinblastine and has filled all open, direct orders. Emergency orders for specific patients may be placed with customer service. Additional product is expected by the end of August

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=578>

## Lorazepam Injection

**July 26, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

- Hikma has lorazepam 4 mg/mL 1 mL vials on back order and the company cannot estimate a release date
- Pfizer has lorazepam 2 mg/mL 1 mL vials on back order and the company estimates a release date of September 2019. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of September 2019. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of January 2020

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

## Fluorescein Sodium and Proparacaine Hydrochloride Ophthalmic Solution

**July 26, 2019**

Reason for the Shortage

- Altaire has recalled several medications due concerns over lack of sterility assurance

Estimated Resupply Dates

- Altaire has fluorescein/proparacaine 5 mL bottles on back order and the company cannot estimate a release date.
- OCuSOFT has Flucaine 5 mL bottles on back order and the company cannot estimate a release date

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=581>

## Bacitracin Ophthalmic Ointment

**July 26, 2019**

Reason for the Shortage

- In early-July 2019, Altaire recalled several lots of certain ophthalmic ointments, including bacitracin ophthalmic ointment. The products were recalled due to a potential for nonsterility.
- Altaire manufactures bacitracin ophthalmic ointment and Perrigo distributes the product

Estimated Resupply Dates

- Perrigo has bacitracin ophthalmic ointment 3.5 gram tubes on back order and the company estimates a release date in mid-August 2019

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=582>

## Azithromycin Injection

**July 26, 2019**

Reason for the Shortage

- Apotex has discontinued azithromycin injection.
- AuroMedics did not provide a reason for the shortage.

- Fresenius Kabi had azithromycin injection on shortage due to increased demand.
- Pfizer has azithromycin injection on shortage due to manufacturing delays.
- Slate Run Pharmaceuticals has azithromycin injection available.
- Sun Pharma is not currently manufacturing azithromycin injection

#### Estimated Resupply Dates

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

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=380>

### Multiple Vitamins for Infusion

**July 29, 2019**

#### Reason for the Shortage

- Pfizer states the shortage is due to manufacturing delays.
- Baxter has all presentations fully available at this time

#### Estimated Resupply Dates

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

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

### Deferoxamine Injection

**July 29, 2019**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Alvogen has short-dated deferoxamine 500 mg vials available with an expiration date of January 2020.
- Pfizer has deferoxamine 500 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=393>

### Ciprofloxacin Ophthalmic Solution

**July 29, 2019**

#### Reason for the Shortage

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



#### Estimated Resupply Dates

- Akorn has ciprofloxacin ophthalmic solution on back order and the company cannot estimate a release date.
- Sandoz has ciprofloxacin ophthalmic solution in 2.5 mL bottles available as short-dated product with expiration dates of December 2019, April 2020, and June 2020. The company estimates a next release date of September 2019

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

#### 50% Dextrose Injection

**July 29, 2019**

##### Reason for the Shortage

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

##### Estimated Resupply Dates

- Pfizer has 50% dextrose 50 mL LifeShield syringes on back order and the company estimates a release date of August 2019. The 50% dextrose 50 mL Ansyr syringes are on back order and the company estimates a release date of December 2019. The 50% dextrose 50 mL vials are on back order and the company estimates a release date of August 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

**July 29, 2019**

##### Reason for the Shortage

- Fresenius Kabi had 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

- Pfizer has 23.4% sodium chloride 200 mL 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=336>

#### Thrombin Topical Solution (Bovine)

**July 30, 2019**

##### Reason for the Shortage

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

##### Estimated Resupply Dates

- Pfizer has Thrombin-JMI 20,000 unit syringe spray kits, 5,000 unit epistaxis kits, 5,000 unit vials, and 5,000 unit syringe spray kits available in limited supply. The 20,000 unit pump spray kits are on back order and the company estimates a release date of September 2019. The 20,000 unit 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=479>

## Norepinephrine Bitartrate Injection

**July 30, 2019**

Reason for the Shortage

- Baxter has norepinephrine injection available.
- Mylan Institutional refuses to provide product availability.
- 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. The 4 mL vials are available in limited supply.

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

## Morphine PCA Vials

**July 30, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

- ICU Medical has morphine 1 mg/mL 30 mL PCA vials on allocation to contracted customers. The 5 mg/mL 30 mL PCA vials are on back order and the company estimates a release date of late-December 2019

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

## Mitoxantrone Hydrochloride Injection

**August 19, 2019**

Reason for the 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

- Pfizer has short-dated mitoxantrone 2 mg/mL 12.5 mL vials available with an expiration date of November 2019
- 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>

## Hypromellose Ophthalmic Solution

**July 31, 2019**

Reason for the Shortage

- Akorn has hypromellose ophthalmic solution on shortage due to lack of raw materials.<sup>1</sup>
- HUB Pharmaceuticals has hypromellose ophthalmic solution on long-term back order and did not provide a reason.<sup>2</sup>
- Altaire did not provide a reason for the shortage.<sup>[3]</sup>

- OcuSoft did not provide a reason for the shortage

#### Estimated Resupply Dates

- Akorn has Gonak 2.5% ophthalmic solution 15 mL bottles on allocation.1
- HUB Pharmaceuticals has Goniovisc 2.5% ophthalmic solution 15 mL bottles on long-term back order and the company cannot estimate a release date.2
- Altaire has Goniotaire 2.5% ophthalmic solution 15 mL bottles on back order and the company cannot estimate a release date.[3]
- OCuSOFT has Goniosoft 2.5% 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=437>

### Bisacodyl Suppositories

**July 31, 2019**

#### Reason for the Shortage

- G&W Laboratories discontinued bisacodyl suppositories.
- Major has bisacodyl suppositories on shortage due to increased demand.
- Perrigo has bisacodyl suppositories on shortage due to increased demand.
- Rugby Laboratories has bisacodyl suppositories on shortage due to increased demand

#### Estimated Resupply Dates

- Major has bisacodyl 10 mg suppositories in 12 count on back order and the company estimates a release date in September 2019. Bisacodyl 10 mg suppositories in 100 count are on back order and the company cannot estimate a release date.
- Perrigo has bisacodyl 10 mg suppositories in 50 count on back order and the company estimates a release date of mid-August 2019.
- Rugby Laboratories has bisacodyl 10 mg suppositories in 100 count on back order and the company estimates a release date in September 2019

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=565>

### Tropicamide 1% Ophthalmic Solution

**August 01, 2019**

#### Reason for the Shortage

- Akorn has tropicamide 1% ophthalmic drops available.
- Alcon has Mydracyl available.
- Bausch Health discontinued tropicamide 1% ophthalmic drops in mid-2018.
- Sandoz has tropicamide 1% ophthalmic drops available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=547>

### Recombinant Zoster Vaccine (Shingrix)

**August 01, 2019**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- GlaxoSmithKline has Shingrix on intermittent back order and the company is shipping orders according to order date and supply available

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

### **Polyvinyl Alcohol (Artificial Tears) Ophthalmic Solution**

**August 01, 2019**

Reason for the Shortage

- Akorn did not provide a reason for the shortage.
- Altaire is not currently marketing polyvinyl alcohol 1.4% ophthalmic solution.
- Major has Liquitears on shortage because they are updating the NDC number.
- Ocusoft did not provide a reason for the shortage.
- Rugby has Artificial Tears solution on shortage because they are updating the NDC number

Estimated Resupply Dates

- Akorn has Artificial Tears Solution ophthalmic drops on allocation.
- Major has Liquitears ophthalmic drops on back order and the company cannot estimate a release date.
- Rugby has Artificial Tears solution on back order and the company cannot estimate a release date.
- Ocusoft has Tears Again 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=451>

### **Physostigmine Salicylate Injection**

**August 01, 2019**

Reason for the Shortage

- Akorn did not provide a reason for the shortage. They are the sole suppliers of physostigmine salicylate injection

Estimated Resupply Dates

- Akorn has physostigmine salicylate 1 mg/mL 2 mL ampules on back order and the company estimates a release date in late-August 2019

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

### **Iopamidol Injection**

**August 01, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

- Bracco Diagnostics has Iovue-300 (iopamidol 61%) in 100 mL and 500 mL bottles on back order and the company cannot estimate a release date. Iovue-370 (iopamidol 76%) in 75 mL, 200 mL, and 500 mL bottles are on back order and the company cannot estimate a release date

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

### **Bisoprolol Fumarate Tablets**

**August 01, 2019**

Reason for the Shortage

- Mylan refuses to provide updated availability information.
- Unichem Pharmaceuticals had product on shortage due to market demand.

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

## Ketorolac Injection

**August 03, 2019**

### Reason for the Shortage

- Alvogen did not provide a reason for the shortage
- Amphastar did not provide a reason for the shortage
- Athenex has ketorolac available
- BD RX is now part of Fresenius Kabi
- Fresenius Kabi has most ketorolac presentations available
- Fosun Pharma has ketorolac 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 discontinued ketorolac in March 2019
- FDA imposed an import ban in mid-2013 on several Wockhardt products including ketorolac.[12]
- Sprix Nasal Spray is not affected by this shortage

### Estimated Resupply Dates

- Alvogen has ketorolac 30 mg/mL 1 mL vials and 2 mL vials on back order and the company cannot estimate a release date
- Amphastar has ketorolac 30 mg/mL 1 mL vials on back order and the company cannot estimate a release date
- Fresenius Kabi has ketorolac 15 mg/mL 1 mL prefilled syringes on back order and the company estimates a release date of 4th quarter 2019. The 30 mg/mL 1 mL vials are on back order and the company estimates a release date of mid- to late-August 2019. The 30 mg/mL 2 mL syringes for intramuscular use are on back order and the company estimates a release date of 4th quarter 2019. The ketorolac 30 mg/mL 1 mL prefilled syringes are available with short expiry of < 7 months.
- Hikma has all ketorolac presentations on back order and the company cannot estimate a release date
- Pfizer has ketorolac 30 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of March 2020. The 30 mg/mL 2 mL Carpuject syringes for intramuscular injection and 30 mg/mL 1 mL iSecure syringes are on back order and the company estimates a release date of August 2020. The ketorolac 30 mg/mL 1 mL vials are on back order and the company estimates a release date of August 2019
- Sagent has ketorolac 15 mg/mL 1 mL vials, 30 mg/mL 1 mL vials, and 30 mg/mL 2 mL vials for intramuscular injection on back order and the company estimates a release date of October 2019

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

## Furosemide Injection

**August 03, 2019**

### Reason for the Shortage

- American Regent is not actively marketing furosemide injection.
- Amneal discontinued furosemide injection.
- Baxter has furosemide injection available.
- Fresenius Kabi has furosemide injection available.

- Heritage did not provide a reason for the shortage.
- Pfizer had furosemide injection on shortage due to manufacturing delays and increased demand

#### Estimated Resupply Dates

- Heritage has furosemide 10 mg/mL 2 mL, 4 mL, and 10 mL vials on back order with no estimated release date.
- Pfizer has short-dated furosemide 10 mg/mL 4 mL syringes available with an expiration date of August 2019. There are short-dated 10 mL vials available with an expiration date of October 2019

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

## Dicyclomine Injection

**August 03, 2019**

#### Reason for the Shortage

- Allergan has Bentyl injection available.
- Akorn has dicyclomine injection for intramuscular use 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

- All marketed presentations are available

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

## Clonidine Hydrochloride Injection

**August 03, 2019**

#### Reason for the Shortage

- American Regent and Fresenius Kabi are not currently marketing clonidine injection.
- Hikma did not provide a reason for the shortage.
- Mylan Institutional refuses to provide availability information.
- X-Gen did not provide a reason for the shortage.

#### Estimated Resupply Dates

- X-Gen has clonidine 0.5 mg/mL 10 mL vials and 0.1 mg/mL 10 mL vials on intermittent back order with regular releases.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=554>

## Bupivacaine Injection

**August 03, 2019**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- AuroMedics has 0.25% bupivacaine 10 mL and 30 mL preservative-free vials on intermittent back order and the company is releasing product as it becomes available. The 0.5% bupivacaine 10 mL and 30 mL preservative-free vials are on intermittent back order and the company is releasing product as

it becomes available. The 0.75% bupivacaine 10 mL and 30 mL preservative-free vials are on intermittent back order and the company is releasing product as it becomes available.

- Fresenius Kabi has 0.25% Sensorcaine 30 mL preservative-free vials on back order and the company estimates a release date of mid-August 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 preservative-free vials on back order and the company estimates a release date of December 2019. The 0.25% bupivacaine 30 mL preservative-free vials are available in limited supply. The 0.25% bupivacaine 50 mL vials are available in limited supply. The 0.5% bupivacaine 10 mL preservative-free vials are on back order and the company estimates a release date of November 2019. The 0.5% bupivacaine 30 mL preservative-free vials are on back order and the company estimates a release date of August 2019. The 0.5% bupivacaine 50 mL vials are on back order and the company estimates a release date of August 2019. The 0.75% bupivacaine 10 mL preservative-free vials are available in limited supply. The 0.75% bupivacaine 30 mL preservative-free vials are on back order and the company estimates a release date of September 2019.
- Pfizer has 0.25% Marcaine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of April 2020 for the 10 mL vials and November 2019 for the 30 mL vials. The 0.25% 50 mL vials are on back order and the company estimates a release date of January 2020. The 0.5% Marcaine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of January 2020. The 0.5% 50 mL vials are on back order and the company estimates a release date of November 2019. The 0.75% Marcaine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of December 2019 for the 10 mL vials and November 2019 for the 30 mL vials.

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

## Amiodarone Injection

**August 03, 2019**

Reason for the Shortage

- Baxter had Nexterone premixed bags on shortage due to manufacturing delays.
- Mylan Institutional refused to provide availability information.
- Hikma did not provide a reason for the shortage; however, the 50 mg/mL, 3 mL 10 count presentation was discontinued in December 2018.
- Sagent discontinued amiodarone 50 mg/mL 3 mL syringes in June 2019.

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.
- Hikma has amiodarone 50 mg/mL 3 mL vials on allocation

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

## Vancomycin Hydrochloride Injection

**August 05, 2019**

Reason for the Shortage

- Alvogen has vancomycin injection available.[1]
- Athenex has vancomycin injection available.[2]
- AuroMedics did not provide a reason for the shortage.[3]



- Pfizer has vancomycin vials on back order due to manufacturing delays.[4]
- Fresenius Kabi has vancomycin injection available.[5]
- Mylan Institutional refuses to provide availability information.[6]
- Baxter has vancomycin injection available.[7]
- Samson Medical Technologies has vancomycin injection available.[8]
- Sagent has vancomycin injection available.[9]
- Xellia Pharmaceuticals has vancomycin injection and vancomycin premixed bags available

#### Estimated Resupply Dates

- Athenex has vancomycin 500 mg vials on back order and the company estimates a release date of early-August 2019.[2]
- AuroMedics has vancomycin 1 gram vials on long-term back order and the company cannot estimate a release date.[3]
- Pfizer has 5 gram vials available in limited supply. There are short-dated 500 mg ADD-Vantage vials available with an expiration date of October 2019. The 750 mg ADD-Vantage vials are on back order and the company estimates a release date of March 2020. The 1 gram ADD-Vantage vials are on back order and the company estimates a release date of August 2019

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

#### Sufentanil Injection

**August 05, 2019**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Pfizer has sufentanil 0.5 mg/mL 1 mL and 2 mL vials on back order and the company estimates a release date of August 2019

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

#### Meropenem Injection

**August 05, 2019**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- AuroMedics has meropenem 1 gram vials on intermittent back order and the company is shipping product as it becomes available.
- Pfizer has Merrem 500 mg vials (NDC 00310-0325-20) and 1 gram vials (NDC 00310-0321-30) on back order and the company estimates a release date of March 2020. Pfizer has generic meropenem 500 mg and 1 gram vials on back order and the company estimates a release date of August 2020.
- Sandoz has meropenem 500 mg vials in 10-count packages on back order and the company cannot estimate a release date

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



## Lidocaine Injection

**August 05, 2019**

### Reason for the Shortage

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

### Estimated Resupply Dates

- AuroMedics has 1% lidocaine 30 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 lidocaine 2 mL vials on back order and the company estimates a release date of mid- to late-August 2019. The 1% Xylocaine 50 mL vial are on back order and the company estimates a release date of early-August 2019. The 1% Xylocaine-MPF 30 mL vial sterile packs are on back order and the company cannot estimate a release date. The 1.5% Xylocaine-MPF 20 mL ampules are on back order and the company cannot estimate a release date. The 2% Xylocaine-MPF 10 mL ampules are on back order and the company estimates a release date of 3rd quarter 2019. Check wholesalers for inventory.
- Pfizer has 1% lidocaine 5 mL preservative-free ampules on back order and the company estimates a release date of March 2020. The 1% lidocaine 30 mL preservative-free vials are on back order and the company estimates a release date of August 2019. The 1% lidocaine 5 mL Lifeshield syringes are on back order and the company estimates a release date of October 2019. The 1.5% lidocaine 20 mL preservative-free ampules are on back order and the company estimates a release date of October 2019. The 2% lidocaine 5 mL vials are on back order and the company estimates a release date of September 2019. The 2% lidocaine 5 mL Lifeshield syringes are on back order and the company estimates a release date of October 2019. The 2% lidocaine 5 mL Ansyr syringes are 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=88>

## Erythromycin Ophthalmic Ointment

**August 05, 2019**

### Reason for the Shortage

- Akorn did not provide a reason for the shortage.
- Bausch Health did not provide a reason for the shortage.
- Perrigo has erythromycin ophthalmic ointment on shortage due to increased demand

### Estimated Resupply Dates

- Bausch Health has erythromycin 0.5% ophthalmic ointment in 1 gram and 3.5 gram tubes on back order and the company estimates a release date of early-September 2019.
- Perrigo has erythromycin 0.5% ophthalmic ointment in 1 gram tubes in 50 count and 3.5 gram tubes in single count and 24 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=540>

## Enalaprilat Injection

**August 05, 2019**

Reason for the Shortage

- Hikma has enalaprilat injection on shortage due to increased demand.
- Pfizer has enalaprilat injection on shortage due to manufacturing delays.

Estimated Resupply Dates

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

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

## Dobutamine Injection

**August 05, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has dobutamine 12.5 mg/mL 20 mL and 40 mL latex-free vials on back order with an estimated release date of March 2020 for the 20 mL vials and December 2019 for the 40 mL vials.
- Pfizer has dobutamine 4 mg/mL in 250 mL bags on back order and the company estimates a release date of August 2019.

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

## Daptomycin Injection

**August 05, 2019**

Reason for the Shortage

- Fresenius Kabi has daptomycin available.
- Mylan Institutional refuses to provide availability information.
- Pfizer has daptomycin on shortage due to manufacturing delays.
- Teva has daptomycin available.
- Sagent had daptomycin on shortage due to manufacturing delays.
- Merck has Cubicin and Cubicin RF available.
- Xellia Pharmaceuticals has daptomycin available

Estimated Resupply Dates

- Pfizer has daptomycin 500 mg vials on back order and the company estimates a release date of March 2020

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

## Betamethasone Acetate/Betamethasone Sodium Phosphate Suspension for Injection

**August 05, 2019**

Reason for the Shortage

- American Regent had betamethasone acetate/betamethasone sodium phosphate on shortage due to minor shipping delays.
- Merck did not provide a reason for the shortage.

- Exela Pharma Sciences has betamethasone acetate/betamethasone sodium phosphate on shortage due to increased demand

#### Estimated Resupply Dates

- Exela has betamethasone acetate/betamethasone sodium phosphate 6 mg/mL 5 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Merck has Celestone Soluspan 5 mL vials on back order and the company estimates a release date of mid-September 2019

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

### BCG Live Intravesical

**August 05, 2019**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Merck has Tice BCG on allocation

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

### Ropivacaine Injection

**August 06, 2019**

#### Reason for the Shortage

- Akorn has ropivacaine on shortage due to increased demand.
- AuroMedics did not provide a reason for the shortage.
- Fresenius Kabi has Naropin on shortage due to increased demand and manufacturing delays.
- Pfizer had ropivacaine on shortage due to manufacturing delays.
- Sagent has ropivacaine premixed bags available.
- Somerset Therapeutics has ropivacaine 5 mg/mL 30 mL vials available

#### Estimated Resupply Dates

- Akorn has ropivacaine 5 mg/mL 30 mL vials on back order and the company cannot estimate a release date.
- AuroMedics has ropivacaine 7.5 mg/mL 20 mL vials 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 20 mL vials are on back order and the company estimates a release date of mid- to late-August 2019. The 5 mg/mL 20 mL Steripak ampules are on back order and the company cannot estimate a release date. There are short-dated 10 mg/mL 10 mL Steripak ampules available with an expiration date of <8 months. Check wholesalers for inventory.
- Pfizer has ropivacaine 2 mg/mL 10 mL and 20 mL vials on back order and the company estimates a release date of October 2019. The 5 mg/mL 30 mL vials are on back order and the company estimates a release date of October 2019. The 7.5 mg/mL 20 mL vials are on back order and the company estimates a release date of October 2019. The 10 mg/mL 10 mL and 20 mL vials are on back

order and the company estimates a release date of November 2019 for the 10 mL vials and October 2019 for the 20 mL vials.

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

## Metoprolol Injection

### August 19, 2019

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Hikma has metoprolol 1 mg/mL 5 mL vials on back order and the company estimates a release date of late-January 2020. The 10 mL vials are on back order and the company estimates a release date of mid-September 2019
- Pfizer has metoprolol 1 mg/mL 5 mL Carpuject syringes on back order and the company estimates a release date of August 2020. The 1 mg/mL 5 mL ampules are on back order and the company estimates a release date of August 2020

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

## Metoclopramide Injection

### August 06, 2019

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- All marketed presentations are available

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

## Levetiracetam Extended-Release Tablets

### August 06, 2019

#### Reason for the Shortage

- Lupin did not provide a reason for the shortage.
- OWP is discontinuing their Roweepra XR formulations.
- Sun Pharma did not provide a reason for the shortage.
- Torrent is not selling their levetiracetam extended-release tablets within the US.

#### Estimated Resupply Dates

- Lupin has levetiracetam extended-release 500 mg and 750 mg tablets on intermittent back order and the company is shipping product as it becomes available.
- Sun Pharma has levetiracetam extended-release 500 mg and 750 mg tablets on intermittent back order and the company is shipping product as it becomes available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=583>

## Heparin Sodium Premixed Bags

**August 06, 2019**

### Reason for the Shortage

- Baxter has heparin premix available.
- BBraun has heparin premixes available.
- Fresenius Kabi has put heparin on a protective allocation due to a potential shortage of raw ingredient. The letter describing this in detail is available at the following link:  
<https://www.fresenius-kabi.com/us/news/fresenius-kabi-responds-to-a-potential-shortage-of-heparin>.
- Pfizer has heparin on shortage due to manufacturing delays.

### Estimated Resupply Dates

- Pfizer has heparin 25,000 units/250 mL in 0.45% sodium chloride premixed bags available in limited supply. Heparin 1,000 units/500 mL 0.9% sodium chloride premixed bags are available in limited supply.
- BBraun has all heparin premixed bags on intermittent back order and the company is releasing product as it becomes available.

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

## Dexamethasone Sodium Phosphate Injection

**August 06, 2019**

### Reason for the Shortage

- American Regent is not marketing dexamethasone sodium phosphate injection at this time.
- AuroMedics has dexamethasone sodium phosphate on intermittent back order.
- Fresenius Kabi has dexamethasone sodium phosphate presentations available.
- Mylan refuses to provide availability information.
- Hikma did not provide a reason for the shortage.
- Somerset Therapeutics has 10 mg/mL 1 mL vials available

### 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 30 mL vials on back order and the company estimates a release date of mid-August 2019. There are short-dated 4 mg/mL 1 mL prefilled syringes available with an expiration date of <8 months.
- Hikma has dexamethasone sodium phosphate 4 mg/mL 5 mL vials on back order and the company estimates a release date of late-August 2019.

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

## Cyclosporine Injection

**August 06, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

- Perrigo has cyclosporine 50 mg/mL 5 mL ampules on back order and the company estimates a release date of mid-August 2019

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

## Ceftriaxone Sodium Injection

**August 06, 2019**

Reason for the Shortage

- Apotex has ceftriaxone available.
- Fresenius Kabi states the reason for the shortage was increased demand.
- Pfizer had ceftriaxone injection on shortage due to increased demand and manufacturing delays.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz did not provide a reason for the shortage.
- Hikma states the reason for the shortage is manufacturing delay.
- Wockhardt has discontinued their ceftriaxone presentations.
- Lupin has discontinued their ceftriaxone presentations.

Estimated Resupply Dates

- Sagent has ceftriaxone 2 gram vials on allocation

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

## RimabotulintoxinB Intramuscular Injection

**August 07, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

- 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>

## Progesterone Injection

**August 07, 2019**

Reason for the Shortage

- American Regent is not currently marketing progesterone injection.
- AuroMedics has progesterone injection available.
- Fresenius Kabi had progesterone on shortage due to increased demand and manufacturing delays.
- Hikma did not provide a reason for the shortage.
- Teva did not provide a reason for the shortage

Estimated Resupply Dates

- Fresenius Kabi has progesterone 50 mg/mL 10 mL vials on back order and the company estimates a release date of early-August 2019

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

### **Prednisolone Acetate 1% Ophthalmic Suspension**

**August 07, 2019**

Reason for the Shortage

- Allergan did not provide a reason for the shortage.
- Greenstone did not provide a reason for the shortage.
- Novartis discontinued Omnipred 1% in 2018.
- Sandoz had prednisolone acetate on shortage due to increased demand.

Estimated Resupply Dates

- Greenstone has all prednisolone acetate 1% presentations on allocation

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=536>

### **Pantoprazole Injection**

**August 07, 2019**

Reason for the Shortage

- AuroMedics has pantoprazole injection on shortage due to increased demand.
- Hikma did not provide a reason for the shortage.
- Pfizer has Protonix injection on shortage due to manufacturing delays

Estimated Resupply Dates

- AuroMedics has pantoprazole 40 mg vials on intermittent back order and the company is releasing product as it becomes available.
- Hikma has pantoprazole 40 mg vials on allocation.
- Pfizer has Protonix 40 mg vials in 10 count and 25 count on back order and the company estimates a release date of August 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=550>

### **Methocarbamol Tablets**

**August 07, 2019**

Reason for the Shortage

- Bayshore states the shortage is due to increased demand.
- Camber states the shortage is due to an API shortage.
- Endo did not provide a reason for the shortage.
- Hikma is not actively marketing methocarbamol tablets.
- Par discontinued methocarbamol tablets in July 2018.
- Solco states the shortage is due to an API shortage.
- Virtus discontinued methocarbamol tablets in June 2019.

Estimated Resupply Dates

- Camber has all methocarbamol tablets available for contracted customers. All presentations are on allocation for non-contracted customers.
- Solco has methocarbamol 500 mg tablets in 500 count 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>

### Hydroxyprogesterone Caproate Injection

**August 07, 2019**

Reason for the Shortage

- AMAG has Makena vials on shortage due to manufacturing delay.
- American Regent has hydroxyprogesterone injection available.
- AuroMedics has hydroxyprogesterone injection available.
- Mylan has hydroxyprogesterone injection available.
- Prasco discontinued the 5 mL vials in mid-2019. Prasco has hydroxyprogesterone 1 mL vials available.
- Slayback Pharma launched hydroxyprogesterone injection in early 2019

Estimated Resupply Dates

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

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=501>

### Fluorescein Sodium Ophthalmic Strips

**August 07, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

- Akorn has Ful-Glo 0.6 mg and 1 mg strips on allocation.
- Hub has Bio-Glo 1 mg in 300 count on back order and the company estimates a release date in late-September to early-October 2019.

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

### Desiccated Thyroid Tablets

**August 07, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

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

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

### Buprenorphine Hydrochloride Injection

**August 07, 2019**

Reason for the Shortage

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

Estimated Resupply Dates



- Pfizer has buprenorphine 0.3 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of August 2020

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

## Asparaginase *Erwinia chrysanthemi*

**August 07, 2019**

Reason for the Shortage

- Jazz Pharmaceuticals did not provide a reason for the shortage

Estimated Resupply Dates

- Jazz Pharmaceuticals has Erwinaze 10,000 unit vials in 1 count and 5 count on back order and the company estimates a release date of mid-August 2019.
- There is a new process for ordering Erwinaze. Additional information regarding the new ordering process is available at [www.erwinazesupply.com](http://www.erwinazesupply.com).

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

## Amyl Nitrite Inhalation

**August 07, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

- James Alexander has amyl nitrite inhalation on back order and the company estimates a release date in mid- to late-August 2019

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

## Temazepam Capsules

**August 08, 2019**

Reason for the Shortage

- Ascend did not provide a reason for the shortage.
- Major had temazepam on shortage due to manufacturing delays.
- Mylan refuses to provide availability information.
- Sun Pharma discontinued temazepam capsules in 2019.
- Teva did not provide a reason for the shortage.
- Mallinckrodt has Restoril capsules available

Estimated Resupply Dates

- Ascend has temazepam 30 mg capsules in 500 count bottles on back order and the company estimates a release date of mid- to late-August 2019.
- Sun Pharma discontinued temazepam 7.5 mg and 22.5 mg capsules

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

## Amphetamine Mixed Salts, Immediate-Release Tablets

**August 08, 2019**

Reason for the Shortage

- Aurobindo refuses to provide updated availability information.
- Mallinckrodt has amphetamine mixed salts on intermittent back order due to increased demand.

- Mylan refuses to provide updated availability information.
- Sun Pharma discontinued amphetamine mixed salts in 2019.
- Teva did not provide a reason for the shortage.
- Zydus has amphetamine mixed salts available

#### Estimated Resupply Dates

- Mallinckrodt has amphetamine mixed salts 15 mg immediate release tablets on intermittent back order and the company is releasing product as it becomes available.
- Sun Pharma has discontinued all amphetamine mixed salts, immediate-release tablets

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

### Thrombin Topical Powder (Recombinant)

**August 09, 2019**

#### Reason for the Shortage

- Baxter did not provide a reason for the shortage

#### Estimated Resupply Dates

- Baxter has Recothrom 5,000 unit and 20,000 unit syringe kits and 20,000 unit pump spray kits on allocation

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

### Tacrolimus Capsules

**August 09, 2019**

#### Reason for the Shortage

- Accord has tacrolimus on allocation due to raw ingredient shortage.
- Astellas has Prograf on allocation.
- Bionpharma did not provide a reason for the shortage.
- Lannett has discontinued tacrolimus capsules.
- Major did not provide a reason for the shortage.
- Mylan refuses to provide availability information.
- Sandoz has tacrolimus available.
- The extended-release products such as Astragraf XL capsules and Envarsus XR tablets are not affected by this shortage

#### Estimated Resupply Dates

- Accord has tacrolimus 0.5 mg, 1 mg, and 5 mg capsules on allocation.
- Astellas has Prograf capsules on allocation.
- Bionpharma has tacrolimus 0.5 mg, 1 mg, and 5 mg capsules on back order and the company cannot estimate a release date.
- Major has tacrolimus 0.5 mg and 5 mg capsules on back order and the company estimates a release date of late-August 2019. The 1 mg capsules are on back order and the company cannot estimate a release date.
- Sandoz has tacrolimus 5 mg capsules on back order and the company cannot estimate a release date.
- Strides has tacrolimus 1 mg capsules on allocation

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=567>

## Octreotide Injection

August 09, 2019

### Reason for the Shortage

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

### Estimated Resupply Dates

- Fresenius Kabi has octreotide 100 mcg/mL 1 mL vials and 500 mcg/mL 1 mL vials on back order and the company estimates a release date of late-August 2019.
- Hikma has octreotide 50 mcg/mL 1 mL vials, 100 mcg/mL 1 mL vials, and 500 mcg/mL 1 mL vials on allocation.
- Sagent has octreotide 50 mcg/mL 1 mL vials, 100 mcg/mL 1 mL vials, 200 mcg/mL 5 mL vials, and 500 mcg/mL 1 mL vials on back order and the company estimates a release date of August 2019. There are short-dated 1,000 mcg/mL 5 mL vials available with an expiration date of February 2020.
- Teva has short-dated 500 mcg/mL 1 mL vials available with an expiration date of October 2019.

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

## Dorzolamide Ophthalmic Solution

August 09, 2019

### Reason for the Shortage

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

### Estimated Resupply Dates

- Akorn has dorzolamide 2% ophthalmic solution in 10 mL bottles on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=359>

## Buspirone Tablets

August 09, 2019

### Reason for the Shortage

- Accord did not provide a reason for the shortage.
- Mylan refuses to provide updated availability information.
- Par has buspirone tablets available.
- Teva did not provide a reason for the shortage.
- Zydus did not provide a reason for the shortage.

### Estimated Resupply Dates

- Accord has all buspirone presentations on back order and the company cannot estimate a release date.

- Teva has buspirone 10 mg tablets in 100 count bottles, 15 mg tablets in 100 count bottles, and 30 mg tablets in 500 count bottles on intermittent back order and the company is releasing supplies as they become available. The 10 mg tablets in 500 count bottles are on back order with an estimated release date in late-September 2019.
- Zydus has all buspirone presentations on allocation.

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

## Secobarbital Capsules

**August 12, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

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

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

## PCA Sterile Empty Vials and Injector

**August 12, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

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

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

## Copper Chloride Injection

**August 12, 2019**

Reason for the Shortage

- Pfizer has copper chloride on shortage due to manufacturing delays. They are the sole supplier of copper chloride

Estimated Resupply Dates

- Pfizer has copper chloride available in limited supply

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=553>

## Atropine Sulfate Injection

**August 12, 2019**

Reason for the Shortage

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

## Estimated Resupply Dates

- Fresenius Kabi has short-dated atropine 0.4 mg/mL 20 mL vials with an expiration date of <8 months.
- Hikma has short-dated atropine 0.4 mg/mL 20 mL vials available with an expiration date of June 2020.
- Pfizer has atropine 0.1 mg/mL 10 mL LifeShield syringes on back order and the company estimates release dates of September 2019. The 0.1 mg/mL 10 mL Ansyr syringes are on back order and the company estimates a release date of December 2019. The 0.1 mg/mL 5 mL LifeShield syringes are on back order and the company estimates release dates of October 2019. The 0.05 mg/mL 5 mL Ansyr syringes are available with an expiration date of December 2019.

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

## Atropine Ophthalmic Solution

**August 12, 2019**

### Reason for the Shortage

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

### Estimated Resupply Dates

- Akorn has short-dated 1% atropine 2 mL, 5 mL, and 15 mL vials available

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

## Sodium Bicarbonate Injection

**August 13, 2019**

### Reason for the Shortage

- Amphastar has sodium bicarbonate injection on shortage due to increased demand.[1]
- Athenex has sodium bicarbonate available.[2]
- Pfizer has sodium bicarbonate injection on shortage due to manufacturing delays.[3]
- Fresenius Kabi had sodium bicarbonate injection temporarily available, but have run out of stock, there is more in production

### Estimated Resupply Dates

- Amphastar has 8.4% sodium bicarbonate 50 mL syringes on allocation.[1]
- Fresenius Kabi has 8.4% sodium bicarbonate 50 mL vials on back order and the company estimates a release date of mid-August 2019. The 4.2% sodium bicarbonate 5 mL vials are on back order and the company estimates a release date of mid-August 2019.[4]
- Pfizer has 8.4% sodium bicarbonate 10 mL syringes available in limited supply. The 4.2% sodium bicarbonate 10 mL syringes are on back order and the company estimates a release date of October 2019. The 7.5% sodium bicarbonate 50 mL syringes are on back order and the company estimates a release date of August 2019. The 8.4% 50 mL LifeShield syringes are on back order and the company estimates a release date of August 2019.[3]
- Pfizer has Neut 4% 5 mL vials on back order and the company estimates a release date of December 2019n at this time

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

## Haloperidol Tablets

**August 13, 2019**

Reason for the Shortage

- Mylan refuses to provide availability information.
- Sandoz has discontinued all haloperidol tablet presentations

Estimated Resupply Dates

- Zydus has all haloperidol tablet presentations on allocation

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

## Cefoxitin Sodium Injection

**August 13, 2019**

Reason for the Shortage

- Apotex has temporarily discontinued cefoxitin vials.
- 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 10 gram vials.
- Sagent has cefoxitin on shortage due to increased demand and manufacturing delay.
- WG Critical Care did not provide a reason for the shortage.

Estimated Resupply Dates

- Apotex has temporarily discontinued cefoxitin 1 gram, 2 gram, and 10 gram vials and the company cannot estimate when product will be available again.
- BBraun has cefoxitin 1 gram and 2 gram DUPLEX bags on back order and the company cannot estimate a next release date.
- Fresenius Kabi has cefoxitin 1 gram and 2 gram vials on back order and the company estimates a release date of mid-September 2019.
- Hikma has cefoxitin 1 gram vials on allocation. The 2 gram vials are on back order and the company estimates a release date of late-September 2019. The 10 gram vials are on back order and the company estimates a release date of January 2020.
- Sagent has cefoxitin 1 gram vials on allocation. The 2 gram and 10 gram vials are on back order and the company estimates a release date of August 2019.
- WG Critical Care has cefoxitin 1 gram and 2 gram vials on back order and the company estimates a release date of mid- to late-September 2019.

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

## Sterile Talc

**August 14, 2019**

Reason for the Shortage

- Lymol has Sclerosol and talc powder on shortage due to manufacturing delays
- Novatech SA has Steritalc available

Estimated Resupply Dates

- Lymol has Sclerosol and talc powder on long-term back order and the company cannot estimate a release date

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=260>

## Labetalol Injection

**August 14, 2019**

### Reason for the Shortage

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

### Estimated Resupply Dates

- Akorn has labetalol 5 mg/mL 20 mL and 40 mL vials on back order and the company cannot estimate a release date
- Alvogen has labetalol 5 mg/mL 20 mL vials on allocation. The 40 mL vials are on back order and the company estimates a release date of mid-September 2019
- Hikma has labetalol 5 mg/mL 20 mL vials on allocation. The 40 mL vials are on back order and the company estimates a release date of late-August 2019
- Pfizer has labetalol 5 mg/mL 20 mL and 40 mL vials on back order and the company estimates a release date of November 2019 for the 20 mL vials and January 2021 for the 40 mL vials. The 5 mg/mL 4 mL Carpuject syringes are available in limited supply

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

## Hydromorphone Hydrochloride Injection

**August 14, 2019**

### Reason for the Shortage

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

### Estimated Resupply Dates

- Fresenius Kabi has Dilaudid 2 mg/mL 1 mL syringes on back order and the company cannot estimate a release date. The hydromorphone 4 mg/mL 1 mL vials are on back order and the company estimates a release date of early-September 2019. The hydromorphone 10 mg/mL 1 mL vials are on back order and the company estimates a release date of late-August 2019. The hydromorphone 10 mg/mL 50 mL vials are on back order and the company estimates a release date of late-September to early-October 2019. Check wholesalers for inventory.
- Pfizer has 2 mg/mL 1 mL vials on back order and the company estimates a release date of August 2019. The 10 mg/mL 1 mL vials are available in limited supply. The 0.5 mg/0.5 mL iSecure syringes are available in limited supply. The 2 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of October 2019. The 1 mg/mL 1 mL ampules, 2 mg/mL 1 mL ampules, and 4 mg/mL 1 mL ampules are on back order and the company estimates a release date of September 2019 for the 1 mL ampules, April 2020 for the 2 mL ampules, and November 2019 for the



4 mL ampules. The 1 mg/mL 1 mL iSecure syringes and 2 mg/mL 1 mL iSecure syringes are on back order and the company estimates a release date of January 2020. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of January 2020

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

## Fentanyl Citrate Injection

**August 14, 2019**

Reason for the Shortage

- Akorn has fentanyl injection available. They are not currently marketing 25 count fentanyl ampules.
- Hikma has fentanyl injection on shortage due to supply and demand issues. They are not currently marketing fentanyl ampules, just vials.
- Pfizer has fentanyl injection on shortage due to manufacturing delays. The 20 mL ampules were discontinued in September 2017.
- Fresenius Kabi has fentanyl injection available.

Estimated Resupply Dates

- Hikma has fentanyl 50 mcg/mL 20 mL vials on back order and the company estimates a release date of late-September 2019.
- Pfizer has fentanyl 50 mcg/mL 2 mL, 20 mL, and 50 mL vials on back order and the company estimates a release date of September 2019 for the 2 mL vials, November 2019 for the 20 mL vials, and August 2019 for the 50 mL vials. The 2 mL Carpuject syringes are on back order and the company estimates a release date of August 2020.

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

## Dexrazoxane Injection

**August 14, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has Zinecard 500 mg vials on back order and the company estimates a release date of December 2019.
- Hikma has dexrazoxane 500 mg vials on back order and the company estimates a release date of late-August 2019.

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

## Cefepime Injection

**August 15, 2019**

Reason for the Shortage

- Apotex has cefepime injection available.
- Baxter has cefepime on allocation due to increased demand.
- BBraun has cefepime on shortage due to manufacturing delays.



- Fresenius Kabi has cefepime injection available.
- Meitheal Pharmaceuticals has cefepime injection available
- Pfizer has Maxipime on shortage due to manufacturing delays.
- Sagent has cefepime injection available.
- Samson Medical Technologies has cefepime injection available.
- Sandoz discontinued cefepime injection in early-2016.
- WG Critical Care has cefepime injection available

#### Estimated Resupply Dates

- Baxter has cefepime 2 gram premixed bags on allocation.
- BBraun has cefepime 1 gram and 2 gram premixed bags on back order and the company cannot estimate a release date.
- Pfizer has Maxipime 1 gram and 2 gram vials and 1 gram and 2 gram ADD-Vantage vials on back order and the company estimates a release date of August 2020

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

## Ampicillin Sodium and Sulbactam Sodium Injection

### August 15, 2019

#### Reason for the Shortage

- AuroMedics has ampicillin sulbactam vials on back order due to increased demand and manufacturing delays.
- Fresenius Kabi is not currently marketing ampicillin sulbactam injection.
- Meitheal Pharmaceuticals did not provide a reason for the shortage.
- Mylan Institutional refuses to provide availability information
- 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 discontinued ampicillin sulbactam.
- WG Critical Care states the shortage is due to increased demand

#### Estimated Resupply Dates

- AuroMedics has ampicillin sulbactam 3 gram and 15 gram vials on intermittent back order and the company is releasing product as it becomes available. The 1.5 gram vials are 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 early-November 2019. The 1.5 gram and 3 gram vials are on back order and the company estimates a release date of mid- to late-August 2019.
- Meitheal Pharmaceuticals has all ampicillin sulbactam presentations on back order and the company estimates a release date of October 2019.
- Pfizer has Unasyn 1.5 gram and 3 gram vials on back order and the company estimates a release date of August 2019 for the 1.5 gram vials and December 2019 for the 3 gram vials. The 15 gram bulk vials are available in limited supply. The 1.5 gram and 3 gram ADD-Vantage vials are on back order and the company estimates a release date of October 2019 for the 1.5 gram vials and September 2019 for the 3 gram vials.

- Sagent has ampicillin sulbactam 1.5 gram vials and 15 gram bulk vials on back order and the company cannot estimate a release date. The 3 gram vials are on back order and the company estimates a release date of September 2019.
- WG Critical Care has ampicillin sulbactam 1.5 gram and 3 gram vials on back order and the company estimates a release date in mid- to late-September 2019. The 15 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=159>

## Valsartan Tablets

**August 16, 2019**

### Reason for the Shortage

- Several drug products containing valsartan were recalled due to an unexpected impurity found in the active pharmaceutical ingredient manufactured by a third party. The impurity is N-nitrosodimethylamine (NDMA) and is classified as a probable human carcinogen. Additional information is available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm>.
- Camber, Major, Solco, and Teva valsartan tablets were affected by the recall. Detailed information on the products is available at <https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615703.pdf>.
- Major, Solco, and Teva discontinued valsartan tablets in July 2018.
- Alembic, Aurobindo, Cadista, Macleod's, and Novartis are not affected by this recall.
- Aurobindo, Macleod's, and Mylan refuse to provide updated availability information.
- Cadista did not provide a reason for the shortage.
- Lupin is not actively marketing valsartan tablets.
- Repackagers may have some presentations affected depending on the source supplier.

### Estimated Resupply Dates

- Camber has valsartan tablets on back order and the company cannot estimate a release date.
- Cadista has all valsartan tablets on back order and the company estimates a release date in mid-September 2019

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

## Valsartan and Hydrochlorothiazide Tablets

**August 16, 2019**

### Reason for the Shortage

- Several drug products containing valsartan were recalled due to an unexpected impurity found in the active pharmaceutical ingredient manufactured by a third party. The impurity is N-nitrosodimethylamine (NDMA) and is classified as a probable human carcinogen. Additional information is available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm>.
- Solco and Teva valsartan/hydrochlorothiazide tablets were affected by the recall. Detailed information on the products is available at <https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615703.pdf>.
- Solco and Teva discontinued valsartan/hydrochlorothiazide tablets in July 2018.
- Alembic, Aurobindo, Lupin, Mylan, MacLeod's, and Novartis are not affected by this recall.
- Aurobindo refused to provide updated availability information.

- Lupin did not provide a reason for the shortage.
- MacLeod's refuses to provide updated availability information.
- Mylan refuses to provide updated availability information.
- Repackagers may have some presentations affected depending on the source supplier.

#### Estimated Resupply Dates

- Lupin has all valsartan/hydrochlorothiazide presentations on allocation

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

### Scopolamine Transdermal System

**August 16, 2019**

#### Reason for the Shortage

- Baxter has scopolamine patches available.
- GlaxoSmithKline states the shortage was due to increased demand.
- Perrigo has temporarily discontinued scopolamine patches.

#### Estimated Resupply Dates

- Perrigo has temporarily discontinued scopolamine patches and the company cannot estimate a date of manufacturing resumption.

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

### Lorazepam Tablets

**August 16, 2019**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Major has lorazepam 0.5 mg and 1 mg tablets in 100 count bottles on back order and the company estimates a release date of late-July 2019. The 1 mg tablets in 100 count unit-dose packages are on back order and the company estimates a release date of mid-August 2019.
- Leading has all lorazepam tablet presentations on intermittent back order and they are releasing product as it becomes available.
- Teva has all lorazepam tablet presentations on back order and the company estimates release dates of late-August 2019

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

### Levetiracetam Injection

**August 16, 2019**

#### Reason for the Shortage

- American Regent did not provide a reason for the shortage.
- Athenex did not provide a reason for the shortage.

- AuroMedics did not provide a reason for the shortage.
- Fresenius Kabi has product available.
- Mylan refuses to provide updated availability information.
- Pfizer did not provide a reason for the shortage.
- 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

- Athenex has levetiracetam 10 mg/mL 100 mL premixed bags on allocation. The 15 mg/mL 100 mL premixed bags are on back order and the company estimates a release date of late-August 2019.
- 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.
- Hikma has levetiracetam 100 mg/mL 5 mL vials on back order and the company estimates a release date in early- to mid-September 2019.
- Pfizer has levetiracetam 100 mg/mL 5 mL vials in limited supply.
- 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>

### Latanoprost Ophthalmic Solution

**August 16, 2019**

#### Reason for the Shortage

- Akorn has discontinued latanoprost ophthalmic solution.
- Bausch Health has latanoprost ophthalmic solution available.
- Greenstone did not provide a reason for the shortage.
- Rising did not provide a reason for the shortage.
- Sandoz (Falcon) has latanoprost ophthalmic solution available.

#### Estimated Resupply Dates

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

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

### Hydroxyethyl Starch in Sodium Chloride Injection

**August 16, 2019**

#### Reason for the Shortage

- BBraun did not provide a reason for the Hespan shortage.
- Pfizer has 6% hetastarch in 0.9% sodium chloride injection available.
- Pfizer has Voluven on back order. They did not provide a reason

#### Estimated Resupply Dates

- BBraun has Hespan on back order and the company cannot estimate a release date.
- Pfizer has Voluven on back order and the company estimates a release date of August 2020.

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

### Ceftazidime Injection

**August 16, 2019**

Reason for the Shortage

- Pfizer has Tazicef available.
- Sagent has ceftazidime injection on shortage due to increased demand and manufacturing delays.
- BBraun had ceftazidime on allocation due to increased demand.
- Teligent discontinued Fortaz 2 gram vials, 6 gram vials, and both 1 gram/50 mL and 2 gram/50 mL premixes in February 2018. They also discontinued the 1 gram and 2 gram Twistvials in April 2019. The Fortaz 500 mg and 1 gram vials are on back order due to manufacturing delays.
- WG Critical Care has ceftazidime available.

Estimated Resupply Dates

- Pfizer has a limited supply of short-dated Tazicef 1 gram and 2 gram vials available and the company estimates next release dates of August 2019. The 6 gram fliptop vials are available in limited supply with a short expiration dating (December 2019).
- Sagent has ceftazidime 2 gram and 6 gram vials on allocation. The 1 gram vials are available with short expiration dating (December 2019).
- Teligent has Fortaz 500 mg vials and 1 gram vials on back order and the company cannot estimate a release date.

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

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

**August 16, 2019**

Reason for the Shortage

- Baxter has 5% dextrose PVC/DEHP-free Viaflo bags available.
- BBraun had 5% dextrose PVC/DEHP-free bags on shortage due to manufacturing delays.
- BD has 5% dextrose PVC/DEHP-free bags available.
- Fresenius Kabi has 5% dextrose PVC/DEHP-free bags available.
- ICU Medical has 5% dextrose PVC/DEHP-free bags on shortage due to manufacturing delays.

Estimated Resupply Dates

- ICU Medical has 5% dextrose PVC/DEHP-free 50 mL bags available to contracted customers.

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

### Protamine Sulfate Injection

**August 19, 2019**

Reason for the Shortage

- Fresenius Kabi has protamine on shortage due to increased demand

Estimated Resupply Dates

- Fresenius Kabi has protamine 10 mg/mL in 25 mL vials on back order and the company estimates a release date in late-August 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=586>

## Prednisone Oral Tablets

**August 19, 2019**

Reason for the Shortage

- Cadista, Hikma, Par, and Teva did not provide a reason for the shortage.

Estimated Resupply Dates

- Hikma has most prednisone tablet presentations on allocation. The 2.5 mg tablets in 100 count unit dose packages are on back order and the company estimates a release date in early-September 2019.
- Teva has most prednisone tablet presentations 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=563>

## Pentamidine Isethionate

**August 19, 2019**

Reason for the Shortage

- Fresenius Kabi is the only supplier of pentamidine isethionate and has Nebupent and Pentam 300 on back order due to a short-term manufacturer delay.
- Seton Pharmaceuticals has pentamidine isethionate injection on shortage due to high demand.

Estimated Resupply Dates

- Fresenius Kabi has Pentam 300 and Nebupent vials on back order and the company estimates a release date of late-August 2019.
- Seton Pharmaceuticals has pentamidine isethionate 300 mg vials for injection on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=584>

## Nystatin Oral Suspension

**August 19, 2019**

Reason for the Shortage

- Akorn discontinued nystatin suspension in 2019.
- Pharmaceutical Associates, Inc. did not provide a reason for the shortage.
- Precision Dose has nystatin suspension available.
- Vista Pharma has nystatin suspension available.
- Wockhardt USA did not provide a reason for the shortage.

Estimated Resupply Dates

- Pharmaceutical Associates, Inc. has nystatin 100,000 units/mL suspension 60 mL bottles on intermittent back order and the company is allocating supplies as they become available.
- Wockhardt USA has nystatin 100,000 units/mL suspension 60 mL bottles on allocation. The 473 mL bottles are on back order and the company estimates a release date of late-September 2019

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

## Morphine Injection

**August 19, 2019**

Reason for the Shortage

- Fresenius Kabi procured morphine syringes from BD in 2016. They discontinued the 8 mg/mL and 10 mg/mL 1 mL syringes in early-2018

- Astramorph injection has been unavailable since 2012. Fresenius Kabi changed manufacturing sites and cannot estimate if Astramorph will return
- Pfizer has a shortage of several prefilled syringe products, including morphine, starting in late-July 2017 due to issues at a manufacturing facility. To minimize the impact of the shortage, Pfizer is prioritizing production of certain morphine Carpuject syringes
- Hikma did not provide a reason for the shortage
- Piramal Critical Care has Mitigo 10 mg/mL 20 mL and 25 mg/mL 20 mL vials available

#### Estimated Resupply Dates

- Fresenius Kabi has morphine 4 mg/mL 1 mL syringes on back order and the company estimates a release date of late-August 2019. The 5 mg/mL 1 mL syringes are on back order and the company estimates a release date of early- to mid-October 2019. The 5 mg/mL 1 mL vials are on back order and the company estimates a release date of mid- to late-August 2019. The 8 mg/mL 1 mL vials are on back order and the company estimates a release date of mid- to late-August 2019. Check wholesalers for inventory
- Hikma has morphine 10 mg/mL 1 mL vials on back order and the company estimates a release date of late-August 2019
- Pfizer has morphine 1 mg/mL 10 mL preservative-free vials on back order and the company estimates a release date of September 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 August 2020. The 8 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of December 2019. The 10 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of December 2019. The 25 mg/mL 1 mL preservative-free vials are 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=41>

### **Methotrexate Injection**

**August 19, 2019**

#### Reason for the Shortage

- Accord has methotrexate injection on back order due to increased demand
- Fresenius Kabi did not provide a reason for the shortage
- Mylan Institutional refuses to provide product availability
- Pfizer has methotrexate injection available
- Teva did not provide a reason for the shortage
- Hikma has methotrexate injection available

#### Estimated Resupply Dates

- Fresenius Kabi has methotrexate 1 gram vials of lyophilized powder for solution on back order and the company estimates a release date in late-August 2019
- Teva has methotrexate 25 mg/mL 40 mL preservative-free vials on allocation. Check availability with wholesalers

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



## Levetiracetam Immediate-Release Tablets

**August 19, 2019**

### Reason for the Shortage

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

### Estimated Resupply Dates

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

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=533>

## Leucovorin Calcium Injection

**August 19, 2019**

### Reason for the Shortage

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

### Estimated Resupply Dates

- Fresenius Kabi has leucovorin 200 mg and 500 mg vials on back order and the company estimates a release date of mid- to late-August 2019. Leucovorin 10 mg/mL 10 mL vials are on back order and the company estimates a release date of 4th quarter 2019.
- Hikma has leucovorin 50 mg vials are on back order and the company estimates a release date of late-August 2019. The 200 mg vials are on back order and the company estimates a release date of mid-August 2019. The 100 mg and 350 mg vials are on allocation.
- Sagent has leucovorin 50 mg, 100 mg, 200 mg, 350 mg, and 500 mg vials on allocation

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

## Irbesartan Tablets

**August 19, 2019**

### Reason for the Shortage

- Beginning in mid-2018, FDA found that several angiotensin II receptor blocker (ARB) medicines contained nitrosamine impurities and have been recalled because they do not meet FDA's safety



standards. Additional information including a list of affected lots can be found at <https://www.fda.gov/drugs/drug-safety-and-availability/recalls-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan>.

- Solco and ScieGen were affected by the recall.
- Camber, Lupin, and Westminster did not provide a reason for the shortage.
- Hikma is not actively marketing irbesartan tablets.
- MacLeod's has irbesartan tablets available to contracted customers only.
- Sanofi-Aventis has Avapro tablets available.
- Repackagers may have some presentations affected depending on the source supplier.

#### Estimated Resupply Dates

- Camber has irbesartan tablets on allocation.
- Lupin has irbesartan tablets on back order and the company cannot estimate a release date.
- Solco has irbesartan tablets on long-term back order and the company cannot estimate a release date.
- Westminster has irbesartan 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=580>

### Gentamicin Sulfate Ophthalmic Ointment

**August 19, 2019**

#### Reason for the Shortage

- Akorn has Gentak ophthalmic ointment on shortage due to manufacturing delays.

Gentamicin ophthalmic solutions are not affected by this shortage

#### Estimated Resupply Dates

- Akorn has Gentak 3.5 gram tubes on back order and the company cannot estimate a release date

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

### Docosate Sodium Oral Liquid in Bulk Bottles

**August 19, 2019**

#### Reason for the Shortage

- Akorn has Docu Liquid on shortage because they are waiting on raw ingredients.
- Geri-Care had a contract manufacturer shut down and they have discontinued the Diocto syrup. The company will be manufacturing Diocto liquid, but don't expect product will be available for at least 4 months.
- Lannett did not provide a reason for the shortage.
- Docosate sodium 10 mL unit dose cups are not affected.

#### Estimated Resupply Dates

- Akorn has Docu Liquid in 473 mL bottles on back order and the company cannot estimate a release date.
- Geri-Care has Diocto liquid in 473 mL bottles on back order and the company estimates a release date in late-2019 to early-2020.
- Lannett has Silace liquid and syrup in 473 mL bottles on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=585>

## Diazepam Injection

**August 19, 2019**

Reason for the Shortage

- Pfizer has diazepam on shortage due manufacturing delays.
- DASH Pharmaceuticals launched diazepam injection in early-April 2019

Estimated Resupply Dates

- Pfizer has diazepam 5 mg/mL 2 mL Carpuject syringes and 10 mL vials available

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

## Clindamycin Phosphate Injection

**August 19, 2019**

Reason for the Shortage

- Alvogen did not provide a reason for the shortage.
- Akorn did not provide a reason for the shortage.
- Baxter has clindamycin injection available.
- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer did not provide a reason for the shortages. Pfizer discontinued Cleocin premixed bags in 2018.
- Sagent has clindamycin injection available.
- Sandoz did not provide a reason for the shortage

Estimated Resupply Dates

- Akorn has clindamycin 600 mg/50 mL and 900 mg/50 mL in dextrose premixes on back order and the company cannot estimate a release date.
- Alvogen has clindamycin 150 mg/mL 2 mL, 4 mL, and 6 mL ADD-Vantage vials on long term back order and the company cannot estimate a release date. Clindamycin 150 mg/mL 2 mL, 4 mL, and 6 mL vials are short-dated with expiration dates of May 2020 for the 2 mL vials, April 2020 for the 4 mL vials, and February 2020 for the 6 mL vials. Clindamycin 150 mg/mL 60 mL vials are on back order and the company cannot estimate a release date.
- Fresenius Kabi has short-dated clindamycin 150 mg/mL 2 mL, 4 mL, 6 mL, and 60 mL vials available with an expiration date of <3 months for the 2 mL vials, <5 months for the 4 mL vials, <2 months for the 6 mL vials, and <5 months for the 60 mL vials.
- Pfizer has Cleocin 150 mg/mL 2 mL, 4 mL, and 6 mL ADD-Vantage vials on back order and the company estimates a release date of June 2020.
- Sagent has short-dated clindamycin 150 mg/mL 2 mL vials with an expiration date of November 2019. The 150 mg/mL 4 mL vials are short-dated with an expiration date of February 2020. Clindamycin 150 mg/mL 60 mL vials are on back order and the company estimates a release date in August 2019.

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

## Cefuroxime Sodium Injection

**August 19, 2019**

Reason for the Shortage

- Sagent had cefuroxime injection on shortage due to manufacturing delays and increased demand.
- 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 allocation

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

## Cefazolin Injection

**August 19, 2019**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Baxter has cefazolin 2 gram/100 mL premixed bags on allocation.
- BBraun has 1 gram/50 mL and 2 gram/50 mL premixed bags on allocation.
- Fresenius Kabi has cefazolin 10 gram vials on back order and the company estimates a release date of 4th quarter 2019.
- Hikma has cefazolin 10 gram vials on back order and the company estimates a release date in late-August 2019.
- Pfizer has 1 gram vials and 10 gram vials on back order and the company estimates a release date of March 2021.
- Sagent has cefazolin 10 gram vials on intermittent back order and the company will release product on a monthly basis. The 500 mg and 1 gram vials are on allocation.
- WG Critical Care has cefazolin 500 mg vials on back order and the company cannot estimate a release date. The 10 gram vials are on allocation.

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

## Bupivacaine with Epinephrine Injection

**August 19, 2019**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 10 mL vials on back order and the company estimates a release date of late-August 2019. The 0.25% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of early- to mid-September 2019. The 0.5% Sensorcaine-MPF with epinephrine 10 mL vials are on back order and the company estimates a release date of late-September to early-October 2019. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of mid- to late-August 2019. The 0.5% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of early-September 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 preservative-free vials on back order and the company estimates a release date of February 2020. The 0.25% bupivacaine with epinephrine 30 mL preservative-free vials are on back order and the company estimates a release date of December 2019. The 0.25% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of December 2019. The 0.5% bupivacaine with epinephrine 10 mL preservative-free vials are on back order and the company estimates a release date of March 2020. The 0.5% bupivacaine with epinephrine 30 mL preservative-free vials are on back order and the company estimates a release date of December 2019. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of March 2020.
- Pfizer has 0.25% Marcaine with epinephrine 10 mL preservative-free vials on back order and the company estimates a release date of October 2019. The 0.25% Marcaine with epinephrine 30 mL preservative-free vials are on back order and the company estimates a release date of August 2019. 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 preservative-free vials are on back order and the company estimates a release date of January 2020. The 0.5% Marcaine with epinephrine 30 mL preservative-free vials are on back order and the company estimates a release date of June 2021. 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>

## **Benzotropine Mesylate Injection**

**August 19, 2019**

Reason for the Shortage

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

Estimated Resupply Dates

- Akorn has benzotropine 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.

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

## Amino Acid Products

**August 19, 2019**

### Reason for the Shortage

- Baxter did not provide a reason for the shortage. Baxter discontinued Premasol 6% in late-2018.
- BBraun did not provide a reason for the shortage.
- ICU Medical has Aminosyn presentations available. ICU Medical discontinued several Aminosyn products in September 2018.

### Estimated Resupply Dates

- BBraun has Trophamine 10% 500 mL and HepatAmine 8% 500 mL in glass containers on intermittent back order and the company is releasing supplies as they become available.
- Baxter has all Premasol, Travasol, Prosol, and Clinisol solutions on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=564>

## Sodium Acetate Injection

**August 19, 2019**

### Reason for the Shortage

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

### Estimated Resupply Dates

- Fresenius Kabi has sodium acetate 4 mEq/mL 100 mL vials on back order and the company estimates a release date of early- to mid-September 2019.
- Pfizer has sodium acetate 2 mEq/mL 20 mL vials available in limited supply. The 100 mL vials are on back order and the company estimates a release date of August 2019. The 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=317>

## Lidocaine with Epinephrine Injection

**August 19, 2019**

### Reason for the Shortage

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

### Estimated Resupply Dates

- Fresenius Kabi has 1% Xylocaine with epinephrine (1:200,000) 10 mL vials on back order and the company estimates release dates of late-August 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-August 2019. The 1% Xylocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates release dates of mid- to late-August 2019. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials are on back order and the company estimates release dates of early- to mid-September 2019. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company cannot estimate a release date. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company cannot estimate a release date. The 2% Xylocaine with epinephrine (1:200,000) 20 mL vials are on back order and the company estimates a release date of mid- to late-August 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 0.5% lidocaine with epinephrine (1:100,000) 20 mL vials on back order and the company estimates a release date of September 2019. The 1% lidocaine with epinephrine (1:100,000) 20 mL vials are on back order and the company estimates a release date of September 2019. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are on back order and the company estimates a release date of August 2019. The 1% lidocaine with epinephrine (1:100,000) 50 mL vials are on back order and the company estimates a release date of August 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 August 2019. The 2% lidocaine with epinephrine (1:100,000) 20 mL vials are on back order and the company estimates a release date of September 2019. The 2% lidocaine with epinephrine (1:100,000) 50 mL vials are on back order and the company estimates a release date of September 2019. The 2% lidocaine with epinephrine (1:200,000) 20 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=98>

## Heparin Injection

### August 19

#### Reason for the Shortage

- Fresenius Kabi has put heparin on a protective allocation due to a potential shortage of raw ingredient. The letter describing this in detail is available at the following link:  
<https://www.fresenius-kabi.com/us/news/fresenius-kabi-responds-to-a-potential-shortage-of-heparin>.
- Hikma did not provide a reason for the shortage.
- Mylan refuses to provide updated availability information.
- Pfizer has heparin on shortage due to manufacturing delays.
- Sagent has heparin on shortage due to manufacturing issues and increased demand

#### Estimated Resupply Dates

- Fresenius Kabi has heparin 5,000 unit/mL 10 mL vials on back order and the company estimates a release date of early-September 2019. The 10,000 unit/mL 4 mL vials are on back order and the company cannot estimate a release date. All other presentations are on allocation.
- Hikma has 1,000 unit/mL 2 mL vials, 5,000 unit/mL 2 mL vials, and 10,000 unit/mL 2 mL vials on allocation.
- Pfizer has 5,000 unit/mL 1 mL Carpuject syringes on back order and the company estimates a release date of August 2019. The 5,000 unit/mL 1 mL glass vials are on back order and the company estimates a release date of December 2019. The 5,000 unit/mL 10 mL vials are on back order and the company estimates a release date of December 2019. The 1,000 unit/mL 10 mL glass vials are on back order and the company estimates a release date of December 2019. The 1,000 unit/mL 30 mL vials are on back order and the company estimates a release date of August 2019. The 10,000 unit/mL 0.5 mL Carpuject syringes and 1 mL glass vials are available in limited supply. The 1,000 unit/mL 10 mL vials (NDC 00069-0058-01) are on back order and the company estimates a release date of September 2019.
- Sagent has 1,000 unit/mL 2 mL and 10 mL vials on back order and the company estimates a release date of August 2019. The 1,000 unit/mL 1 mL and 30 mL vials are on back order and the company



estimates a release date of September 2019. The 5,000 unit/mL 1 mL and 10 mL vials are on back order and the company estimates a release date of August 2019. The 10,000 unit/mL 1 mL and 4 mL vials are on back order and the company estimates a release date of August 2019. There are short-dated 20,000 unit/mL 1 mL vials available with an expiration date

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

## Hydralazine injection

**August 19, 2019**

Reason for the Shortage

- Akorn had 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

- X-Gen has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of late-August 2019

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

## Acetylcysteine Oral and Inhalation Solution

**August 19, 2019**

Reason for the Shortage

- American Regent has acetylcysteine oral and inhalation solution on shortage due to manufacturing delays.
- Arbor discontinued Cetylev effervescent tablets in April 2019.
- Fresenius Kabi has acetylcysteine oral and inhalation solution available.
- Pfizer has acetylcysteine oral and inhalation solution available.
- Roxane Labs discontinued acetylcysteine oral and inhalation solution in April 2014

Estimated Resupply Dates

- American Regent has acetylcysteine solution 200 mg/mL 30 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has short-dated acetylcysteine 100 mg/mL 10 mL vials available with an expiration date of <9 months.

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

## Acetazolamide Injection

**August 19, 2019**

Reason for the Shortage

- Hikma did not provide a reason for the shortage.
- Mylan Institutional refuses to provide availability information.
- X-Gen had acetazolamide on shortage due to manufacturing delays

Estimated Resupply Dates

- Hikma has acetazolamide 500 mg vials on allocation

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

## Dexmedetomidine Hydrochloride 100 mcg/mL Vials for Injection

August 20, 2019

### Reason for the Shortage

- Accord has dexmedetomidine vials available.
- Akorn is no longer manufacturing dexmedetomidine vials.
- Athenex has dexmedetomidine vials available.
- AuroMedics has dexmedetomidine vials available.
- Fresenius Kabi did not provide a reason for the shortage.
- Hikma did not provide a reason for the shortage.
- Mylan refused to provide availability information.
- Par has dexmedetomidine vials available.
- Pfizer has dexmedetomidine vials available.
- Sandoz has dexmedetomidine vials available.
- Sun Pharma is no longer manufacturing dexmedetomidine.
- Teva discontinued dexmedetomidine vials in July 2019.
- WG Critical Care has dexmedetomidine vials on back order due to manufacturing delays.

### Estimated Resupply Dates

- Hikma has dexmedetomidine 100 mcg/mL 2 mL vials on back order and the company estimates a release date of early-November 2019

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

## Tuberculin

August 20, 2019

### Reason for the Shortage

- Par did not provide a reason for the supply interruption of Aplisol.
- Sanofi Pasteur has Tubersol available

### Estimated Resupply Dates

- Sanofi Pasteur has Tubersol 1 mL and 5 mL vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=573>

## Orphenadrine Citrate Injection

August 20, 2019

### Reason for the Shortage

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

### Estimated Resupply Dates

- Hikma has orphenadrine 30 mg/mL 2 mL vials on allocation

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

## Lorazepam Injection

August 20, 2019

### Reason for the Shortage

- Bedford discontinued lorazepam injection in May, 2011
- Hikma has product on shortage due to manufacturing delays



- Pfizer has product on shortage due to increased demand and manufacturing delays. Pfizer discontinued 4 mg/mL 10 mL vials in December 2017
- Akorn has not provided a reason for the shortage
- Amphastar has product available

#### Estimated Resupply Dates

- Pfizer has lorazepam 4 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of January 2020

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

## Dexmedetomidine Hydrochloride 100 mcg/mL Vials for Injection

**August 20, 2019**

#### Reason for the Shortage

- Accord has dexmedetomidine vials available.
- Akorn is no longer manufacturing dexmedetomidine vials.
- Athenex has dexmedetomidine vials available.
- AuroMedics has dexmedetomidine vials available.
- Fresenius Kabi did not provide a reason for the shortage.
- Hikma did not provide a reason for the shortage.
- Mylan refused to provide availability information.
- Par has dexmedetomidine vials available.
- Pfizer has dexmedetomidine vials available.
- Sandoz has dexmedetomidine vials available.
- Sun Pharma is no longer manufacturing dexmedetomidine.
- Teva discontinued dexmedetomidine vials in July 2019.
- WG Critical Care has dexmedetomidine vials on back order due to manufacturing delays.

#### Estimated Resupply Dates

- Hikma has dexmedetomidine 100 mcg/mL 2 mL vials on back order and the company estimates a release date of early-November 2019.

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

## Cosyntropin Injection

**August 20, 2019**

#### Reason for the Shortage

- Amphastar has Cortrosyn on shortage due to increased demand.
- Mylan Institutional refuses to provide availability information.
- Sandoz did not provide a reason for the shortage

#### Estimated Resupply Dates

- Amphastar and Sandoz have cosyntropin available

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=522>