PERFORMRx℠

Drug Information Update

July 2019

TABLE OF CONTENTS

NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
HYDROCODONE/ ACETAMINOPHEN	2.5 MG - 108 MG/5 ML, 5 MG - 217 MG/10 ML ORAL SOLUTION	PHARMACEUTICAL, VISTAPHARM	HYDROCODONE-ACETAMINOPHEN
DOXYLAMINE SUCCINATE/ PYRIDOXINE (VIT B6)	10 MG-10 MG TABLET	ACTAVIS/TEVA, ANALOG PHARMA	DICLEGIS
FEBUXOSTAT	40 MG, 80 MG TABLET	MYLAN, ALEMBIC PHARMACEUTICALS	ULORIC
OXYMORPHONE HCL	5 MG, 7.5 MG, 10 MG, 15 MG, 20 MG, 30 MG, 40 MG TABLET ER 12H	AMNEAL PHARMACEUTICALS,	OXYMORPHONE HCL ER
RABEPRAZOLE SODIUM	10 MG CAPSULE DR SPRINKLE	SARRAS HEALTH	ACIPHEX SPRINKLE
ORPHENADRINE/ ASPIRIN/CAFFEINE	50 MG-770 MG-60 MG TABLET	GALT PHARMACEUTICALS	NORGESIC FORTE
ICATIBANT ACETATE	30 MG/3 ML SYRINGE	TEVA	FIRAZYR
SELENIUM	60 MCG/ML VIAL	AMER. REGENT	SELENIOUS ACID

PERFORMRx℠

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
CYSTIC FIBROSIS-CFTR POTENTIATOR-CORRECTOR COMBIN.	SYMDEKO	TEZACAFTOR/ IVACAFTOR	50 MG-75MG TABLET	NEW STRENGTH
CHOLINESTERASE INHIBITORS	PYRIDOSTIGMINE BROMIDE	PYRIDOSTIGMINE BROMIDE	30 MG TABLET	NEW STRENGTH
ANTIHYPERLIPIDEMIC-HMGCOA REDUCTASE INHIB(STATINS)	EZALLOR SPRINKLE	ROSUVASTATIN CALCIUM	5, 10, 20, 40 MG CAPSULE SPRINKLE	NEW DOSAGE FORM
EYE ANTIBIOTIC, GLUCOCORTICOID AND NSAID COMB.	PREDNISOLONE AC-MOXIFLOX-NEPAF	PREDNISOLONE/ MOXIFLO/NEPAFENAC	1-0.5-0.1% OPHTHALMIC SUSPENSION	NEW COMBINATION
EYE ANTIBIOTIC AND GLUCOCORTICOID COMBINATIONS	PREDNISOLONE ACET-MOXIFLOXACIN	PREDNISOLONE/ MOXIFLOXACIN HCL	1 %-0.5 % OPHTHALMIC SUSPENSION	NEW COMBINATION
EYE ANTIBIOTIC, GLUCOCORTICOID AND NSAID COMB.	PREDNISOLONE AC-MOXIFLOX-BROMF	PREDNISOLONE/ MOXIFLOX/BROMFEN	1 %-0.5 % OPHTHALMIC SUSPENSION	NEW COMBINATION
EYE ANTIBIOTIC AND GLUCOCORTICOID COMBINATIONS	PREDNISOLONE PHOS-MOXIFLOXACIN	PREDNISOLONE SOD PH/MOXIFLOX	1 %-0.5 % OPHTHALMIC SUSPENSION	NEW COMBINATION
FLUORIDE PREPARATIONS	FLUORIDEX SENSITIVITY RELIEF	SODIUM FLUORIDE/ POTASSIUM NIT	1.1 %-5 % PASTE	NEW DOSAGE FORM
NARCOLEPSY AND SLEEP DISORDER THERAPY AGENTS	SUNOSI	SOLRIAMFETOL HCL	75 MG, 150 MG TABLET	NEW ENTITY
ADRENERGICS, AROMATIC, NON-CATECHOLAMINE	EVEKEO ODT	AMPHETAMINE SULFATE	5 MG, 10 MG, 15 MG, 20 MG TABLETS RAPID DISINTEGRATING	NEW DOSAGE FORM
NSAID AND TOPICAL IRRITANT COUNTER-IRRITANT COMB.	INFLATHERM	DICLOFENAC SOD/ TROLAMINE SALIC	75 MG-10 % KIT CRTBDR	NEW COMBINATION
OXYTOCICS	CARBOPROST TROMETHAMINE	CARBOPROST TROMETHAMINE	250 MCG/ML VIAL	NEW GENERIC
CONTRACEPTIVES, ORAL	SLYND	DROSPIRENONE	4 MG (28) TABLET	NEW ENTITY

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANAPHYLAXIS THERAPY AGENTS	SYMJEPI	EPINEPHRINE	0.15 MG/0.3 mL SYRINGE	NEW STRENGTH
KIDNEY STONE AGENTS	THIOLA EC	TIOPRONIN	100 MG, 300 MG TABLET DR	NEW DOSAGE FORM/ STRENGTH
ANTINEOPLASTIC-SELECT INHIB OF NUCLEAR EXP (SINE)	XPOVIO	SELINEXOR	60 MG, 80 MG, 100 MG, 160 MG TABLET PER WEEK	NEW ENTITY
INFLUENZA VIRUS VACCINES	AFLURIA QUAD 2019-20 (6-35MO)	FLU VACC QS 2019 (6-35MOS)/PF	30 MCG/0.25 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUZONE QUAD PEDI 2019-2020	FLU VACC QS 2019 (6-35MOS)/PF	30 MCG/0.25 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	AFLURIA QUAD 2019-20 (3YR UP)	FLU VACC QS2019-20 36MOS UP/PF	60 MCG/0.5 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUARIX QUAD 2019-2020	FLU VACC QS2019-20(6MOS UP)/PF	60 MCG/0.5 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLULAVAL QUAD 2019-2020	FLU VACC QS2019-20(6MOS UP)/PF	60 MCG/0.5 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUZONE QUAD 2019-2020	FLU VACC QS2019-20(6MOS UP)/PF	60 MCG/0.5 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUAD 2019-2020	FLU VACC TS2019(65UP)/MF59C/ PF	45 MCG/0.5 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	AFLURIA QUAD 2019-2020	FLU VACC QUAD 2019-20(6MOS UP)	60 MCG/0.5 ML VIAL	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLULAVAL QUAD 2019-2020	FLU VACC QUAD 2019-20(6MOS UP)	60 MCG/0.5 ML VIAL	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUZONE QUAD 2019-2020	FLU VACC QUAD 2019-20(6MOS UP)	60 MCG/0.5 ML VIAL	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUBLOK QUAD 2019-2020	FLU VAC QV 2019(18YR UP)RCM/PF	180 MCG/0.5 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUZONE HIGH-DOSE 2019-2020	FLU VACC TS2019-20(65YR UP)/PF	180 MCG/0.5 ML SYRINGE	NEW ENTITY

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
INFLUENZA VIRUS VACCINES	FLUZONE QUAD 2019-2020	FLU VACC QS2019-20(6MOS UP)/PF	60 MCG/0.5 ML VIAL	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUCELVAX QUAD 2019-2020	FLU VAC QS 19-20 (4YR UP) CELL	60 MCG/0.5 ML VIAL	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUCELVAX QUAD 2019-2020	FLU VAC QS 19-20(4YR UP)CEL/PF	60 MCG/0.5 ML SYRINGE	NEW ENTITY
ANTIHISTAMINES - 1ST GENERATION	RYCLORA	DEXCHLORPHENIR-AMINE MALEATE	2 MG/5 ML ORAL SOLUTION	GCN CHANGE
MYDRIATICS	ATROPINE SULFATE	ATROPINE SULFATE	0.01 % DROPS EMULSION	NEW DOSAGE FORM/ STRENGTH
CONTRACEPTIVES, INTRAVAGINAL, SYSTEMIC	ANNOVERA	SEGESTERONE AC/ETHIN ESTRADIOL	0.15-0.013 MG VAGINAL RING	NEW ENTITY
OPHTHALMIC ANTIBIOTICS	MOXIFLOXACIN	MOXIFLOXACIN IN NACL,ISO-OS/PF	1 MG/ML INTRAOCCULAR	NEW STRENGTH
INFLUENZA VIRUS VACCINES	FLUMIST QUAD 2019-2020	FLU VACC QV LIVE 2019 (2-49YRS)	10E6.5-7.5 NASAL SPRAY	NEW ENTITY

NEW INDICATIONS (EXISTING DRUGS)

SYMDEKO®

June 21, 2019

BOSTON--(BUSINESS WIRE)--Jun. 21, 2019-- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced the U.S. Food and Drug Administration (FDA) approved SYMDEKO® (tezacaftor/ivacaftor and ivacaftor) for use in children with cystic fibrosis ages 6 through 11 years who have two copies of the F508del-CFTR mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to SYMDEKO. It was previously approved by the FDA for use in patients with cystic fibrosis 12 years and older with two copies of the F508del mutation or one copy of a responsive mutation in the U.S. An additional dosage strength of SYMDEKO tablets is now available (tezacaftor 50 mg/ivacaftor 75 mg and ivacaftor 75 mg) in connection with this approval.

Source: Vertex Pharmaceuticals Incorporated

BOTOX®

June 21, 2019

DUBLIN, June 21, 2019 /PRNewswire/ -- Allergan plc (NYSE: AGN) today announced that the U.S. Food and Drug Administration (FDA) approved the company's supplemental biologics application (sBLA) for BOTOX® for the treatment of pediatric patients (2 to 17 years of age) with upper limb spasticity. BOTOX® was granted a six-month Priority Review by the FDA, which is typically granted to therapies that if approved, could offer significant improvements in safety and effectiveness when compared to current standard of care. The FDA is also reviewing an additional sBLA for the use of BOTOX® to treat pediatric patients with lower limb spasticity, with a decision expected in the fourth quarter of this year.

Source: Allergan plc

DEXTENZA®

June 21, 2019

BEDFORD, Mass.--(BUSINESS WIRE)--Jun. 21, 2019--Ocular Therapeutix™, Inc. (NASDAQ: OCUL), a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye, today announced the U.S. Food and Drug Administration (FDA) approved a Supplemental New Drug Application (sNDA) for DEXTENZA to include the treatment of ocular inflammation following ophthalmic surgery as an additional indication. With the approval of the sNDA, DEXTENZA is now approved for the treatment of both ocular inflammation and pain following ophthalmic surgery.

Source: Ocular Therapeutix™, Inc.

VICTOZA®

June 17, 2019

PLAINSBORO, N.J., June 17, 2019 /PRNewswire/ -- Novo Nordisk today announced that the U.S. Food and Drug Administration (FDA) has approved an expanded indication for Victoza® (liraglutide) injection to lower blood sugar along with diet and exercise in children and adolescents aged 10-17 years with type 2 diabetes. As the first glucagon-like peptide-1 (GLP-1) receptor agonist approved for children and adolescents with type 2 diabetes, Victoza® provides this population with a new treatment option beyond metformin and insulin for the first time in 19 years. Victoza® was first approved in the U.S. in 2010 as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

Source: Novo Nordisk

KEYTRUDA®

June 18, 2019

KENILWORTH, N.J., June 18, 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 metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy. This accelerated approval is based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. This marks the first indication for KEYTRUDA in SCLC.

Source: Merck

SOLIRIS®

June 27, 2019

BOSTON--(BUSINESS WIRE)--Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) today announced that the U.S. Food and Drug Administration (FDA) approved SOLIRIS® (eculizumab) for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. Approximately three quarters (73%) of all patients with NMOSD test positive for anti-AQP4 auto-antibodies. The FDA approved SOLIRIS following an expedited six-month priority review. NMOSD is a rare, severe autoimmune disease that attacks the central nervous system without warning. These attacks, also referred to as relapses, can cause progressive and irreversible damage to the brain, optic nerve and spinal cord, which may lead to long-term disability. Complement activation due to anti-AQP4 antibodies is one of the primary underlying causes of the destruction in these patients. In the PREVENT trial, SOLIRIS, a first-in-class complement inhibitor, demonstrated safety and efficacy and met its primary endpoint of prolonging the time to first adjudicated relapse and reducing the risk of relapse.

Source: Alexion Pharmaceuticals, Inc

DOPTELET®

June 27, 2019

DURHAM, N.C., June 27, 2019 (GLOBE NEWSWIRE) -- Dova Pharmaceuticals, Inc. (NASDAQ: DOVA), a pharmaceutical company focused on acquiring, developing and commercializing drug candidates for diseases where there is a high unmet need, today announced the U.S. Food and Drug Administration (FDA) approved a supplemental New Drug Application (sNDA) that expands the use of DOPTELET (avatrombopag) to include the treatment of thrombocytopenia in adults with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

Source: Dova Pharmaceuticals, Inc.

DUPIXENT®

June 26, 2019

PARIS and TARRYTOWN, N.Y., June 26, 2019 /PRNewswire/ -- The U.S. Food and Drug Administration (FDA) has approved Dupixent® (dupilumab) for use with other medicines to treat chronic rhinosinusitis with nasal polyposis (CRSwNP) in adults whose disease is not controlled. CRSwNP can be a debilitating condition, with many patients opting for systemic steroids or nasal surgery which often cannot control this disease. Moreover, CRSwNP often occurs in combination with severe asthma.

Source: Sanofi

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

All Unexpired Sterile Drug Product Lots by Premier Pharmacy Labs: Recall- Due to Lack of Sterility Assurance

[Posted 06/18/2019]

ISSUE: Premier Pharmacy Labs is voluntarily recalling all unexpired products, intended to be sterile, due to a lack of sterility assurance. The Unexpired Sterile Drug Product Lots (include dates dispensed) are being recalled due to concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination and lack of product specific process validations. The nationwide recall includes lots of sterile drug products to the consumer/user level.
Administration of a drug product intended to be sterile that is not sterile could result in serious infections that may be life-threatening. To date, Premier Pharmacy Labs has not received any reports of adverse events related to the products but is issuing this recall out of an abundance of caution following a commitment made during a recent inspection of the company's facility.
The scope of this recall is all commercially distributed product lots compounded in the Weeki Wachee, FL location currently within their labeled expiration date in response to an FDA concerns raised during the most recent inspection carried out from 29 April, 2019 to 12 June, 2019.
Premier Pharmacy Labs is notifying customers of the voluntary recall by certified letter. Customers that have any of the affected medications that are being recalled should immediately quarantine the product, discontinue use and destroy per the hospital protocol. Customers with any of the affected medications can also reference Premier Pharmacy Labs Website at https://premierpharmacylabs.com/External Link Disclaimer for more information on the specific lot numbers affected and contact information.
Patients and healthcare providers with questions regarding this recall can contact Premier Pharmacy Labs at 1-800-752-7139, Monday through Friday, between 8:30am and 5pm, Central Standard Time or via e-mail at recalls@premierpharmacylabs.com.
Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to the use of these products.
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

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

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

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

MacLeod's Pharmaceutical Limited Issues Voluntary Nationwide Consumer Level Recall of Losartan Potassium 50mg and Losartan Potassium/Hydrochlorothiazide combination Tablets 50mg/12.5mg, 100mg/12.5mg, and 100mg/25mg due to detection of NMBA (N-Nitroso-N-Mtehyl-4-aminobutyric acid) Impurity.

[Posted 06/26/2019]

MacLeod's Pharmaceuticals Limited has initiated a voluntary recall in the United States, to the patient level, of 32 lots of Losartan Potassium USP Tablets (2 lots of 50mg strength) and Losartan

Potassium/Hydrochlorothiazide combination Tablets (12 lots of 50mg/12.5mg strength, 3 lots of 100mg/12.5mg strength and 15 100mg/25mg strength) to the patient level due to the detection of trace amounts of an unexpected impurity, N-Nitroso-N-methyl-4-aminobutyric acid (NMBA). The impurity was found in 32 lots of active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited that is above the US Food & Drug Administration's interim acceptable exposure limit of 9.82 ppm. Based on the available information, the risk of developing cancer in a few patients following long-term use of the product cannot be ruled out.

Losartan Potassium Tablets and Losartan Potassium/Hydrochlorothiazide combination Tablets are indicated to treat hypertension and hypertensive patients with Left Ventricular Hypertrophy. Patients who are on Losartan Potassium Tablets and Losartan Potassium/Hydrochlorothiazide combination Tablets, USP should continue taking their medication and contact their pharmacist, physician, or medical provider for advice regarding an alternative treatment, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment.

To date, MacLeod's Pharmaceuticals Limited has not received any reports of adverse events related to this recall.

The products subject to recall are listed below and packaged in bottles. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products.

Losartan Potassium Tablets 50 mg

NDC	Manufacturer	Product Description	Lot/Batch	Expiration Date
33342-045-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium Tablets USP 50mg 90ct	BLI711A	Nov-19
33342-045-44	MacLeod's Pharmaceuticals Limited	Losartan Potassium Tablets USP 50mg 1000ct	BLI710A	Nov-19

Losartan Potassium and Hydrochlorothiazide Tablets 50 mg/12.5 mg

NDC	Manufacturer	Product Description	Lot/Batch	Expiration Date
33342-050-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 50mg/12.5mg	BLK719A	Sep-19
33342-050-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 50mg/12.5mg	BLK720A	Sep-19
33342-050-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 50mg/12.5mg	BLK721A	Sep-19
33342-050-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 50mg/12.5mg	BLK722A	Sep-19
33342-050-10	MacLeod's Pharmaceuticals	Losartan Potassium and Hydrochlorothiazide	BLK723A	Sep-19

	Limited	Tablets 50mg/12.5mg		
33342-050-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 50mg/12.5mg	BLK724A	Sep-19
33342-050-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 50mg/12.5mg	BLK725A	Oct-19
33342-050-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 50mg/12.5mg	BLK726A	Oct-19
33342-050-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 50mg/12.5mg	BLK804A	Jan-20
33342-050-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 50mg/12.5mg	BLK806A	Jan-20
33342-050-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 50mg/12.5mg	BLK825A	Oct-21
33342-050-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 50mg/12.5mg	BLK826A	Oct-21

Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/12.5 mg

NDC	Manufacturer	Product Description	Lot/Batch	Expiration Date
33342-051-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/12.5mg	BLL801A	Dec-19
33342-051-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/12.5mg	BLL802A	Dec-19
33342-051-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/12.5mg	BLL803A	Dec-19

Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/25 mg

NDC	Manufacturer	Product Description	Lot/Batch	Expiration Date
33342-052-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/25mg	BLM716A	Jul-19
33342-052-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/25mg	BLM717A	Jul-19
33342-052-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/25mg	BLM719A	Aug-19
33342-052-10	MacLeod's	Losartan Potassium and	BLM720A	Aug-19

	Pharmaceuticals Limited	Hydrochlorothiazide Tablets 100mg/25mg		
33342-052-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/25mg	BLM21A	Sep-19
33342-052-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/25mg	BLM722A	Sep-19
33342-052-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/25mg	BLM723A	Oct-19
33342-052-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/25mg	BLM724A	Oct-19
33342-052-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/25mg	BLM725A	Oct-19
33342-052-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/25mg	BLM726A	Nov-19
33342-052-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/25mg	BLM802A	Dec-19
33342-052-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/25mg	BLM803A	Dec-19
33342-052-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/25mg	BLM825A	Sep-21
33342-052-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/25mg	BLM826A	Sep-21
33342-052-10	MacLeod's Pharmaceuticals Limited	Losartan Potassium and Hydrochlorothiazide Tablets 100mg/25mg	BLM827A	Sep-21

Losartan Potassium Tablets 50mg and Losartan Potassium/Hydrochlorothiazide combination Tablets 50mg/12.5mg, 100mg/25mg and 100mg/12.5mg were distributed nationwide to MacLeod's wholesale distributor and retail customers. MacLeod's Pharmaceuticals Limited is notifying its distributors and customers by phone and/or in writing to immediately discontinue distribution of the specific lot being recalled and to notify their sub-accounts. MacLeod's is arranging for return of all recalled products to Qualanex. Instructions for returning recalled products are given in the recall letter.

Consumers with medical questions regarding this recall or to report an adverse event can contact MacLeod's Pharmaceuticals Limited at 855-926-3384 (8:00 am - 5:00 pm EST).

If you have any general questions regarding the return of this product, please contact Qualanex via email at recall@qualanex.com or call 888-280-2046 (7:00 am to 4:00 pm CST Monday to Friday).

Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the

FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. Source: U.S. Food and Drug Administration (FDA)

Source: U.S. Food and Drug Administration

Fresenius Kabi Issues Voluntary Recall of Two Lots of Fluorouracil Injection Due to the Potential for Glass Particulate

[Posted 07/01/2019]

Fresenius Kabi USA, LLC is voluntarily recalling two lots of Fluorouracil Injection, USP 5 g/100 mL (50 mg/mL), 100 mL fill in 100 mL vials, to the user level due to the potential for glass particulate. The affected lots, distributed between December 6, 2018 and February 20, 2019, are listed below:

Product Name/ Size	NDC Number	Product Code	Lot Number	Expiration Date	First Ship Date	Last Ship Date
Fluorouracil Injection, USP, 5 g/100 mL (50 mg/mL), 100 mL fill in a 100 mL vial	63323-117-69	NP101761	6120341	04-2020	12/06/2018	12/18/2018
	63323-117-61	101761	6120420	04-2020	12/07/2018	02/20/2019

Products containing glass particulate should not be administered intravenously due to the potential for life-threatening consequences. Reports in the literature suggest that sequelae of thromboembolism, such as pulmonary emboli, phlebitis, granulomas, or fibrosis may occur.
To date, Fresenius Kabi has not received any complaints or reports of adverse events related to this recall.
The company is issuing this notification after finding glass particulate in five vials in retained sample inventory of lot 6120341 during an inspection for a quality investigation. The second lot (6120420) is included in the recall as a precautionary measure as it was produced in the same filling campaign.
Fluorouracil is a chemotherapy drug that is administered intravenously and indicated for the treatment of a variety of cancers.
Fresenius Kabi is notifying its distributors and customers by letter and asking customers and distributors to check their stock immediately and to quarantine and discontinue the use and distribution of any affected product. Distributors should notify their customers and direct them to quarantine and

discontinue distributing or dispensing any affected lots, and to return the product to Fresenius Kabi. The recall letter and response form are available at https://www.fresenius External Link Disclaimer-https://www.fresenius-kabi.com/us/pharmaceutical-product-updates -External Link Disclaimer Consumers with questions regarding this recall may contact Fresenius Kabi at 1-800-551-7176 Monday through Friday, during the hours of 8:00 a.m. to 5:00 p.m. or via email at productcomplaint.USA@fresenius-kabi.com or adverse.events.USA@freseniuskabi.com Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product.
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.
• Complete and submit the report Online
• 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
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration

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

Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products

[Posted 07/02/2019]

Altaire Pharmaceuticals, Inc., announces today that it is voluntarily recalling the prescription drug products and lots, within expiry, distributed during the time period as indicated in the tables below. As a precautionary measure, Altaire is initiating the recall due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility. This recall is being carried out to the retail level and is only for the specific lots listed. No other lots are being recalled.
Administration of a non-sterile product intended to be sterile may result in serious and potentially life-threatening infections or death. To date, Altaire has received no reports of adverse events, nor has Altaire obtained any out of specifications results including sterility testing, for the products.

Product Description: Neomycin and Polymixin B and Bacitracin Zinc Ophthalmic Ointment NDC Number: 0574-4250-35 Package Size: 3.5 gm

Lot Number	Expiration Date	Manufacturer Initial Ship Date
SAC	1/20	1/29/2018
SLK	12/20	1/30/2019

Product Description: NEO-POLY DEX (Neomycin and Polymixin B and Dexamethasone) Ophthalmic Ointment NDC Number: 0574-4160-35 Package Size: 3.5 gm

Lot Number	Expiration Date	Manufacturer Initial Ship Date
RGC	7/19	8/7/2017
RHB	8/19	8/30/2017
RHC	8/19	8/30/2017
RID	9/19	10/2/2017
RIC	9/19	10/2/2017
RIG	9/19	10/23/2017

RKH	11/19	12/8/2017
RKI	11/19	12/8/2017
RKJ	11/19	12/15/2017
RKK	11/19	12/15/2017
RKL	11/19	12/20/2017
RLM	12/19	1/29/2018
SAI	1/20	2/26/2018
SBG	2/20	3/12/2018
SBH	2/20	3/22/2018
SCF	3/20	4/23/2018
SEA	5/20	5/23/2018
SFA	6/20	6/20/2018
SFB	6/20	8/14/2018
SHA	8/20	8/30/2018
SIB	9/20	10/2/2018
SJC	10/20	11/9/2018
TAB	1/20	1/30/2019
TAF	1/21	2/18/2019
TBP	2/21	3/18/2019
TBQ	2/21	3/18/2019
TCV	3/21	5/1/2019
TCW	3/21	5/1/2019

Product Description: NEO-POLYCIN HC (Neomycin and Polymixin B and Bacitracin Zinc and Hydrocortisone Acetate) Ophthalmic Ointment NDC Number: 0574-4144-35 Package Size: 3.5 gm

Lot Number	Expiration Date	Manufacturer Initial Ship Date
SEE	5/20	5/31/2018
SEG	5/20	7/13/2018
SIE	9/20	10/17/2018
SKD	11/20	12/27/2018

Product Description: POLYCIN (Polymixin B and Bacitracin Zinc) Ophthalmic Ointment NDC Number: 0574-4021-35 Package Size: 3.5 gm

Lot Number	Expiration Date	Manufacturer Initial Ship Date
RGD	7/19	8/17/2017
RHL	8/19	9/28/2017
RHB	9/19	10/23/2017
RJF	10/19	11/8/2017
RJG	10/19	11/7/2017
SAJ	1/20	2/12/2018
SAK	1/20	2/19/2018
SAL	1/20	2/19/2018
SAM	1/20	2/22/2018
SBK	2/20	3/22/2018
SHE	5/20	6/20/2018
TCD	3/21	5/1/2019

Product Description: Bacitracin Ophthalmic Ointment NDC Number: 0574-4022-35 Package Size: 3.5 gm

Lot Number	Expiration Date	Manufacturer Initial Ship Date
RGA	7/19	7/31/2017
RGE	7/19	8/11/2017
RGG	7/19	8/11/2017
RGH	7/19	8/17/2017
RHM	8/19	9/14/2017
RJB	10/19	10/23/2017
RJA	10/19	10/23/2017
SCA	3/20	3/22/2018
SIC	9/20	10/9/1018
TAP	1/21	2/26/2019
TDE	4/21	5/30/2019

Product Description: Sulfacetamide Sodium Ophthalmic Ointment NDC Number: 0574-4190-35 Package Size: 3.5 gm

Lot Number	Expiration Date	Manufacturer Initial Ship Date
RID	10/19	10/30/2017
SHG	8/20	9/13/18

Product Description: Puralube Ophthalmic Ointment (Please note: Puralube is an OTC product)

Lot Number	Expiration Date	NDC Number	Package Size	Manufacturer Initial Ship Date
RJH	10/19	0574-4205-35	3.5 gm	11/13/2017
SCC	3/21			3/29/2018
SGA	7/21			7/31/2018
SGH	7/21			8/30/2018
SHH	8/21			9/12/2018
SLL	12/21			1/30/2019
TAC	1/22			2/18/2019

Lot Number	Expiration Date	NDC Number	Package Size	Manufacturer Initial Ship Date
RKM	11/19	0574-4025-20	1 gm	12/8/2017
SGA	7/20			7/31/2018
SIF	9/20			10/17/2018
SKE	11/20			12/27/2018

The products are manufactured and labeled exclusively for Perrigo Company PLC. Altaire ships the products only to Perrigo Company PLC. The products are distributed by Perrigo Company PLC.

Altaire has notified Perrigo by e-mail on July 2, 2019 announcing the recalls of the products/lots identified herein, with specific directions for return of all units of the impacted lots. Altaire has also requested that Perrigo perform a subrecall, and that Perrigo notify its customers.
Customers with questions regarding this recall can contact Altaire Pharmaceuticals Inc., by calling 1-800-258-2471, or e-mailing otcdruggist@aol.com Monday thru Friday from 8:30 a.m. to 5:00 p.m. ET.

Customers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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

- Complete and submit the report Online
- 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.
Altaire takes its mission of customer safety and providing quality products very seriously. The company is committed to, and diligently working to, ensure the sufficiency of Quality Assurance controls over critical systems in its manufacturing facility.

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

STUDIES AND RECENT TOPICS

Many epinephrine self-injectors still potent long after expiration date
June 13, 2019

EpiPens and other autoinjectors filled with epinephrine to treat severe allergic reactions may still be potent enough to work many months past their labeled expiration date, according to a new study that concludes patients might need expensive refills less often.

Source: reuters.com

Common nerve pain drug linked to suicidal behavior, overdose
June 17, 2019

A class of medications used for nerve and muscle pain, including the popular drug Lyrica, increases users' risks for suicidal behavior, unintentional overdoses, injuries and car accidents - and the risks are particularly high for teens and young adults, new research shows.

Source: reuters.com

New Treatment Option Available for Advanced Biliary Tract Cancers
June 25, 2019

In this open-label randomized trial, patients with metastatic biliary tract cancer were assigned randomly to receive either GEMOX or XELOX as first-line treatment, given every 3 weeks, for a total of 8 cycles. Findings suggest XELOX may be an effective alternative in the first-line treatment of advanced biliary tract cancers.

Source: cancernetwork.com

Can a PARP Inhibitor Plus Immunotherapy Improve Recurrent Ovarian Cancer Outcomes
June 25, 2019

The combination of niraparib and pembrolizumab was well tolerated and showed promising antitumor activity in patients with recurrent ovarian carcinoma, according to a phase I/II trial. The combination was active across several subgroups, and researchers say it warrants further investigation.

Source: cancernetwork.com

FDA warns companies selling kratom products on opioid addiction claims
June 25, 2019

The U.S. Food and Drug Administration issued warning letters on Tuesday to two privately held companies for illegally selling unapproved, misbranded drugs containing kratom claiming to cure opioid addiction and withdrawal symptoms. Leaves of the kratom tree, native to southeast Asia, can be used as a stimulant or sedative and the U.S. Drug Enforcement Administration has listed it as a "drug and chemical of concern."

Source: reuters.com

Commonly prescribed drugs are tied to nearly 50% higher dementia risk in older adults, study says
June 25, 2019

Scientists have long found a possible link between anticholinergic drugs and an increased risk of dementia. A study suggests that the link is strongest for certain classes of anticholinergic drugs -- particularly antidepressants such as paroxetine or amitriptyline, bladder antimuscarinics such as oxybutynin or tolterodine, antipsychotics such as chlorpromazine or olanzapine and antiepileptic drugs such as oxcarbazepine or carbamazepine.

Source: cnn.com

Future is in doubt for cheaper versions of biologic drugs
June 27, 2019

They were the drugs that were supposed to save the U.S. tens of billions of dollars.
Called “biosimilars,” they are near-copies of complex and expensive biologic drugs to treat cancer, rare diseases and autoimmune disorders like rheumatoid arthritis and colitis.

Source: apnews.com

Carbamazepine and Lamotrigine Associated With Increased Risk for SCC
June 27, 2019

Treatment with carbamazepine and lamotrigine was associated with an increased risk for squamous cell carcinoma (SCC).

Source: cancertherapyadvisor.com

Rapid Diagnostic Testing Helps Rule Out Bacterial Infections, Decreasing Antibiotic Use
July 1, 2019

A pharmacist-led protocol using rapid diagnostic testing to rule out methicillin-resistant Staphylococcus aureus (MRSA) pulmonary infections at an Ohio hospital last year led to 80% of patients being de-escalated on vancomycin within 24 hours of receiving negative test results.

Source: pharmacytechnologyreport.com

Product News: New Label Color for Medication Requiring Special Handling
July 2, 2019

Clearly identifying medications that require special handling, such as those covered by USP <800>, is important for the safety of staff and patients. To assist in these efforts, Medi-Dose® has created bright yellow Lid-Label® Covers for use with the company’s Circular and Oval Medi-Cup® Blisters.

Source: pharmacytimes.com

TNF Inhibitors Safer Than Previously Thought for AS Patients

July 8, 2019

TNF inhibitors, or blockers, are safer than previously thought for patients with ankylosing spondylitis (AS) and may have fewer unwanted side effects than non-steroidal anti-inflammatory drugs (NSAIDs), the standard first-line therapy for AS, a retrospective study has found.

Source: ankylosingspondylitisnews.com

RECALLS

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
Drugs	Hydromorphone HCl in 0.9% sodium chloride, 0.5mg per mL, 1 mL in 3mL BD Syringe, PharMEDium 913 N Davis Ave Cleveland, MS 38732, 800-523-7749, NDC 61553-352-78	Class I	Lot #: 190670030D,190670031D, 190670032D, 190670033D, Exp. 6/9/2019; 190710015D, 190710016D, 190710017D, 190710018D, 190710019D, Exp. 6/11/2019; 190730028D, 190730029D, 190730030D, Exp. 6/13/2019; 190740018D, Exp.6/16/2019; 190770028D, 190770029D, Exp. 6/17/2019; 190780027D, 190780028D, 190780029D, Exp. 6/18/2019; 190790030D, Exp. 6/19/2019; 190800012D, 190800013D, 190800014D, 190800015D, 190800016D, Exp.6/20/2019; 190810033D, 190810034D, 190810035D,190810036D, Exp.6/23/2019; 190840002D, Exp. 6/24/2019; 190870008D, Exp. 6/27/2019; 190910015D, Exp. 7/1/2019; 190980033D, Exp. 7/8/2019;	Incorrect Product Formulation; Firm's customer resource center (CRC) statement indicates that the product is sulfite free, however the product is produced with a raw material that contains sulfite	PharMEDium Services, LLC

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
			190990017D, 190990030D, Exp. 7/9/2019; 191000035D, Exp. 7/10/2019; 191010008D,191010009D, 191010010D, Exp. 7/11/2019; 191050002D, Exp.7/15/2019; 191120002D, Exp.7/22/2019; 191160001D, Exp. 7/28/2019; 191210020D, 191210021D, 191210022D, Exp.7/31/2019; 191220017D, Exp.8/1/2019.		
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	GMP Deviations; possible cross contamination of product due to cleaning procedure failure.	American Health Packaging
Drugs	Pramipexole Dihydrochloride Tablets, 0.125 mg, 30 Tablets (6 tablets per blister card), Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217 NDC Blister Card:	Class II	Lot, expiry: Lot 179049, exp 12/31/2019; Lot 182571, exp 8/31/2020	GMP Deviations; possible cross contamination of product due to cleaning procedure failure.	American Health Packaging

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	68084-793-95; NDC Carton: 68084-793-25				
Drugs	Pramipexole Dihydrochloride Tablets, 0.25 mg, 100 Tablets (10 x 10), Rx Only, Packaged and Distributed by: American Health Packaging, Columbus, Ohio 43217 NDC Blister Card: 68084-440-11; NDC Carton: 68084-440-01	Class II	Lot, expiry: Lot 172669, exp 05/31/2019; Lots 175872, 177086, exp 09/30/2019; Lot 179047, exp 12/31/2019; Lot 182584, exp 07/31/2020	GMP Deviations; possible cross contamination of product due to cleaning procedure failure.	American Health Packaging
Drugs	Pramipexole Dihydrochloride Tablets, 0.5 mg, 30 Tablets (6 tablets per blister card), Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217 NDC Blister Card: 68084-974-95; NDC Carton: 68084-974-25	Class II	Lot, expiry: Lots 175820, 176569, exp 09/30/2019; Lots 177866, 179627A, 179627B, exp 12/31/2019; Lot 181627, exp 06/30/2020	GMP Deviations; possible cross contamination of product due to cleaning procedure failure.	American Health Packaging
Drugs	Pramipexole Dihydrochloride Tablets, 1.0 mg, 30 Tablets (6 tablets per blister card), Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217 NDC Blister Card:	Class II	Lot, expiry: Lot 176179, exp 05/31/2019; Lot 176616, exp 07/31/2019; Lot 178562, exp 09/30/2019; Lot 179947, exp 12/31/2019; Lot 182048, exp 04/30/2020; Lot 183136, exp 06/30/2020; Lot	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination and lack of product specific process	Premier Pharmacy Labs Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	68084-982-95; NDC Carton: 68084-982-25		184217, exp 08/31/2020	validations that can result in a lack of sterility assurance.	
Drugs	Atropine Sulfate PF INJ, 0.8 mg/2 mL (0.4 mg/mL), 2mL Single Dose Syringe, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-131-12, barcode 0 69623 13112 6.	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination and lack of product specific process validations that can result in a lack of sterility assurance.	Premier Pharmacy Labs Inc
Drugs	Brilliant Blue Ophthalmic PF INJ, 0.5mg/mL (0.05%), 1 mL SDV, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-211-31, barcode 2 69623 21131 0.	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination and lack of product specific process validations that can result in a lack of sterility assurance.	Premier Pharmacy Labs Inc
Drugs	ChlorproMAZINE HCL INJ, 25mg/mL, *Contains Sulfites*, 1mL in a 5mL Sterile SDV, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination	Premier Pharmacy Labs Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	Wachee, FL 34613, NDC: 69623-122-28, barcode 7 69623 12228 4.			and lack of product specific process validations that can result in a lack of sterility assurance.	
Drugs	Dexamethasone Sodium Phosphate Preservative Free Sterile Solution for INJ, 24mg/mL, 1mL Sterile Single-Use Syringe, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-252-10, barcode 0 69623 25210 4.	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination and lack of product specific process validations that can result in a lack of sterility assurance.	Premier Pharmacy Labs Inc
Drugs	Droperidol Injectable Sterile Solution, 0.625mg/mL, 1mL in a 3mL Sterile Single-Use Syringe, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-185-10, barcode 0 69623 18510 5.	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination and lack of product specific process validations that can result in a lack of sterility assurance.	Premier Pharmacy Labs Inc
Drugs	Isoproterenol HCL in D5W (Sterile to Sterile), 200mcg/50mL (4mcg/mL), 50mL Sterile Single-Dose	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental	Premier Pharmacy Labs Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	Bag, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-230-57, barcode 0 69623 23057 7.			controls, potential cross contamination and lack of product specific process validations that can result in a lack of sterility assurance.	
Drugs	Isoproterenol HCL in D5W (Non Sterile to Sterile), 200mcg/50mL (4mcg/mL), 50mL Sterile Single-Dose Bag, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-240-57, barcode 0 69623 24057 7.	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination and lack of product specific process validations that can result in a lack of sterility assurance.	Premier Pharmacy Labs Inc
Drugs	Isoproterenol HCL in D5W, 500mcg/50mL (10mcg/mL), 50mL Sterile Single-Dose Bag, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-107-57, barcode 3 69623 10757 3.	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination and lack of product specific process validations that can result in a lack of sterility assurance.	Premier Pharmacy Labs Inc
Drugs	Lidocaine 0.5%/Phenylephrine 0.75% P.F. INJ,	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA	Premier Pharmacy Labs Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	1mL Sterile SDV, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-176-31, barcode 6 69623 17631 0.			inspection found insufficient environmental controls, potential cross contamination and lack of product specific process validations that can result in a lack of sterility assurance.	
Drugs	Mitomycin Preservative Free Irrigation, 40mg/10mL (4mg/mL), 10mL SDV, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-160-35, barcode 5 69623 16035 0.	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination and lack of product specific process validations that can result in a lack of sterility assurance.	Premier Pharmacy Labs Inc
Drugs	Naloxone HCL Preserved INJ, 500mg/50mL (10mg/mL), 50mL Sterile MDV, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-235-39, barcode 6 69623 23539 0.	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination and lack of product specific process validations that can result in a lack of sterility assurance.	Premier Pharmacy Labs Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
Drugs	Neostigmine Methylsulfate, 5mg/5mL (1mg/mL), 5mL Single Dose Syringe, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-234-15, barcode 5 69623 23415 0.	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination and lack of product specific process validations that can result in a lack of sterility assurance.	Premier Pharmacy Labs Inc
Drugs	Orphenadrine Citrate Sterile Injectable Solution *Contains Sulfites*, 30mg/mL, 1mL Sterile Single-Use Syringe, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-104-10, barcode 7 69623 10410 5.	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination and lack of product specific process validations that can result in a lack of sterility assurance.	Premier Pharmacy Labs Inc
Drugs	Phenylephrine HCL PF INJ in 0.9% Sodium Chloride, 1000mcg/10mL (100mgc/mL), *Contains Sulfites*, 10mL Single-Dose Syringe, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination and lack of product specific process validations that	Premier Pharmacy Labs Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	34613, NDC: 69623-236-16, barcode 8 69623 23616 2.			can result in a lack of sterility assurance.	
Drugs	Riboflavin 5-Phosphate Sodium Ophthalmic Solution, 19.05mg/3mL (6.35 mg/mL), 3 mL Dropper Bottle, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-106-61, barcode 1 69623 10661 9.	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination and lack of product specific process validations that can result in a lack of sterility assurance.	Premier Pharmacy Labs Inc
Drugs	Sodium Bicarbonate INJ 8.4%, 50 mEq/50mL (84mg/mL) (1mEq/mL), 50mL Sterile SDV, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-232-39, barcode 8 69623 23239 3.	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination and lack of product specific process validations that can result in a lack of sterility assurance.	Premier Pharmacy Labs Inc
Drugs	SUCCINYLcholine Chloride, 100mg/5mL (20mg/mL), 5mL Sterile Single-Use Syringe, Rx only, Premier Pharmacy Labs, 8265 Commercial Way,	Class II	All lots remaining within expiry.	Lack of Assurance of Sterility: FDA inspection found insufficient environmental controls, potential cross contamination	Premier Pharmacy Labs Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	Weeki Wachee, FL 34613, NDC: 69623-239-15, barcode 0 69623 23915 0.			and lack of product specific process validations that can result in a lack of sterility assurance.	
Drugs	SUCCINYLcholine Chloride, 200mg/10mL (20mg/mL), 10mL Sterile Single Dose Syringe, Rx only, Premier Pharmacy Labs, 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-239-16, barcode 9 69623 23916 0.	Class II	All lots remaining within expiry.	Microbial Contamination of Non-sterile Products: Potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	H J Harkins Company Inc dba Pharma Pac
Drugs	Acetaminophen Children's Liquid, 160 mg/5 mL, 4 oz bottle, Manufactured by Torrent Pharma, Inc., Levittown, PA 19057, NDC 52959-0309-04	Class II	Lot #: ACL75M, Exp. 02/20; ACL76M, Exp. 08/19; ACL77M, Exp. 05/20	Microbial Contamination of Non-sterile Products: Potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	H J Harkins Company Inc dba Pharma Pac
Drugs	Diphenhydramine HCL Liquid, 12.5 mg/5 mL, 4 oz bottle, Manufactured by Torrent Pharma, Inc., Levittown, PA 19057, NDC 52959-0123-03.	Class II	Lot #: DHI56M, Exp. 12/19	CGMP Deviations: impurity for N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) detected in the active pharmaceutical ingredient (API)	Teva Pharmaceuticals USA

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
				used to manufacture finished products.	
Drugs	LOSARTAN POTASSIUM 50 mg TABLET BULK 90 count bottles and 1000 count bottles	Class II	Arrow Malta (Teva) Bulk Product Lot # 1169752A, exp. date 01/2020, 1000 tablets/bottle 1169753A, exp. date 01/2020, 90 tablets/bottle Golden State Medical Finished Product Lot # GS017387, exp. date 01/2020 GS017651, exp. date 01/2020 GS017479, exp. date 01/2020	CGMP Deviations: impurity for N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) detected in the active pharmaceutical ingredient (API) used to manufacture finished products.	Teva Pharmaceuticals USA
Drugs	LOSARTAN POTASSIUM 100 mg TABLET BULK 90 count bottles	Class II	Arrow Malta (Teva) Bulk Product Lot # 1163892A, exp. date 01/2020 1163893A, exp. date 01/2020 1163894A, exp. date 01/2020 1163895A, exp. date 01/2020 Golden State Medical Finished Product Lot # GS017042, exp. date 01/2020 GS017043, exp. date 01/2020 GS017044, exp. date 01/2020 GS017541, exp. date 01/2020	CGMP Deviations: impurity for N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) detected in the active pharmaceutical ingredient (API) used to manufacture finished products.	MacLeod's Pharma USA Inc
Drugs	Losartan Potassium Tablets, USP 50 mg 90 tablets Rx Only Manufactured for: MacLeod's Pharma USA Inc. Plainsboro, NJ 08536 Manufactured by:	Class II	BLI711A Nov 2019	CGMP Deviations: impurity for N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) detected in the active pharmaceutical	MacLeod's Pharma USA Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	MacLeod's Pharmaceuticals, Ltd. Baddi, Himachal Pradesh, INDIA NDC 33342-045-10			ingredient (API) used to manufacture finished products.	
Drugs	Losartan Potassium Tablets 50 mg 1000 Tablets, USP Rx Only Manufactured for: MacLeod's Pharma USA Inc. Plainsboro, NJ 08536 Manufactured by: MacLeod's Pharmaceuticals, Ltd. Baddi, Himachal Pradesh, INDIA NDC 33342-045-44	Class II	BLI710A Nov 2019	CGMP Deviations: impurity for N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) detected in the active pharmaceutical ingredient (API) used to manufacture finished products.	MacLeod's Pharma USA Inc
Drugs	Losartan Potassium and Hyrdochlorothiazide Tablets, USP 50 mg/12.5 mg 90 Tablets, USP Manufactured for: MacLeod's Pharma USA Inc. Plainsboro, NJ 08536 Manufactured by: MacLeod's Pharmaceuticals, Ltd. Baddi, Himachal Pradesh, INDIA NDC 33342-050-10	Class II	BLK719A Sep-19 BLK720A Sep-19 BLK721A Sep-19 BLK722A Sep-19 BLK723A Sep-19 BLK724A Sep-19 BLK725A Oct-19 BLK726A Oct-19 BLK804A Jan-20 BLK806A Jan-20 BLK825A Oct-21 BLK826A Oct-21	CGMP Deviations: impurity for N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) detected in the active pharmaceutical ingredient (API) used to manufacture finished products.	MacLeod's Pharma Usa Inc
Drugs	Losartan Potassium and Hydrochlorthiazide Tablets, USP 100	Class II	BLL801A Dec-19 BLL802A Dec-19 BLL803A Dec-19	CGMP Deviations: impurity for N-Nitroso-N-	MacLeod's Pharma Usa Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	mg/12.5 mg 90 Tablets, USP Manufactured for: MacLeod's Pharma USA Inc. Plainsboro, NJ 08536 Manufactured by: MacLeod's Pharmaceuticals, Ltd. Baddi, Himachal Pradesh, INDIA NDC 33342-051-10			methyl-4-aminobutyric acid (NMBA) detected in the active pharmaceutical ingredient (API) used to manufacture finished products.	
Drugs	Losartan Potassium and Hydrochlorthiazide Tablets 100 mg/25 mg 90 tablets, USP Rx Only, Manufactured for: MacLeod's Pharma USA Inc. Plainsboro, NJ 08536 Manufactured by: MacLeod's Pharmaceuticals, Ltd. Baddi, Himachal Pradesh, INDIA NDC 33342-052-10	Class II	BLM716A Jul-19 BLM717A Jul-19 BLM719A Aug-19 BLM720A Aug-19 BLM721A Sep-19 BLM722A Sep-19 BLM723A Oct-19 BLM724A Oct-19 BLM725A Oct-19 BLM726A Nov-19 BLM802A Dec-19 BLM803A Dec-19 BLM825A Sep-21 BLM826A Sep-21 BLM827A Sep-21	CGMP Deviations: impurity for N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) detected in the active pharmaceutical ingredient (API) used to manufacture finished products.	Golden State Medical Supply Inc.
Drugs	Losartan Potassium, 50 mg tablets, 30 count bottle, NDC 60429-317-30	Class II	Lot #: GS017479, Expiration 01/2020	CGMP Deviations: impurity for N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) detected in the active pharmaceutical ingredient (API) used to	Golden State Medical Supply Inc.

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
				manufacture finished products.	
Drugs	Losartan Potassium, 50 mg tablets, 90 count bottle, NDC 60429-317-90	Class II	Lot #: GS017651, Expiration 01/2020	CGMP Deviations: impurity for N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) detected in the active pharmaceutical ingredient (API) used to manufacture finished products.	Golden State Medical Supply Inc.
Drugs	Losartan Potassium, 50 mg tablets, 1000 count bottle, NDC 60429-317-10	Class II	Lot #: GS017387, Expiration 01/2020	CGMP Deviations: impurity for N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) detected in the active pharmaceutical ingredient (API) used to manufacture finished products.	Golden State Medical Supply Inc.
Drugs	Losartan Potassium, 100 mg tablets, 90 count bottle, NDC 60429-318-90	Class II	Lot #: GS017042, Expiration 01/2020; GS017043, Expiration 01/2020; GS017044, Expiration 01/2020; GS017541, Expiration 01/2020	CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level at	MAJOR PHARMACEUTICALS

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
				the manufacturer	
Drugs	Losartan Potassium Tablets, USP. 50 mg. NDC# 0904-6390-61. Rx only. 100 count Unit Dose Cartons. Manufactured by Major Pharmaceuticals 17177 N. Laurel Park Drive Suite 233, Livonia, MI 48152.	Class II	Major Label Unit Does 10 x 10 Cartons, Major Item # 301835. Lot Number: R-00474. Expiration date: 07/2019.	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy
Drugs	Testosterone Cypionate 100 mg/mL Sesame Oil Injection, 12mL vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252	Class II	Lot #: 04192019@1, Exp. 07/21/2019; 05312019@4, Exp. 09/03/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy
Drugs	Testosterone Cypionate 150 mg/mL Sesame Oil Injection, 12 mL vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252.	Class II	Lot #: 04202019@1, Exp. 07/21/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy
Drugs	Testosterone Cypionate 200 mg/mL Sesame Oil Injection, packaged in a) 9 mL, b) 12 mL vials, Rx only, First Pharma Associates	Class II	Lot #: a) 05022019@31, Exp. 08/4/2019; 05152019@18, Exp. 08/13/2019; b) 05292019@4, Exp. 08/28/2019.	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252				
Drugs	Testosterone Cypionate 200 mg/mL Ethyl Oleate Injection, packaged in a) 7.2 mL. b) 9.6 mL, c) 10.8mL vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252.	Class II	Lot #: a) 05032019@18, Exp. 08/04/2019; b) 05062019@20, Exp. 08/06/2019; c) 05132019@1, Exp. 08/13/2019.	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy
Drugs	Testosterone Cypionate 100 mg/mL Oil Injection Injection, 12 mL vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252.	Class II	Lot #: 05152019@36, Exp. 09/09/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy
Drugs	Testosterone Cyp/Estradiol Cyp 50 mg/2.5 mg/mL Injection, 3mL vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252.	Class II	Lot #: 06102019@31, Exp. 09/09/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy
Drugs	Hydroxyprogesterone Caproate 250 mg/mL Sesame Oil	Class II	Lot #: 05152019@17, Exp. 08/13/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	Injection, 5 mL vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252				Pharmacy
Drugs	Prostaglandin 20 mcg/mL/Procaine 0.1% Injection, packaged in a) 2.5mL and b)10 mL vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205 (509) 343-6252	Class II	Lot #: a) 06182019@16, Exp. 08/04/2019 b) 06032019@8, Exp. 07/18/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy
Drugs	Hydroxocobalamin 10 mg/mL Injection (ALT) Solution, 30 mL vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252	Class II	Lot #: 05282019@53, Exp. 08/26/2019 and Exp. 08/28/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy
Drugs	Methylcobalamin 1 mg/mL Injection, 8 mL vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252	Class II	Lot #: 06102019@6, Exp. 08/09/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy
Drugs	Methylcobalamin 10 mg/mL Injection, 5.4 mL	Class II	Lot #: 06202019@29, Exp. 08/19/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252.				Pharmacy
Drugs	PAP/PHEN/PGE1 22 mg/0.8mg/8mcg/ mL Injection, 5mL vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252	Class II	Lot #: 06112019@32, Exp. 07/27/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy
Drugs	PAP/PHEN/PGE1 30 mg/2mg/20mcg/ mL Injection, 10mL vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252	Class II	Lot #: 06122019@16, Exp. 07/27/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy
Drugs	PAP/PHEN/PGE1 30 mg/0.83mg/10mcg/mL Injection, 5 mL, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252	Class II	Lot #: 06122019@9, Exp. 07/28/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy
Drugs	PAP/PHEN/PGE1 18 mg/0.6mg/5.88mcg/mL Injection, 5	Class II	Lot #: 06152019@1, Exp. 08/2/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	mL vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252				
Drugs	Chorionic Gonadotropin 2,000U/mL PF Injection, 8 mL vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252	Class II	Lot #: 06212019@15, Exp. 07/24/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy
Drugs	Glutathione 100 mg/mL Inhalation Solution (PF), 45 mL vial, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252	Class II	Lot #: 06172019@3, Exp. 08/18/2019	Lack of Assurance of Sterility.	First Pharma Associates LLC dba Riverpoint Pharmacy
Drugs	Serum Tears 20% Eye Drops PF Solution, packaged in a) 15 EA, b)15 mL vials, c) 12 EA, Rx only, First Pharma Associates dba Riverpoint Pharmacy, Spokane, WA 99205, (509) 343-6252	Class II	Lot #: a) 06042019@20, Exp. 07/19/2019; 06052019@24, Exp. 07/28/2019; 06062019@10, Exp. 07/21/2019; b) 06132019@6, Exp. 07/29/2019; c) 06182019@28, Exp. 12/17/2019, 06192019@28, Exp. 12/18/2019.	GMP Deviations: Potential cross contamination due to cleaning procedure failure.	American Health Packaging
Drugs	Anastrozole Tablets, USP, 1	Class II	Count, Lot, Expiry: [30-count bottle] Lots	Subpotent Drug: Out of	Amneal Pharmaceuticals

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	mg, a) 30-count (NDC 68001-155-04) and 1000-count (NDC 68001-155-08) bottles, Rx Only, Manufactured by: Cadila Healthcare Ltd., Ahmedabad, India For BluePoint Laboratories		M711214, M711215, M711216, M711217, exp 8/31/2019; Lots M802198, M802199, exp 1/31/2020; Lots M805203, M805204, M805207, exp 3/31/2019; Lots M812455, exp 6/30/2020; Lot M815766, exp 9/30/2020; Lots M818633, M818634, exp 10/31/2020; Lots M819858, M819859, exp 11/30/2020 [1000-count bottle] Lot M711218, exp 8/31/2019; Lot M802197, exp 1/31/2020; Lots M805209, M805946, exp 3/31/2020; Lot M812456, exp 6/30/2020; Lots M815767, M818273, exp 9/30/2020; Lot M819857, exp 11/30/2020	specification assay result in Esterified Estrogen and Methyltestostero ne tablets.	, Inc.
Drugs	ANASTROZOLE Tablets, 1 mg, Rx Only, 30-count bottle, Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India. Distributed by: Zydus Pharmaceuticals (USA) Inc. Pennington, NJ 08534 NDC 68382-209-06	Class II	Lot: M706674, M706676, M707685 EXP Jun-19; M711219, M711220, M711221, M711222, M711269, EXP Sep-19; M801027, EXP Dec-19; M801028, M801029, M801030, EXP Jan-20; M802206, EXP Feb-20, M805195, M805196, M805197, EXP Mar-20; M805199, M805202, M805944, M805945, M805948, M805951, M805953, M805956, M805957,	Subpotent Drug: Out of specification assay result in Esterified Estrogen and Methyltestostero ne tablets.	Amneal Pharmaceuticals , Inc.

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
			M805958, M805959 Apr-20; M812457, EXP Jul-20, M812458, M812459, M813912, M813913, M813914, M813915, M813916, EXP Aug-20; M815768, M815769, M818274, EXP Oct-20; M818119, M818120, M818121, M818635, EXP Nov-20; M819270, M819861, M819862, EXP Dec-20; M900921, M900922, M900923, M900924, M900925, EXP Jan-21; M902634, M902635, EXP Feb-21.		
Drugs	Anastrozole Tablets, USP, 1 mg, 1,000-count bottle, Rx only, Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India Distributed by: Zydus Pharmaceuticals (USA) Inc. Pennington, NJ 08534. NDC 68382-209-10	Class II	Lot EXP Date: M708570 Jun-19, M711270 Sep-19, M802207 Feb-20, M812460 Aug-20	CGMP Deviations: Cross Contamination with other products due to CGMP cleaning failure.	Zydus Pharmaceuticals USA Inc
Drugs	Pramipexole Dihydrochloride Tablets 0.125 mg, 1,000-count bottle, Rx only, Manufactured by: Cadila Healthcare Ltd Ahmedabad, India, Distributed by: Zydus Pharmaceuticals USA Inc. Pennington, NJ	Class II	Lot: M714919, EXP Dec-19, M815081, EXP Aug-20, M900475, EXP Dec-20	CGMP Deviations: Cross Contamination with other products due to CGMP cleaning failure.	Zydus Pharmaceuticals USA Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	08534. NDC 68382-196-10				
Drugs	Pramipexole Dihydrochloride Tablets 0.125 mg, 90-count bottle, Rx Only, Manufactured by: Cadila Healthcare Ltd Ahmedabad, India. Distributed by: Zydus Pharmaceuticals USA Inc. Pennington, NJ 08534. NDC 68382-196-16	Class II	Lot: M714176, M714177, EXP Oct-19; M714917, EXP Nov-19; M714918, M715594, M715595, EXP Dec-19; M802190, EXP Jan-20; M802191, EXP Feb-20, M808673, EXP May-20; M811125, M811126, M811127, M811128, M811129, EXP Jun-20; M815082, M815083, M815084, M815085, M815086 EXP Aug-20; M900476, M900477, M900478, M900479, M900481, Dec-20;	CGMP Deviations: Cross Contamination with other products due to CGMP cleaning failure.	Zydus Pharmaceuticals USA Inc
Drugs	Pramipexole Dihydrochoride Tablets 0.25 mg, 90-count bottle, Rx Only, Manufactured by: Cadila Healthcare Ltd Ahmedabad, India Distributed by: Zydus Pharmaceuticals USA Inc. Pennington, NJ 08534. NDC 68382-197-16	Class II	Lots: M706802, M706804, M706907, M706909, M707028, EXP May-19; M714180, M714181, EXP Oct-19; M717063, M717064, M801705, M801706, M801707, M801708, M714923, M714924, M714925 EXP Dec-19; M808307, M808308, M808309, M808310, EXP May-20; M812479, M812481, M812482, M812483, EXP Jul-20; M815787 M815789, M815790, M815791, M815788, EXP Sep-20; M820266, M820267, M820268, M820269, M820265 EXP Nov-20; M903040, M903041, M903042 EXP Jan-21.	CGMP Deviations: Cross Contamination with other products due to CGMP cleaning failure.	Zydus Pharmaceuticals USA Inc
Drugs	Pramipexole Dihydrochloride Tablets 0.25 mg,	Class II	Lots: M706803, EXP Jun-19; M713438, EXP Oct-19; M801704, EXP Jan-	CGMP Deviations: Cross Contamination	Zydus Pharmaceuticals USA Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	1000-count bottle, Rx only, Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India. NDC 68382-197-10		20; M808306, EXP Jun-20; M812484, EXP Aug-20; M820264, EXP Dec-20	with other products due to CGMP cleaning failure.	
Drugs	Pramipexole Dihydrochloride Tablets 0.5 mg, 90-count bottle, Rx only, Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India Distributed by: Zydus Pharmaceuticals USA Inc. Pennington, NJ 08534. NDC 68382-198-16	Class II	Lots:M713431, M713432, M714172, EXP Sep-19; M714173, Oct-19; M800552, M800553, M800554, M800555 M800556 EXP Dec-19; M811135 M812818 M812819 M812820 M812821 EXP Jun-20, M815777 M815778 M815779 M815780 M815781 EXP Aug-20; M901927 M901929 M901931 M901933 M902089 EXP Jan-21	CGMP Deviations: Cross Contamination with other products due to CGMP cleaning failure.	Zydus Pharmaceuticals USA Inc
Drugs	Pramipexole Dihydrochloride Tablets 1 mg, 90-count bottle, Rx only, Manufactured by: Cadila Healthcare Ltd Ahmedabad, India Distributed by: Zydus Pharmaceuticals USA Inc. Pennington, NJ 08534. NDC 68382-199-16	Class II	Lots: M714186 M714187 M714188 EXP Oct-19; M714903 M714904 M714905 M715586 M715587 EXP Nov-19; M801441 M801442 M801443 M801444 M801445 EXP Dec-19; M811152 M811153 M811154 M811155 M811156 M814298 EXP Jul-20; M814299 M814300 M814301 M814302 EXP Aug-20; M818136 M818137 M818138 M818139 M818140 EXP Nov-20	CGMP Deviations: Cross Contamination with other products due to CGMP cleaning failure.	Zydus Pharmaceuticals USA Inc
Drugs	MethylPREDNISolone Tablets, USP, 4 mg, 100 tablets, Rx only,	Class II	Lots: M800144, M800145, EXP, Feb-20; M808193, EXP Jun-20; M811096, EXPJul-20	CGMP Deviations: Cross Contamination with other	Zydus Pharmaceuticals USA Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	Manufactured by: Cadila Healthcare Ltd Ahmedabad, India NDC 68382-916-01			products due to CGMP cleaning failure.	
Drugs	MethylPREDNISolone Tablets, USP 4 mg per tablet, 21 Tablets dosepack, Rx Only, Made in India Distributed by: Zydus Pharmaceuticals USA Inc. Pennington, NJ 08534. NDC 68382-916-34	Class II	Lots: M800150 Feb-20; M803930, M806006, M806007, M806008, M806009, M806010, M806011, EXP Mar-20; M807299, M807300, M807301, M807302, M807303, M807304, M807305, M807306, M807307, M807308, EXP May-20; M807779, M807780, M808194, M808195, M808196, M808197, M808198, EXP Jun-20; M811092, M811093, M811094, M811097, M811665, M811666, M811667, M813781, EXP Jul-20; M816286, M816288, M816289, M816290, M817612, EXP OCT-20; M817613, M817614, M817615, M817616, M818315, EXP Nov-20; M820619, M820620, M820621, M901594, M901595, M901596, M901597, M903484, EXP Mar-21	CGMP Deviations: Cross Contamination with other products due to CGMP cleaning failure.	Zydus Pharmaceuticals USA Inc
Drugs	MethylPREDNISolone Tablets, USP 16 mg, 50 tablets, Rx only, Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India NDC 68382-918-18	Class II	lots: M713034, M713035, M713036, EXP Nov-19; M814747 Sep-20; M819266, EXP Dec-20	CGMP Deviations: Cross Contamination with other products due to CGMP cleaning failure.	Zydus Pharmaceuticals USA Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
Drugs	MethylPREDNISolone Tablets, USP 32 mg, 25 tablets, Rx Only, Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India NDC 68382-919-11	Class II	Lots: M713043, M713047, EXP Dec-19; M713045, EXP Nov- 19; M816143, EXP Oct-20.	CGMP Deviations: Cross Contamination with other products due to CGMP cleaning failure.	Zydus Pharmaceuticals USA Inc
Drugs	Pramipexole Dihydrochloride Tablets 1.5 mg 90-count bottle, Rx only Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India Distributed by: Zydus Pharmaceuticals USA Inc. Pennington, NJ NDC 68382-200-16	Class II	Lots: M713435 M713436 EXP Sep-19; M714191 EXP Oct-19; M808185 M808184 M808186 EXP May-20; M817634 M817635 EXP Nov-20	CGMP Deviations: Cross Contamination with other products due to CGMP cleaning failure.	Zydus Pharmaceuticals USA Inc
Drugs	MethylPREDNISolone Tablets, USP 8 mg, 25 tablets, Rx Only, Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India NDC 68382-917-11	Class II	Lots: M713224, M713225, M713226, EXP Nov-19; M814746 EXP Sep-20; M816148 EXP Oct-20; M901600, M901601 EXP Feb-21	CGMP Deviations: Cross Contamination with other products due to CGMP cleaning failure.	Zydus Pharmaceuticals USA Inc
Drugs	Anastrozole Tablets, USP, 1mg, 30-count unit dose blisters per carton, Rx Only, Packaged and Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC 60687-112-21.	Class II	Lot #: 175289A, 175286B, 175290B, Exp. 08/31/2019; 179906A, Exp. 03/31/2020; 183252A, Exp. 09/30/2020; 184611A, Exp. 11/30/2020	CGMP Deviations: Cross Contamination with other products due to CGMP cleaning failure.	Zydus Pharmaceuticals USA Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
Drugs	Allergy Relief D, Fexofenadine HCl 60 mg/ Pseudoephedrine HCl 120 mg, Extended Release Tablets, USP, 30-count box, Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895. Made in India. UPC 0 50428 39131 0	Class II	Lot: GKT0484B, EXP 04/2020	GMP Deviations: Potential cross contamination due to cleaning procedure failure.	American Health Packaging
Drugs	Allergy Relief D, Fexofenadine HCl 60 mg/ Pseudoephedrine HCl 120 mg, Extended Release Tablets, USP, 20-count box, Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895. Made in India. UPC 0 50428 43023 1	Class II	Lot GKT0791, EXP 06/2020	Testing of Fexofenadine HCl and Pseudoephedrine Failed Impurities/Degradation Specifications: elevated substance results that were reported above or near the specification limit	Sun Pharmaceutical Industries, Inc.
Drugs	Wal-Fex D Fexofenadine HCl 60 mg/ Pseudoephedrine HCl 120 mg/ Extended-Release Tablets, USP, Allergy & Congestion, 30-count box. Distributed by: Walgreen Co. 200 Wilmore Rd.	Class II	Lot: GKS1014, EXP 09/2019; GKT0484A, EXP 04/2020	Testing of Fexofenadine HCl and Pseudoephedrine Failed Impurities/Degradation Specifications: elevated substance results that were reported above or near the	Sun Pharmaceutical Industries, Inc.

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	Deerfield, IL 40015. Made in India. UPC 3 11917 19454 7			specification limit	
Drugs	Wal-Fex D Fexofenadine HCl 60 mg/ Pseudoephedrine HCl 120 mg, Extended-Release Tablets, USP, Allergy & Congestion, 20-count box. Distributed by: Walgreen Co. 200 Wilmore Rd. Deerfield, IL 40015. Made in India UPC 3 11917 19453 0	Class II	Lot GKT0406, EXP 3/2020	Testing of Fexofenadine HCl and Pseudoephedrine Failed Impurities/Degradation Specifications: elevated substance results that were reported above or near the specification limit	Sun Pharmaceutical Industries, Inc.
Drugs	Robafen DM, Generic for Robitussin DM, In each teaspoonful (5mL): Dextromethorphan HBr, USP 10mg,/Guaifenesin, USP 100mg, 118mL (4oz) bottle, Manufactured for Preferred Pharmaceuticals, Inc., Anaheim, CA 92807 by Major Pharmaceuticals, Livonia, MI 48152, NDC 68788-0841-01	Class II	Lot: J0218L, Batch: 10021812, Exp. 02/2020; Lot: L2718D, Batch numbers from consecutively from L2718D001 to L2718D096, Exp. 07/2020	Testing of Fexofenadine HCl and Pseudoephedrine Failed Impurities/Degradation Specifications: elevated substance results that were reported above or near the specification limit	Sun Pharmaceutical Industries, Inc.
Drugs	Cetirizine HCL Oral Solution 1 mg/mL, Children's Allergy, Antihistamine,	Class II	Lot #s: C00138; A48440, Exp. 5/19; C02434; C04186, Exp. 6/19; C07864, Exp. 7/19;	CGMP Deviations: Potential product contamination	Preferred Pharmaceuticals, Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	Dye Free, Gluten Free, Grape Flavor, 5 mg/5mL, 4 FL. oz. Bottle, Distributed by Dolgencorp, LLC, 100 mission ridge, Goodlettsville, TN 37072, NDC 55910-878-04, UPC 359726178051.		F13277; C08962; F13778, Exp. 10/19; C11746; F05899; F13777, Exp. 12/19; F09356; F10784; F13595, Exp. 2/20; F22355; F23239, Exp. 8/20.	with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	
Drugs	Cetirizine Oral Solution 1 mg/mL, Children's Allergy, Antihistamine, Dye Free, Grape Flavor, 4 FL. oz. Bottle, Distributed by C.D.M.A. Inc., Novi, MI 48376, Quality Choice, NDC 63868-430-04, UPC 635515992474.	Class II	Lot #s: C04866; C09863, Exp. 10/19; F01267, Exp. 12/19; F12609, Exp. 2/20; F25327, Exp. 8/20.	cGMP Deviations: Firm was notified by their supplier of Cetirizine HCL Oral Solution, USP, 1mg/mL, 4oz, of the voluntary recall that they have initiated due to potential contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	P & L Developments, LLC
Drugs	Cetirizine Oral Solution 1 mg/mL, Up & Up, Children's allergy relief, Antihistamine, Dye Free, Grape Flavor, 4 FL. oz. (118 mL) Bottle, Distributed by Target Corporation, Minneapolis, MN	Class II	Lot #s: A98495; C03882; A49664, Exp. 5/19; C06541, Exp. 6/19; C05532; F00527, Exp. 10/19; F00528; F07279, Exp. 12/19; F07842; F10237, Exp. 2/20.	cGMP Deviations: Firm was notified by their supplier of Cetirizine HCL Oral Solution, USP, 1mg/mL, 4oz, of the voluntary recall that they have initiated due to potential contamination	P & L Developments, LLC

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	55403, NDC 11673-178-04, UPC 359726178044.			with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	
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)00304092776 028.	Class II	Lot #s: 86-615-KL, Exp. 1FEB2020; 87-701-KL, Exp. 1MAR2020; 90-114-KL, Exp. 1JUN2020	cGMP Deviations: Firm was notified by their supplier of Cetirizine HCL Oral Solution, USP, 1mg/mL, 4oz, of the voluntary recall that they have initiated due to potential contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	P & L Developments, LLC
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)00304092776 233.	Class II	Lot #s: 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.	Failed Impurities/Degradation Specifications	Teligent Pharma, Inc.
Drugs	Esterified Estrogens & Methyltestosterone Tablets, USP 0.625 mg/1.25	Class III	Lot #: HL05715, HL05815, Exp. 11/2017	Labeling: Label mix-up: Product secondary carton erroneously states 40mg	Akorn Inc

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	mg, 100-count bottles, Rx Only, Manufactured by: Amneal Pharmaceuticals of NY Hauppauge, NY 11788 Distributed by: Seton Pharmaceuticals Manasquan, NJ 08736, NDC 13925-171-01			instead of 30 mg, primary carton is label correctly.	
Drugs	Esterified Estrogens & Methyltestosterone Tablets, USP 1.25 mg/2.5 mg, 100-count bottles, Rx Only, Manufactured by: Amneal Pharmaceuticals of NY Hauppauge, NY 11788 Distributed by: Seton Pharmaceuticals Manasquan, NJ 08736, NDC 13925-172-01	Class III	Lot #: HL06015, HL06115, Exp. 10/2017	Incorrect/undeclared excipients: Hand sanitizer was made using the wrong alcohol raw material.	Ecolab Inc
Drugs	Betamethasone Dipropionate Ointment USP, 0.05%* (Augmented), a) 15 gram (NDC 52565-019-15) and b) 50 gram (NDC 52565-019-51) tubed, Rx Only, Manufactured by: Teligent Pharma, Inc. Buena, New	Class III	Lot 11852, exp date 08/2020	Presence of Particulate Matter; glass particulates	Fresenius Kabi USA, LLC

Product Type	Product Description	Classification	Code Info	Reason For Recall	Recalling Firm
	Jersey 06310				
Drugs	Myorisan (isotretinoin capsules, USP), 40 mg, packaged in cartons of 30 Capsules containing 3 x 10 Prescription Packs, Rx Only, Distributed by: VersaPharm Inc. - An Akorn Company, Lake Forest, IL 60045, NDC 61748-304-13	Class III	Lot#: V30M56A, Exp 9/20	Lack of Assurance of Sterility: Bags have the potential to leak.	Pfizer Inc.
Drugs	QUIK-CARE Aerosol Foam Hand Sanitizer (62.5% Ethyl Alcohol), packaged in 7 oz cans, Ecolab, 370 Wabasha Street N, St. Paul, MN 55102-1390 USA, NDC 47593-490-82	Class III	Lot #: C040591, Exp 4/21	Lack of Assurance of Sterility: Bags have the potential to leak.	Pfizer 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, Manufactured by: Lupin Limited,	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
	Pithampur (M.P.) 454 775, India, NDC 68180-435-01.				

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

CURRENT DRUG SHORTAGES

Methocarbamol Tablets

June 25, 2019

Reason for the Shortage

- Bayshore states the shortage is due to increased demand.
- Hikma and Endo did not provide a reason for the shortage.
- Camber states the shortage is due to an API shortage.
- Par discontinued methocarbamol tablets in July 2018.
- Solco states the shortage is due to an API shortage.
- 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.
- Hikma has methocarbamol 500 mg and 750 mg tablets in 100 and 500 count on back order and the company cannot estimate a release date.
- Solco has methocarbamol 750 mg tablets in 100 count on allocation.
- 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

Polyvinyl Alcohol (Artificial Tears) Ophthalmic Solution

June 26, 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 has polyvinyl alcohol 1.4% ophthalmic solution available.
- 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.

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

Iopamidol Injection

June 26, 2019

Reason for the Shortage

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

Estimated Resupply Dates

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

76%) in 150 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

Hydroxyprogesterone Caproate Injection

June 26, 2019

Reason for the Shortage

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

Estimated Resupply Dates

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

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

Bisacodyl Suppositories

June 26, 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 all bisacodyl suppositories on back order. The company estimates a release date of mid-July 2019 for the 12 count presentation and mid-August 2019 for the 50 count presentation.
- 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

Ranitidine Injection

June 27, 2019

Reason for the Shortage

- Teligent has Zantac IV on shortage due to production delays.
- Zydus has ranitidine injection available.
- Mylan refuses to provide availability updates.

Estimated Resupply Dates

- Teligent has all Zantac injection presentations 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=426

Prochlorperazine Maleate Tablets

June 27, 2019

Reason for the Shortage

- Cadista had prochlorperazine maleate tablets on shortage due to increased demand.[1]
- Mylan refuses to provide availability updates.[2]

Estimated Resupply Dates

- Cadista has prochlorperazine maleate 5 mg and 10 mg tablets available.[1]

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=549

Orphenadrine Citrate Injection

June 27, 2019

Reason for the Shortage

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

Estimated Resupply Dates

- 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

Nystatin Oral Suspension

June 27, 2019

Reason for the Shortage

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

Estimated Resupply Dates

- Akorn has nystatin 100,000 unit/mL suspension 60 mL and 473 mL bottles on back order and the company cannot estimate a release date.
- Pharmaceutical Associates, Inc. has all nystatin suspension presentations on intermittent back order and the company is allocating supplies as they become available.
- Precision Dose has all nystatin suspension presentations 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 and 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=500

Methotrexate Injection

June 27, 2019

Reason for the Shortage

- Accord has methotrexate injection on back order due to increased demand.[1]
- Fresenius Kabi has methotrexate injection available.[2]
- Mylan Institutional refuses to provide product availability.[3]
- Pfizer has methotrexate injection available.[4]
- Teva has methotrexate injection available.[5]
- Hikma has methotrexate injection available.[6]

Estimated Resupply Dates

- Teva has methotrexate 25 mg/mL 40 mL preservative-free vials on allocation. Check availability with wholesalers.[5]

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

Acetylcysteine Oral and Inhalation Solution

June 27, 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 4 mL and 30 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=43

Thrombin Topical Solution (Bovine)

June 28, 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 August 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

Rocuronium Injection

June 28, 2019

Reason for the Shortage

- Athenex has rocuronium available.
- AuroMedics did not provide a reason for the shortage.
- Fresenius Kabi has rocuronium available.
- Mylan Institutional refused to provide availability information.
- Pfizer has rocuronium on shortage due to manufacturing delays.
- Sagent has rocuronium available.
- Sandoz has rocuronium available.
- X-Gen has rocuronium available.

Estimated Resupply Dates

- AuroMedics has rocuronium 10 mg/mL 10 mL vials on intermittent back order and the company is releasing product as it becomes available.

- Pfizer has rocuronium 10 mg/mL 5 mL and 10 mL vials available in limited supply.

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

Diphenhydramine Injection

June 28, 2019

Reason for the Shortage

- Fresenius Kabi has diphenhydramine injection available.[1]
- Hikma did not provide a reason for the shortage.[2]
- Mylan refuses to provide availability information.[3]
- Pfizer has diphenhydramine injection on shortage due to manufacturing delays.[4]

Estimated Resupply Dates

- Pfizer has diphenhydramine 50 mg/mL 1 mL vials on back order and the company estimates a release date of August 2020.[4]
- Fresenius Kabi has short-dated diphenhydramine 50 mg/mL 1 mL Simplist syringes available with an expiration date of <9 months.[1

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

Sterile Water for Injection – Small Volume Vials

July 1, 2019

Reasons for the Shortage

- American Regent has sterile water for injection available.
- Fresenius Kabi had sterile water on shortage due to increased demand.
- Hikma has sterile water for injection available.
- Pfizer had sterile water for injection in vials on shortage due to increased demand.

Estimated Resupply Dates

- Fresenius Kabi has sterile water for injection 100 mL vials on back order and the company estimates a release date of mid- to late-August 2019.

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

Metoclopramide Injection

July 1, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

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

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

Mannitol Injection

July 1, 2019

Reasons for the Shortage

- American Regent is not currently marketing mannitol.
- Baxter did not provide a reason for the mannitol shortage.
- BBraun has mannitol 500 mL premixed bags available. The 250 mL premixed bags were discontinued.
- Fresenius Kabi had mannitol on shortage due to increased demand.

- Pfizer has mannitol on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has mannitol 250 mg/mL 50 mL vials 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=341

Furosemide Injection

July 1, 2019

Reasons 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

- Fresenius Kabi has furosemide 10 mg/mL 2 mL vials on back order and the company estimates a release date of late-July 2019.
- 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

Pantoprazole Injection

July 2, 2019

Reasons for the Shortage

- AuroMedics did not provide a reason for the shortage.
- 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 on back order and the company estimates a release date of July 2019. There are short-dated 40 mg vials in 25 count available in limited supply with an expiration date of November 2019.

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

Ciprofloxacin Oral Suspension

July 2, 2019

Reasons for the Shortage

- Lupin did not provide a reason for the shortage.
- Bayer has Cipro oral suspension available.

Estimated Resupply Dates

- Lupin has ciprofloxacin oral suspension 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=255

Aspirin Suppositories

July 2, 2019

Reasons for the Shortage

- Perrigo did not provide a reason for the shortage.

Estimated Resupply Dates

- Perrigo has aspirin 300 mg suppositories on back order and the company estimates a release date of mid-July 2019. The 600 mg suppositories are on back order and the company estimates a release date of late-July 2019.

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

Tacrolimus Capsules

July 3, 2019

Reasons for the Shortage

- Accord has tacrolimus on allocation due to raw ingredient shortage.
- 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 did not provide a reason for the shortage.
- Astellas has Prograf 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.
- 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-June 2019. The 1 mg capsules are on back order and the company cannot estimate a release date.
- Sandoz has tacrolimus 0.5 mg, 1 mg, and 5 mg capsules on back order with an estimated release date of early- to mid-July 2019.
- Strides has short-dated tacrolimus 1 mg capsules available with an expiration date of April 2020.

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

Prednisolone Acetate 1% Ophthalmic Suspension

July 3, 2019

Reasons 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

Meropenem Injection

July 3, 2019

Reasons 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

Hypromellose Ophthalmic Solution

July 3, 2019

Reasons for the Shortage

- Akorn has hypromellose ophthalmic solution on shortage due to lack of raw materials.1
- HUB Pharmaceuticals has hypromellose ophthalmic solution on long-term back order and did not provide a reason.2
- Altaire did not provide a reason for the shortage.[3]
- OcuSoft has Goniosoft available.[4]

Estimated Resupply Dates

- Akorn has Gonak 2.5% ophthalmic solution 15 mL bottles on back order and the company estimates a release date in mid-July 2019.1
- 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]

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

Hepatitis B Vaccine (Recombinant)

July 3, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

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

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

Hepatitis A Virus Vaccine Inactivated

July 3, 2019

Reasons for the Shortage

- Merck has Vaqta available.
- Merck discontinued Vaqta adult formulation 50 U/1 mL vials in 1 count in January 2019.
- GlaxoSmithKline has Havrix available.
- GlaxoSmithKline discontinued the Havrix pediatric vials in March 2019. The Havrix adult vials were discontinued in November 2017.

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

Daptomycin Injection

July 3, 2019

Reasons 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 has 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.
- Sagent has daptomycin in 1 count and 10 count on allocation.

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

Cefuroxime Sodium Injection

July 5, 2019

Reasons for the Shortage

- Sagent has 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 back order and the company estimates a release date of July 2019.

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

Cefoxitin Sodium Injection

July 5, 2019

Reasons 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- to late-August 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 mid-July to early-August 2019.
- Sagent has cefoxitin 1 gram and 2 gram vials on back order and the company estimates a release date of July 2019. The 10 gram vials are on back order and the company estimates a release date of July 2019.
- WG Critical Care has cefoxitin 1 gram, 2 gram, and 10 gram vials on intermittent back order and the company is releasing supplies as they become available.

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

Amiodarone Injection

July 5, 2019

Reasons 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.
- Fresenius Kabi has amiodarone 50 mg/mL 9 mL vials on back order and the company estimates a release date of early-August 2019.
- 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

Acetazolamide Injection

July 5, 2019

Reasons 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

Vitamin K (Phytonadione) Injection

July 8, 2019

Reasons for the Shortage

- Pfizer had vitamin K injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- All marketed presentations are available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=566

Copper Chloride Injection

July 8, 2019

Reasons 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

Yellow Fever Vaccine

July 9, 2019

Reasons for the Shortage

- Sanofi Pasteur states the shortage of YF-Vax is due to production delays. [1]
- There are no other suppliers of yellow fever vaccine.
- Additional information on the yellow fever shortage is available at http://wwwnc.cdc.gov/travel/news-announcements/yellow-fever-vaccine-shortage-2015.

Estimated Resupply Dates

- Sanofi Pasteur has YF-Vax multi-dose vials and single dose vials on back order and the company does not expect product to return to market in 2019.[1]
- FDA accepted an investigational new drug application in October 2016. This is for the importation of another yellow fever vaccine from France. The trade name of the imported product is Stamaril. The product information can be found at https://s3.amazonaws.com/filecache.drivetheweb.com/mr5str_sanofipasteur/202281/969800.pdf. The initial rollout began in April 2017. More information can be found at https://www.cdc.gov/mmwr/volumes/66/wr/mm6617e2.htm?s_cid=mm6617e2_w or at https://www.vaccineshoppe.com/index.cfm?fa=anon.content&n=YellowFever&title=.

- Stamaril is on allocation due to supply demand.[1]

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

Tirofiban Hydrochloride Injection

July 9, 2019

Reasons for the Shortage

- Medicure Pharma has Aggrastat on shortage due to an interruption at their third-party manufacturing site.

Estimated Resupply Dates

- Medicure Pharma has Aggrastat 5 mg/mL 100 mL premixed vials on back order and the company estimates a release date of fall 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=571

RimabotulintoxinB Intramuscular Injection

July 9, 2019

Reasons 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

Promethazine Injection

July 9, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Hikma has Phenergan 25 mg/mL 1 mL vials on back order and the company estimates a release date in August to September 2019.

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

Piperacillin and Tazobactam Injection

July 9, 2019

Reasons for the Shortage

- Apotex has piperacillin/tazobactam injection available.
- Athenex has piperacillin/tazobactam injection available.
- AuroMedics did not provide a reason for the shortage.
- Baxter has piperacillin/tazobactam injection available.
- Fresenius Kabi has piperacillin/tazobactam injection available.
- Mylan Institutional refuses to provide updated availability information.

- Pfizer has Zosyn single dose vials and piperacillin/tazobactam on shortage due to manufacturing delays.
- Sagent has piperacillin/tazobactam injection on shortage due to increased demand.
- Sandoz has piperacillin/tazobactam injection available.
- WG Critical Care has piperacillin/tazobactam injection available.
- Wockhardt has piperacillin/tazobactam injection available.
- X-Gen has piperacillin/tazobactam injection available.

Estimated Resupply Dates

- Auromedics has piperacillin/tazobactam 3.375 gram vials on intermittent back order and the company is releasing supplies as they become available.
- Pfizer has Zosyn 2.25 gram vials, 3.375 gram vials, 4.5 gram vials, and 40.5 gram vials on back order and the company estimates a release date of March 2020. The piperacillin/tazobactam 2.25 gram ADD-Vantage vials are on back order and the company estimates a release date of September 2019.
- Sagent has piperacillin/tazobactam 3.375 gram and 4.5 gram vials on back order and the company estimates a release date of August 2019. There are short-dated 2.25 gram vials available with an expiration date of October 2019.

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

Octreotide Injection

July 9, 2019

Reasons 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 500 mcg/mL 1 mL vials on back order and the company estimates a release date of late-August 2019.
- Hikma has octreotide 100 mcg/mL 1 mL vials, 200 mcg/mL 5 mL vials, and 1,000 mcg/mL 5 mL vials on back order and the company estimates a release date of mid-July 2019.
- 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.

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

Nitrofurantoin Oral Suspension

July 9, 2019

Reasons for the Shortage

- Amneal did not provide a reason for the shortage.
- Casper Pharma did not provide a reason for the Furadantin shortage.

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

Estimated Resupply Dates

- Amneal has nitrofurantoin oral suspension on intermittent back order and the company is releasing supplies as they become available.
- Casper has Furadantin oral suspension on back order and the company cannot estimate a release date.
- Teva has nitrofurantoin oral suspension on back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=433

Mupirocin Calcium 2% Nasal Ointment

July 9, 2019

Reasons for the Shortage

- GlaxoSmithKline states the shortage is due to manufacturing issues. GlaxoSmithKline is looking for an alternative supply source.[1]

Estimated Resupply Dates

- GlaxoSmithKline has Bactroban Nasal 2% Ointment in 1 gram tubes on long-term back order and the company cannot estimate a release date.[1]

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=148

Mupirocin Calcium 2% Cream

July 9, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- GlaxoSmithKline has Bactroban 2% cream in 15 gram and 30 gram sizes on long-term back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=162

Enalaprilat Injection

July 9, 2019

Reasons 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

July 9, 2019

Reasons 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 July 2019.

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

Dexmedetomidine Hydrochloride 100 mcg/mL Vials for Injection

July 9, 2019

Reasons 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 has dexmedetomidine vials available.
- Hikma has dexmedetomidine vials available.
- 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

- WG Critical Care has dexmedetomidine 100 mcg/mL 4 mL and 10 mL vials on intermittent back order and the company is releasing supplies as they become available.

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

Atropine Ophthalmic Solution

July 9, 2019

Reasons 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 1% atropine 15 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=514

Asparaginase Erwinia chrysanthemi

July 9, 2019

Reasons 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 cannot estimate a release date. There is a new process for ordering Erwinaze. Additional information regarding the new ordering process is available at www.erwinazesupply.com.

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

Amyl Nitrate Inhalation

July 9, 2019

Reasons 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 late-July to mid-August 2019.

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

Mineral Oil and Petrolatum Ophthalmic Ointment

July 10, 2019

Reasons for the Shortage

- Allergan states the shortage is due to production delays.
- Bausch Health has Soothe Night Time ointment available.
- Major did not provide a reason for the shortage.
- Alcon states the shortage is due to manufacturing issues.
- Perrigo discontinued Puralube ointment products in early-2019.
- Rugby discontinued Artificial Tears 3.5 gram tubes in January 2019.

Estimated Resupply Dates

- Alcon has Systane Nighttime ointment and Genteal PM ointment on back order and the company estimates a release date in late-July 2019.
- Allergan has Lacri-Lube SOP ointment 3.5 gram, and Lacri-Lube SOP ointment 7 gram tubes on back order and the company estimates a release date in late-July 2019.
- Major has Lubrifresh PM 3.5 gram tubes 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=435

Melphalan Injection

July 10, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Par has melphalan 50 mg vials on back order and the company cannot estimate a release date.
- Sagent has melphalan 50 mg vials on back order and the company cannot estimate a release date.

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

Lorazepam Tablets

July 10, 2019

Reasons for the Shortage

- Aurobindo refuses to provide availability information.
- 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.

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.

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

Hydroxyzine Pamoate Oral Capsules

July 10, 2019

Reasons for the Shortage

- Amneal did not provide a reason for the shortage.
- Mylan refuses to provide availability updates.
- Pfizer did not provide a reason for the shortage.
- Rising discontinued hydroxyzine pamoate capsules.
- Sandoz did not provide a reason for the shortage.
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates

- Amneal has all hydroxyzine pamoate capsules on back order and the company estimates a release date of late-August 2019.
- Pfizer has Vistaril 25 mg and 50 mg capsules in 100 count bottles on back order and the company estimates a release date of October 2019 for the 25 mg capsules and August 2019 for the 50 mg capsules.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=545

Heparin Sodium Premixed Bags

July 10, 2019

Reasons 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

- Fresenius Kabi has all heparin premixes on allocation.
- Pfizer has heparin 25,000 units/250 mL in 0.45% sodium chloride premixed bags on back order and the company estimates a release date of July 2019. Heparin 1,000 units/500 mL 0.9% sodium chloride premixed bags are available in limited on back order and the company estimates a release date of July 2019.

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

Bivalirudin Injection

July 10, 2019

Reasons for the Shortage

- Accord has temporarily discontinued bivalirudin.
- Apotex has discontinued bivalirudin.
- AuroMedics did not provide a reason for the shortage.
- Baxter has 250 mg/50 mL bivalirudin premixed bags available. The company is not actively producing the 500 mg/100 mL bags due to low demand.
- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has bivalirudin on shortage due to manufacturing delays.
- Sandoz did not provide a reason for the shortage.

Estimated Resupply Dates

- AuroMedics has bivalirudin 250 mg vials on allocation.
- Pfizer has bivalirudin 250 mg vials available in limited supply. The 250 mg ADD-Vantage 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=569

Progesterone Injection

July 11, 2019

Reasons for the Shortage

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

- Teva did not provide a reason for the shortage.

Estimated Resupply Dates

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

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

Midodrine Tablets

July 11, 2019

Reasons for the Shortage

- Impax discontinued midodrine tablets in July 2018.
- Mylan refuses to provide availability updates.
- Sandoz discontinued midodrine tablets in mid-2018.
- Upsher-Smith has midodrine tablets on allocation due to increased demand.

Estimated Resupply Dates

- Upsher-Smith has midodrine 5 mg tablets on allocation.

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

Metronidazole Hydrochloride Injection

July 11, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Baxter has metronidazole 100 mL bags (NDC 36000-0001-24) on back order and the company cannot estimate a release date.

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

Metoprolol Injection

July 11, 2019

Reasons for the Shortage

- Alvogen has metoprolol injection available.[1]
- American Regent is not currently marketing metoprolol injection.[2]
- Athenex has metoprolol injection available.[3]
- Baxter has metoprolol injection available.[4]
- Fosun Pharma has metoprolol injection available.[5]
- Fresenius Kabi had metoprolol injection on shortage due to increased demand.[6]
- Mylan Institutional acquired metoprolol injection from Sagent. They discontinued metoprolol injection in March 2018.[7]
- Pfizer has metoprolol injection on shortage due to manufacturing delays.[8]
- Hikma did not provide a reason for the shortage.[9]

Estimated Resupply Dates

- Hikma has metoprolol 1 mg/mL 5 mL vials on back order and the company estimates a release date of late-August 2019. The 5 mL vials are on back order and the company estimates a release date of late-July to early-August 2019.[9]
- 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.[8]

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

Lidocaine Injection

July 11, 2019

Reasons 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 late-July 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.
- Hikma has 1% lidocaine 5 mL vials on back order and the company estimates a release date of mid-July 2019. The 2% lidocaine 5 mL vials are on back order and the company estimates a release date of mid-July 2019.
- 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 September 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 July 2019. The 2% lidocaine 20 mL vials are available in limited supply. The 2% lidocaine 5 mL Lifeshield syringes are on back order and the company estimates a release date of September 2019. The 2% lidocaine 5 mL Ansyr syringes 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=88

Labetalol Injection

July 11, 2019

Reasons for the Shortage

- Akorn did not provide a reason for the shortage.[1]
- Alvogen did not provide a reason for the shortage.[2]
- Pfizer has labetalol injection on shortage due to manufacturing delays.[3]
- Hikma has labetalol injection on shortage due to increase demand.[4]

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.[1]
- Alvogen has labetalol 5 mg/mL 20 mL vials on allocation.[2]
- 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.[4]
- 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 on back order and the company estimates a release date of July 2019.[3]

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

Potassium Acetate Injection

July 15, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Pfizer has potassium acetate 2 mEq/mL 20 mL and 50 mL vials available in limited supply.

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

Mycophenolate Mofetil Capsules and Tablets

July 15, 2019

Reasons for the Shortage

- Accord did not provide a reason for the shortage.
- Ascend did not provide a reason for the shortage.
- Hikma did not provide a reason for the shortage.
- Mylan refuses to provide updated availability information.
- Genentech has Cellcept available.
- Sandoz did not provide a reason for the shortage.

Estimated Resupply Dates

- Accord has all mycophenolate mofetil presentations on allocation.
- Ascend has all mycophenolate mofetil presentations on intermittent back order and the company is releasing product as it becomes available.

- Hikma has mycophenolate mofetil 250 mg capsules in 100 count and 500 count and 500 mg tablets in 100 count and 500 count on allocation.
- Sandoz has mycophenolate mofetil 250 mg capsules in 1,440 count are on back order and the company cannot estimate a release date.

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

Morphine Injection

July 15, 2019

Reasons for the Shortage

- Fresenius Kabi procured morphine syringes from BD in 2016. They discontinued the 8 mg/mL and 10 mg/mL 1 mL syringes in early-2018.[1-2]
- Astramorph injection has been unavailable since 2012. Fresenius Kabi changed manufacturing sites and cannot estimate if Astramorph will return.[2]
- Pfizer 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.[3]
- Hikma did not provide a reason for the shortage.[4]
- Piramal Critical Care has Mitigo 10 mg/mL 20 mL and 25 mg/mL 20 mL vials available.[5]

Estimated Resupply Dates

- Fresenius Kabi has morphine 4 mg/mL 1 mL syringes on back order and the company estimates a release date of mid-July 2019. The 5 mg/mL 1 mL syringes 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 early-August 2019. Check wholesalers for inventory.[2]
- Pfizer has morphine 0.5 mg/mL 10 mL preservative-free vials available in limited supply. The 1 mg/mL 10 mL preservative-free vials are available in limited supply. The 2 mg/mL 1 mL iSecure syringes, 4 mg/mL 1 mL iSecure syringes, and 8 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 November 2019. The 10 mg/mL 1 mL iSecure syringes and 10 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of September 2019. The 25 mg/mL 1 mL preservative-free vials are on back order and the company estimates a release date of March 2020. The 50 mg/mL 20 mL vials are on back order and the company estimates a release date of August 2019.[3]

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

Mepivacaine Injection

July 15, 2019

Reasons for the Shortage

- Fresenius Kabi has Polocaine available.
- Pfizer states the reason for the shortage is manufacturing delays.

Estimated Resupply Dates

- Pfizer has 2% Carbocaine 20 mL preservative-free vials, 2% Carbocaine 50 mL multiple-dose vials, 1% Carbocaine 30 mL preservative-free vials, 1% Carbocaine 50 mL multiple-dose vials, and 1.5% Carbocaine 30 mL preservative-free vials on back order and the company estimates a release date of March 2020.

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

Melphalan Tablets

July 15, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Apo-Pharma has melphalan 2 mg tablets available.
- Alvogen has melphalan 2 mg tablets available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=472

Lorazepam Injection

July 15, 2019

Reasons for the Shortage

- Bedford discontinued lorazepam injection in May, 2011.[1]
- Hikma has product on shortage due to manufacturing delays.[2]
- Pfizer has product on shortage due to increased demand and manufacturing delays. Pfizer discontinued 4 mg/mL 10 mL vials in December 2017.[3]
- Akorn has not provided a reason for the shortage.[4]
- Amphastar has product available.[5]

Estimated Resupply Dates

- Hikma has lorazepam 4 mg/mL 1 mL vials on back order and the company estimates a release date of mid-July 2019.[2]
- 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.[3]

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

Leucovorin Calcium Injection

July 15, 2019

Reasons 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 vials on back order and the company estimates a release date of mid-July 2019. There are short-dated 10 mg/mL 50 mL vials available with an expiration date of <9 months.
- Hikma has leucovorin 50 mg and 200 mg vials on back order and the company estimates a release date of mid-July 2019. The 200 mg vials are on back order and the company estimates a release date

of late-July to early-August 2019. The 350 mg vials are on allocation. There are short-dated 100 mg vials available with an expiration date of April 2020.

- 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

Immune Globulin, Intravenous or Subcutaneous (Human)

July 15, 2019

Reasons for the Shortage

- CSL Behring has Hizentra and Privigen on shortage due to increased demand.[2]
- Grifols has Gamunex-C and Flebogamma on shortage due to increased demand.[3]
- Kedrion Biopharma has Gammaked available to current customers.[4]
- Octapharma has Octagam on shortage due to increased demand.[5]
- Takeda has HyQvia, Cuvitru, and Gammagard on shortage due to increased demand.[6]

Estimated Resupply Dates

- ADMA Biologics received approval on April 1, 2019 for Asceniv (immune globulin intravenous, human - slra) 10% liquid. The company also recently received approval for Bivigam intravenous immune globulin. The company cannot estimate a launch date but hope to have both products launched sometime in 2019.[1]
- CSL Behring is releasing Hizentra and Privigen regularly and wholesalers are allocating product.[2]
- Grifols has all Gamunex-C and Flebogamma presentations on intermittent back order and the company is releasing product as it becomes available.[3]
- Grifols received approval on July 3, 2019 for Xembify (immune globulin subcutaneous, human - klhw) 20% solution. The company cannot estimate a launch date.[3]
- Octapharma has all Octagam presentations on allocation.[5]
- Takeda has Cuvitru and HyQvia on allocation and the company is reviewing all orders.[6]
- Takeda has all Gammagard Liquid presentations on intermittent back order and the company is allocating product as it becomes available.[6]
- ADMA Biologics received approval on April 1, 2019 for Asceniv (immune globulin intravenous, human - slra) 10% liquid. The company cannot estimate a launch date.

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

Hydromorphone Hydrochloride Injection

July 15, 2019

Reasons for the Shortage

- Akorn has hydromorphone injection on shortage due to increased demand.[1]
- Fresenius Kabi has Dilaudid syringes on shortage due to increased demand. They are focusing their product on the 0.5 mg strength. They launched hydromorphone vials in late-June 2018.[2]
- Pfizer did not provide a reason for the shortage.[3]
- Purdue discontinued Dilaudid and Dilaudid HP in May 2017 for marketing reasons.[4]
- Teva did not provide a reason for the shortage.[5]
- Hikma did not provide a reason for the shortage.[6]

Estimated Resupply Dates

- Fresenius Kabi has Dilaudid 2 mg/mL 1 mL syringes on back order and the company cannot estimate a release date. The hydromorphone 1 mg/mL 1 mL vials are on back order and the company estimates a release date of mid-July 2019. The hydromorphone 10 mg/mL 1 mL vials are on back order and the company estimates a release date of late-July to early-August 2019. The hydromorphone 10 mg/mL 50 mL vials are on back order and the company estimates a release date of mid- to late-August 2019. Check wholesalers for inventory.[2]
- Pfizer has 2 mg/mL 1 mL vials available in limited supply. The 10 mg/mL 1 mL, 5 mL, and 50 mL vials are on back order and the company estimates a release date of July 2019. 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 July 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 December 2019.[3]

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

Diazepam Injection

July 15, 2019

Reasons 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

Degarelix Acetate Injection

July 15, 2019

Reasons for the Shortage

- Ferring did not provide a reason for the shortage.

Estimated Resupply Dates

- Ferring has Firmagon 80 mg and 120 mg vials available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=560

Carisoprodol Tablets

July 15, 2019

Reasons for the Shortage

- Cadista discontinued carisoprodol tablets.
- Endo Pharmaceuticals discontinued carisoprodol tablets.
- Mylan discontinued generic carisoprodol tablets. Mylan refuses to provide availability information for Soma.
- Rising discontinued carisoprodol tablets.

Estimated Resupply Dates

- Teva has all presentations temporarily unavailable and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=558

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

Aminophylline Injection

July 15, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Pfizer has aminophylline 25 mg/mL 20 mL vials on back order and the company estimates a release date of March 2020.

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

5% Lidocaine and 7.5% Dextrose Injection

July 15, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

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

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

Vancomycin Hydrochloride Injection

July 16, 2019

Reasons 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.[10]

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 750 mg 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 July 2019. The 5 gram vials are available in limited supply.[4]

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

Sodium Bicarbonate Injection

July 16, 2019

Reasons for the Shortage

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

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-July 2019. The 4.2% sodium bicarbonate 5 mL vials are on back order and the company estimates a release date of late-July 2019.[3]
- Pfizer has 8.4% sodium bicarbonate 10 mL syringes available in limited supply. 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.[2]
- Pfizer has Neut 4% 5 mL vials on back order and the company estimates a release date of December 2019.[2]

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

Ketorolac Injection

July 16, 2019

Reasons for the Shortage

- Alvogen did not provide a reason for the shortage.[1]
- Amphastar did not provide a reason for the shortage.[2]
- Athenex has ketorolac available.[3]
- BD RX is now part of Fresenius Kabi.[4]
- Fresenius Kabi has most ketorolac presentations available.[5]
- Fosun Pharma has ketorolac available.[9]
- Pfizer has ketorolac injection on back order due to manufacturing delays.[6]
- Sagent states the reason for the shortage is manufacturing delay.[7]
- Hikma did not provide a reason for the shortage.[8]
- Ben Venue closed its plant in Bedford, Ohio in July 2014.[10]
- Virtus discontinued ketorolac in March 2019.[11]
- FDA imposed an import ban in mid-2013 on several Wockhardt products including ketorolac.[12]

- Sprix Nasal Spray is not affected by this shortage.[13]

Estimated Resupply Dates

- Alvogen has ketorolac 30 mg/mL 1 mL vials and 2 mL vials on back order and the company estimates a release date of mid-July 2019.1
- Amphastar has ketorolac 30 mg/mL 1 mL vials on back order and the company cannot estimate a release date.[2]
- 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 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.[5]
- Hikma has all ketorolac presentations on back order and the company cannot estimate a release date.[8]
- Pfizer has ketorolac 30 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of September 2019. 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 July 2019.[6]
- Sagent has ketorolac 15 mg/mL 1 mL vials, 30 mg/mL 1 mL vials, and 30 mg/mL 2 mL vials for intramuscular injection on back order and the company estimates a release date of October 2019.[7]

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

Heparin Injection

July 16, 2019

Reasons 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 late-July to early-August 2019. The 5,000 unit/mL 1 mL syringes are on back order and the company estimates a release date of mid-August 2019. The 10,000 unit/mL 4 mL vials are on back order and the company cannot estimate a release date. There are short-dated 20,000 unit/mL 1 mL vials available with an expiration date of < 7 months. 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 and 1,000 unit/mL 30 mL glass vials on back order and the company estimates a release date of July 2019. The 1,000 unit/mL 10 mL vials are on back order and the company estimates a release date of November 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 are available in limited supply. The 5,000 unit/mL 10 mL vials are on back order and the company estimates a release date of October 2019.

- Sagent has 1,000 unit/mL 1 mL, 2 mL, and 10 mL vials on back order and the company estimates a release date of July 2019. The 1,000 unit/mL 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 July 2019. The 10,000 unit/mL 1 mL and 4 mL vials are on back order and the company estimates a release date of July 2019. There are short-dated 20,000 unit/mL 1 mL vials available with an expiration date of

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

Fluticasone and Salmeterol Powder for Inhalation

July 16, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Teva Respiratory has AirDuo Respiclick available.
- Teva Respiratory has fluticasone and salmeterol available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=544

Cefazolin Injection

July 16, 2019

Reasons 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 500 mg vials on back order and the company estimates a release date of mid-August 2019. The 10 gram vials are on back order and the company estimates a release date of 4th quarter 2019.
- Hikma has cefazolin 1 gram and 10 gram vials on allocation.

- 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 500 mg and 1 gram vials on intermittent back order and the company will release product on a monthly basis. The 10 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

Tuberculin

July 17, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Par has Aplisol 5 mL vials on back order and the company cannot estimate a release date. The 1 mL vials are on allocation.
- 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

Sufentanil Injection

July 17, 2019

Reasons 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 July 2019.

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

Spironolactone Tablets

July 17, 2019

Reasons for the Shortage

- Accord and Sun Pharma did not provide a reason for the shortage.
- Amneal and Cadista have spironolactone tablets available.
- Mylan refuses to provide updated availability information.
- Par discontinued spironolactone tablets in August 2018.
- Pfizer has Aldactone available.

Estimated Resupply Dates

- Accord has spironolactone 50 mg tablets in 500 count on back order and the company estimates a release date in mid-July 2019.

- Sun Pharma has spironolactone 25 mg tablets in 100 and 1000 count, 50 mg tablets in 60 and 500 count, and 100 mg in 100 count on back order and the company cannot estimate a release date.

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

Rosuvastatin Calcium Tablets

July 17, 2019

Reasons for the Shortage

- Accord, Biocon, Rising, and Sandoz did not provide a reason for the shortage.
- Apotex has discontinued production of all rosuvastatin presentations.
- Aurobindo refuses to provide updated availability information.
- Camber, Glenmark, and Sandoz have rosuvastatin presentations available.
- Mylan has discontinued all rosuvastatin presentations.
- Sun Pharma is discontinuing production of all rosuvastatin presentations.

Estimated Resupply Dates

- Accord has rosuvastatin 10 mg tablets in 1,000 count bottles on back order and the company estimates a release date of late-July 2019.
- Biocon has rosuvastatin 40 mg tablets in 30 count bottles on back order and the company cannot estimate a release date.
- Rising has rosuvastatin 5 mg tablets in 90 count bottles on back order and the company cannot estimate a release date. All other rosuvastatin presentations are on allocation.

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

Prednisone Oral Tablets

July 17, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Hikma has all prednisone presentations, except 2.5 mg tablets in 100 count bottles, on allocation. The 2.5 mg tablets in 100 count bottles are available.
- Teva has prednisone 5 mg and 10 mg tablets in 24 count and 48 count unit-dose packs on back order and the company estimates a release date of late-July 2019. The 10 mg tablets in 100 count and 500 count sizes are on back order and the company estimates a release date of early-August 2019. The 10 mg tablets in 1,000 count bottles are on back order and the company estimates a release date of late-July 2019. The 20 mg tablets in 100 count bottles are on back order and the company estimates a release date of early-August 2019. The 20 mg tablets in 500 count bottles are on back order and the company estimates a release date of mid-October 2019. The 20 mg tablets in 1,000 count bottles are on back order and the company estimates a release date of mid-July 2019.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=563

Midazolam Injection

July 17, 2019

Reasons for the Shortage

- Athenex did not provide a reason for the shortage.
- Fresenius Kabi has midazolam injection on back order due to increased demand.
- Hikma has midazolam injection available.
- Pfizer has midazolam injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Akorn has short-dated midazolam 5 mg/mL 10 mL vials.
- Athenex has midazolam 5 mg/mL 5 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has midazolam 1 mg/mL 10 mL vials on back order and the company cannot estimate a release date. There are short-dated midazolam 5 mg/mL 5 mL vials available with an expiration date of <1 month. There are short-dated midazolam 5 mg/mL 10 mL vials and 1 mL fill in 2 mL vials available with expiration dates of <9 months.
- Pfizer has midazolam 1 mg/mL 2 mL Carpuject syringes, 1 mg/mL 2 mL iSecure syringes, and 5 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=576

Losartan Tablets

July 17, 2019

Reasons 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.
- Camber, Heritage, Teva, and Torrent been affected by the recall.
- Alembic has losartan tablets available.
- Aurobindo and Mylan refuse to provide updated availability information.
- Cadista states the reason for their shortage is issues with obtaining active ingredient.
- Camber has unaffected lots on allocation to contracted customers.
- Lupin, Rising, Sandoz, and Zydus did not provide a reason for the shortage.
- Major has losartan tablets in unit-dose packages available.
- Merck has Cozaar available.
- Torrent recalled several lots of losartan tablet presentations due to an impurity found in the active pharmaceutical ingredient. Additional information can be found at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium.
- Torrent has been unavailable to provide updated availability information.

Estimated Resupply Dates

- Cadista has losartan potassium tablets on back order and the company cannot estimate a release date.
- Camber has all losartan potassium tablets on allocation.
- Heritage has losartan potassium tablets on back order and the company cannot estimate a release date.
- Lupin has losartan potassium tablets on back order and the company cannot estimate a release date.
- Sandoz has losartan potassium tablets on back order and the company cannot estimate a release date.
- Teva has losartan potassium tablets on back order and the company cannot estimate a release date.
- Zydus has losartan potassium tablets on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=572

Levetiracetam Injection

July 17, 2019

Reasons 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 5 mg/mL 100 mL and 10 mg/mL 100 mL premixed bags on back order and the company estimates a release date of 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.
- Pfizer has levetiracetam 100 mg/mL 5 mL vials on back order and the company estimates a release date of August 2019.
- 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

Levetiracetam Immediate-Release Tablets

July 17, 2019

Reasons 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 levetiracetam 500 mg immediate-release tablets on back order and the company estimates a release date in late-July 2019.
- OWP has Roweepra immediate-release tablets on back order and the company cannot estimate a release date.
- Torrent has levetiracetam immediate-release tablets on allocation

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

Fluvastatin Capsules

July 17, 2019

Reasons for the Shortage

- Mylan refuses to provide updated availability information.
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates

- Teva has fluvastatin 20 mg and 40 mg capsules in 100 count 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=561

Exenatide Extended-Release Suspension for Injection

July 17, 2019

Reasons for the Shortage

- AstraZeneca has Bydureon BCise available.
- AstraZeneca has Bydureon Pen available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=548

Ethiodized Oil

July 17, 2019

Reasons for the Shortage

- Guerbet has Lipiodol injection available.[1]
- Guerbet has transferred the manufacturing of Lipiodol injection to the US. As of March 2019, Lipiodol Ultra-Fluide is no longer being imported.[1]
- Guerbet had Lipiodol injection in short supply due to manufacturing problems at Jubilant HollisterStier, the manufacturing site in Canada that supplies Lipiodol for Guerbet.[1-2]

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

Erythromycin Ophthalmic Ointment

July 17, 2019

Reasons 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 late-July 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

Cyclosporine Injection

July 17, 2019

Reasons 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 late-July 2019.

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

Ceftriaxone Sodium Injection

July 17, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Lupin has all ceftriaxone presentations on back order and the company cannot estimate a release date.
- Hikma has ceftriaxone 500 mg vials on back order and the company estimates a release date of July 2019. The 2 gram vials are on allocation.
- Sagent has ceftriaxone 500 mg vials on back order and the company estimates a release date of July 2019. The 2 gram and 10 gram vials are on allocation.

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

Cefepime Injection

July 17, 2019

Reasons 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 did not provide a reason for the shortage.
- Pfizer has Maxipime on shortage due to manufacturing delays.
- Sagent has cefepime injection on shortage due to increased demand.
- 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 2 gram premixed bags on back order and the company estimates a release date of mid-July 2019.
- Fresenius Kabi has cefepime 2 gram vials on back order and the company estimates a release date of mid-August 2019
- 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.
- Sagent has cefepime 2 gram vials on back order and the company estimates a release date of July 2019.

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

Ampicillin Sodium and Sulbactam Sodium Injection

July 17, 2019

Reasons for the Shortage

- AuroMedics has ampicillin sulbactam vials on back order due to increased demand and manufacturing delays.
- Pfizer has discontinued generic ampicillin sulbactam except for the 1.5 gram and 3 gram ADD-Vantage vials.
- Sagent has ampicillin sulbactam vials on back order due to manufacturing delays and increased demand.
- Sandoz cannot provide a reason for the shortage.

- WG Critical Care states the shortage is due to increased demand.
- Mylan Institutional refuses to provide availability information

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.
- Fresenius Kabi has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on long-term back order and the company cannot estimate a release date.
- Hikma has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on back order and the company cannot estimate a release date.
- Pfizer has Unasyn 1.5 gram, 3 gram, and 15 gram bulk vials are on back order and the company estimates a release date of September 2019. 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.
- Sandoz has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on long-term back order and the company cannot estimate a release date.
- Sagent has ampicillin sulbactam 1.5 gram vials, 3 gram vials, and 15 gram bulk vials on back order and the company cannot estimate a release date.
- WG Critical Care has ampicillin sulbactam 15 gram vials on back order and the company cannot estimate a release date.

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

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

July 17, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- ICU Medical has 0.9% sodium chloride 100 mL VisIV bags on intermittent back order and the company is releasing supplies as they become available. The 50 mL VisIV bags are available to contracted customers only.
- Pfizer has 0.9% sodium chloride 50 mL preservative-free vials in limited supply.

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

Griseofulvin Oral Presentations

July 18, 2019

Reasons for the Shortage

- Amneal did not provide a reason for the shortage.
- Rising did not provide a reason for the shortage

Estimated Resupply Dates

- Amneal has griseofulvin ultramicrocrystalline 125 mg tablets on back order and the company estimates a release date of late-August 2019.
- Rising has all griseofulvin presentations on back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=579

Fluconazole Injection

July 18, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Renaissance Lakewood has fluconazole 200 mg/100 mL in 0.9% sodium chloride 10 count premixes and 400 mg/200 mL in 0.9% sodium chloride 10 count premixes on back order and the company cannot estimate release dates.

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

Enoxaparin Sodium Injection

July 18, 2019

Reasons for the Shortage

- Amphastar has enoxaparin available.
- Apotex launched enoxaparin in early-2019.
- Fresenius Kabi has enoxaparin available.
- Sandoz discontinued enoxaparin presentations in mid-2018 due to a supplier issue.
- Sanofi-Aventis did not provide a reason for the shortage.
- Teva did not provide a reason for the shortage.
- Winthrop did not provide a reason for the shortage.

Estimated Resupply Dates

- Sanofi-Aventis has all Lovenox prefilled syringes on allocation.
- Teva has enoxaparin 60 mg/0.6 mL prefilled syringes on back order and the company is allocating product as it becomes available.

- Winthrop has all enoxaparin prefilled syringes on allocation.

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

Carbidopa and Levodopa Extended-Release Tablets

July 18, 2019

Reasons for the Shortage

- Accord has discontinued carbidopa and levodopa 25 mg/100 mg extended-release tablets. The 50 mg/200 mg tablets are on shortage due to problems obtaining active ingredient.
- Sun Pharma had carbidopa and levodopa extended-release tablets on shortage due to increased demand.
- Merck discontinued Sinemet CR in July 2019.
- Mylan refuses to provide availability information.

Estimated Resupply Dates

- Accord has carbidopa and levodopa 50 mg/200 mg extended-release tablets on allocation.
- Merck has Sinemet CR 25 mg/100 mg extended release tablets in 100 count bottles on back order and the company cannot estimate a release date.

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

Buprenorphine Hydrochloride Injection

July 18, 2019

Reasons 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

Vinblastine Sulfate Injecton

July 19, 2019

Reasons 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 vinblastine 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=578

Sodium Acetate Injection

July 19, 2019

Reasons 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 late-July to early-August 2019.
- Pfizer has sodium acetate 2 mEq/mL 20 mL and 50 mL vials available in limited supply. The 100 mL vials are on back order and the company estimates a release date of July 2019.

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

Lidocaine with Epinephrine Injection

July 19, 2019

Reasons 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-July to early-August 2019. The 1% Xylocaine with epinephrine (1:200,000) 20 mL vials are on back order and the company estimates release dates of late-July 2019. The 1% Xylocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates release dates of early-August 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 late-July to early-August 2019. The 2% Xylocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates a release date of early-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 available in limited supply. The 1% lidocaine with epinephrine (1:100,000) 20 mL vials are on back order and the company estimates a release date of July 2019. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are on back order and the company estimates a release date of July 2019. The 1% lidocaine with epinephrine (1:100,000) 50 mL vials are on back order and the company estimates a release date of July 2019. The 1.5% lidocaine with epinephrine (1:200,000) 30 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) 5 mL glass ampules 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 July 2019. The 2% lidocaine with epinephrine (1:100,000) 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) 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 available in limited supply.

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

Irbesartan Tablets

July 19, 2019

Reasons 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 marketing several presentations of 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.
- Hikma has irbesartan 150 mg tablets in 90 count bottles on back order and the company estimates a release date of mid-July 2019. Other irbesartan presentations are not currently being marketed.
- 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

Erythromycin Lactobionate Injection

July 19, 2019

Reasons for the Shortage

- Pfizer has Erythrocin on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Erythrocin 500 mg ADD-Vantage 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=247

Dopamine Hydrochloride Injection

July 19, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Pfizer has dopamine 40 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of September 2019 for the 5 mL vials and June 2020 for the 10 mL vials. The 400 mg/250 mL premixed bags are on back order and the company estimates a release date of September 2019. There are short-dated 800 mg/250 mL premixed bags available with an expiration date of September 2019.

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

Diltiazem Hydrochloride Injection

July 19, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Hikma has diltiazem 5 mg/mL 25 mL vials on allocation.
- Pfizer has 100 mg ADD-Vantage vials on back order and the company estimates a release date of August 2019. The 5 mg/mL 5 mL and 10 mL vials are also on back order and the company estimates a release date of March 2020 for the 5 mL vials and November 2019 for the 10 mL vials.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=26

Cyclosporine Capsules

July 19, 2019

Reasons for the Shortage

- Apotex has cyclosporine capsules available.
- Sandoz has discontinued cyclosporine (modified) capsules.
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates

- All marketed presentations are available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=476

Bupivacaine with Epinephrine Injection

July 19, 2019

Reasons 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 30 mL vials on back order and the company estimates a release date of early-August 2019. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of late-July

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

50% Dextrose Injection

July 19, 2019

Reasons 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 July 2019. The 50% dextrose 50 mL Ansyr syringes are on back order and the company estimates a release date of August 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

25% Dextrose Injection

July 19, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Pfizer has 25% dextrose 10 mL Ansyr syringes 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=483

14.6% Sodium Chloride Concentrated Solution for Injection

July 19, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Pfizer has 14.6% sodium chloride concentrated solution for injection 20 mL and 40 mL vials on back order and the company estimates a release date of March 2020 for the 20 mL vials and September 2019 for the 40 mL vials.

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

Thiamine Injection

July 22, 2019

Reasons for the Shortage

- Fresenius Kabi has thiamine injection on shortage due to short manufacturing delay.
- Mylan Institutional refuses to provide availability information.

Estimated Resupply Dates

- Fresenius Kabi has thiamine 100 mg/mL 2 mL vials available.

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

Ropivacaine Injection

July 22, 2019

Reasons 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.

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 late-July to early-August 2019. The 5 mg/mL 20 mL Steripak ampules are on back order and the company cannot estimate a release date. 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 September 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 October 2019.

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

Remifentanil Injection

July 22, 2019

Reasons for the Shortage

- Mylan Institutional refuses to provide availability information.
- Fresenius Kabi launched generic remifentanil in January 2018.

Estimated Resupply Dates

- Fresenius Kabi has all remifentanil presentations available.

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

Ranitidine Injection

July 22, 2019

Reasons for the Shortage

- Teligent has Zantac IV on shortage due to production delays.
- Zydus has ranitidine injection on shortage due to increased demand.
- Mylan refuses to provide availability updates.

Estimated Resupply Dates

- Zydus has ranitidine 25 mg/mL 2 mL and 6 mL vials on allocation.
- Teligent has all Zantac injection presentations 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=426

Potassium Phosphate Injection

July 22, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Pfizer has potassium phosphate 3 mmol/mL 15 mL vials available in limited supply.

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

Penicillamine

July 22, 2019

Reasons for the Shortage

- Mylan refuses to provide availability information.
- Bausch Health did not provide a reason for the shortage.

Estimated Resupply Dates

- Bausch Health has Cuprimine 250 mg capsules available.

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

Morphine Sulfate Immediate-Release Tablets

July 22, 2019

Reasons for the Shortage

- Hikma did not provide a reason for the shortage.

Estimated Resupply Dates

- Hikma has morphine 15 mg immediate-release tablets in 100 count unit-dose packages on allocation.

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

Meperidine Hydrochloride Injection

July 22, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Hikma has meperidine 100 mg/mL 1 mL vials on allocation.
- Pfizer has Demerol 100 mg/mL 20 mL vials and on back order and the company estimates a release date of June 2020. The 25 mg/mL 1 mL Carpuject syringes, 50 mg/mL 1 mL Carpuject syringes, and 50 mg/mL 1 mL ampules are on back order and the company estimates a release date of October 2020. The 75 mg/mL 1 mL Carpuject syringes and 100 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of March 2020. The 100 mg/mL 1 mL ampules 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=347

Letermovir Tablets

July 22, 2019

Reasons for the Shortage

- Merck did not provide a reason for the shortage.

Estimated Resupply Dates

- Merck has Prevymis 240 mg and 480 mg tablets in 14 count and 28 count available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=575

Letermovir Injection

July 22, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

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

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

Furosemide Tablets

July 22, 2019

Reasons for the Shortage

- Major discontinued furosemide tablets in early-2018.
- Mylan refuses to provide availability information.
- Hikma states the shortage is due to manufacturing delays.
- Sandoz discontinued furosemide tablets in late-August 2017.
- Teva discontinued furosemide tablets in June 2018.

Estimated Resupply Dates

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

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

Etomidate Injection

July 22, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Athenex has short-dated etomidate 2 mg/mL 10 mL and 20 mL vials available.
- AuroMedics has etomidate 2 mg/mL 10 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Hikma has short-dated etomidate 2 mg/mL 10 mL and 20 mL vials available with an expiration date of November 2019.
- Pfizer has Amidate 2 mg/mL 20 mL vials available in limited supply. The 2 mg/mL 20 mL LifeShield syringes on back order and the company estimates a release date of March 2020.
- Zydus has short-dated etomidate 2 mg/mL 10 mL and 20 mL vials available with an expiration date of

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=147

Doxycycline Hyclate Injection

July 22, 2019

Reasons for the Shortage

- Mylan Institutional refuses to provide availability information.
- Zydus has doxycycline injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Zydus has doxycycline 100 mg vials on back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=559

Doxorubicin Injection

July 22, 2019

Reasons for the Shortage

- Hikma did not provide a reason for the shortage of Adriamycin.[1]
- Teva had doxorubicin solution for injection on shortage due to increased demand. They discontinued doxorubicin presentations with NDCs starting in 00703 in early-January 2019.[2-3]
- Fresenius Kabi did not provide a reason for the shortage.[4]
- Caraco has discontinued doxorubicin solution for injection 25 mL and 100 mL vials.[5]
- Pfizer has doxorubicin on shortage due to manufacturing delays.[6]
- Sagent has doxorubicin available.[7]
- Mylan Institutional discontinued doxorubicin 10 mg lyophilized powder for injection in early 2019.[8]
- Athenex has doxorubicin available.[9]
- FDA was allowing temporary importation of doxorubicin lyophilized powder for injection 50 mg vials. These vials were manufactured for Hospira UK Limited. The labeling as well as bar coding for the imported product is different from the US version. FDA has the Dear Healthcare Professional Letter linked on their website. The letter includes a link to both the US and United Kingdom package inserts to help explain the differences in labeling and packaging. The link to the letter is http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM507498.pdf. Ordering can be done directly with Hospira Customer Care at 877-946-7747.[10-11]

Estimated Resupply Dates

- Hikma has short-dated Adriamycin 10 mg vials available with an expiration date of June 2020. The 2 mg/mL 100 mL vials are on back order and the company estimates a release date of late-August 2019.[1]
- Pfizer has short-dated doxorubicin 2 mg/mL 75 mL and 100 mL vials available in limited supply.[6]

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

Diphenhydramine Injection

July 22, 2019

Reasons for the Shortage

- Fresenius Kabi has diphenhydramine injection available.[1]
- Hikma did not provide a reason for the shortage.[2]
- Mylan refuses to provide availability information.[3]
- Pfizer has diphenhydramine injection on shortage due to manufacturing delays.[4]

Estimated Resupply Dates

- Pfizer has diphenhydramine 50 mg/mL 1 mL vials on back order and the company estimates a release date of August 2020.[4]

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

Dexamethasone Sodium Phosphate Injection

July 22, 2019

Reasons 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.

Estimated Resupply Dates

- AuroMedics has dexamethasone sodium phosphate 4 mg/mL 1 mL, 5mL, and 30 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has dexamethasone sodium phosphate 4 mg/mL 1 mL vials are on back order and the company estimates a release date of late-July 2019. The 4 mg/mL 30 mL vials are 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

Deferoxamine Injection

July 22, 2019

Reasons 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.
- Fresenius Kabi has deferoxamine 500 mg vials on back order and the company estimates a release date of late-July 2019.
- 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

Clonidine Hydrochloride Injection

July 22, 2019

Reasons 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

- Hikma has clonidine 0.5 mg/mL 10 mL vials on back order and the company cannot estimate a release date. The 0.1 mg/mL 10 mL vials are on back order and the company estimates a release date of late-July 2019.
- 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

July 22, 2019

Reasons 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 late-July 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 July 2019. The 0.25% bupivacaine 30 mL preservative-free vials are on back order and the company estimates a release date of August 2019. The 0.25% bupivacaine 50 mL vials are on back order and the company estimates release dates of August 2019. The 0.5% bupivacaine 10 mL preservative-free vials are on back order and the company estimates a release date of October 2019. The 0.5% bupivacaine 30 mL preservative-free vials are available in limited supply. 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 September 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 November 2019 for the 10 mL vials and January 2020 for the 30 mL vials. The 0.5% 50 mL vials are on back order and the company estimates a release date of October 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 April 2020 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

23.4% Sodium Chloride Injection

July 22, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has 23.4% sodium chloride 100 mL vials on back order and the company estimates a release date of late-July 2019. Check wholesalers for inventory.
- 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

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

July 22, 2019

Reasons for the Shortage

- Fresenius Kabi has recalled multiple lots of 0.9% sodium chloride 10 mL and 20 mL vials due to labels incorrectly stating the stoppers are latex-free. The letter and the lot numbers affected can be found at https://www.fresenius-kabi.com/us/news/fresenius-kabi-issues-voluntary-nationwide-recall-of-sodium.
- Pfizer had 0.9% sodium chloride preservative-free vials on shortage due to manufacturing delays.

Estimated Resupply Dates

- All marketed presentations are available.

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

Temazepam Capsules

July 23, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

- Ascend has temazepam 15 mg capsules in 100 count bottles on allocation. The 15 mg capsules in 500 count bottles and 30 mg capsules in 100 and 500 count bottles are on back order and the company

estimates release dates of late-July 2019 for the 30 mg in 100 count bottles and mid-August 2019 for the 15 mg and 30 mg in 500 count bottles.

- Major has temazepam 7.5 mg capsules in 30 count bottles available in limited supply. The 7.5 mg capsules in 100 count bottles are on back order and the company estimates a release date in late-July 2019.
- Teva has temazepam 30 mg capsules in 500 count on back order and the company estimates a release date in early-August 2019.

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

Olanzapine Intramuscular Injection

July 23, 2019

Reasons for the Shortage

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

Estimated Resupply Dates

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

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

Nicardipine Hydrochloride Injection

July 23, 2019

Reasons for the Shortage

- Hikma has nicardipine vials available.
- Mylan refuses to provide availability information.
- Chiesi did not provide a reason for the shortage.
- Chiesi discontinued Cardene 40 mg/200 mL in 5% dextrose premixed bags in mid-2019.

Estimated Resupply Dates

- Chiesi has all Cardene IV premixed bags on allocation via drop shipment through wholesaler.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=574

Methyldopa Tablets

July 23, 2019

Reasons for the Shortage

- Accord has methyldopa tablets available.
- Mylan refuses to provide availability information.
- Teva discontinued methyldopa tablets in 2018.

Estimated Resupply Dates

- Accord has methyldopa 250 mg tablets in 500 count on back order and the company estimates a release date of late-August 2019. The 500 mg tablets in 500 count are on back order and the company estimates a release date of late-July 2019.

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

Losartan and Hydrochlorothiazide Tablets

July 23, 2019

Reasons 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.
- Alembic did not provide a reason for the shortage.
- Aurobindo refused to provide updated availability information
- Cadista did not provide a reason for the shortage.
- Lupin did not provide a reason for the shortage.
- Merck has Hyzaar tablets available.
- Rising did not provide a reason for the shortage.
- Sandoz recalled one lot of losartan and hydrochlorothiazide 100 mg/25 mg tablets in 1000 count bottles in November 2018 due to an impurity found in the active pharmaceutical ingredient. Additional information can be found at https://www.fda.gov/Safety/Recalls/ucm625492.htm.
- Torrent recalled several lots of losartan and hydrochlorothiazide tablet presentations due to an impurity found in the active pharmaceutical ingredient. Additional information can be found at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium.
- Torrent has losartan and hydrochlorothiazide tablets available in all presentations (from lots unaffected by the recall).
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates

- Alembic has losartan and hydrochlorothiazide tablets on allocation to contracted customers
- Cadista has losartan and hydrochlorothiazide tablets on back order and the company cannot estimate a release date.
- Lupin has losartan and hydrochlorothiazide tablets on back order and the company cannot estimate a release date.
- Rising has losartan and hydrochlorothiazide tablets on back order and the company cannot estimate a release date.
- Sandoz has losartan and hydrochlorothiazide tablet presentations on back order and the company cannot estimate a release date.
- Teva has all losartan and hydrochlorothiazide tablets on back order and the company estimates release dates in late-September 2019.

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

Guanfacine Hydrochloride Tablets

July 23, 2019

Reasons for the Shortage

- Amneal did not provide a reason for the shortage.
- Mylan refuses to provide updated availability information.
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates

- Amneal has guanfacine 1 mg tablets on back order and the company estimates a release date in mid-August 2019.
- Teva has guanfacine 1 mg and 2 mg tablets in 100 count bottles on back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=508

Dicyclomine Oral Presentations

July 23, 2019

Reasons for the Shortage

- Hikma did not provide a reason for the shortage.
- Lannett did not provide a reason for the shortage.
- Mylan refuses to provide availability information.
- Par Pharmaceuticals has dicyclomine oral solution available.
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates

- Teva has 10 mg capsules in 1,000 count 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=521

Argatroban Injection

July 23, 2019

Reasons for the Shortage

- AuroMedics did not provide a reason for the shortage.
- Chiesi did not provide a reason for the shortage.
- Fresenius Kabi has argatroban available.
- Hikma did not provide a reason for the shortage.
- Mylan Institutional refuses to provide availability information.
- Par has argatroban available.
- Pfizer had argatroban on shortage due to manufacturing delay.
- Sandoz discontinued argatroban 1 mg/mL 50 mL vials in April 2019.
- Teva has argatroban temporarily unavailable.

Estimated Resupply Dates

- AuroMedics has argatroban 1 mg/mL 50 mL vials on intermittent back order.

- Chiesi has argatroban 1 mg/mL 50 mL vials on back order and the company cannot estimate a release date.
- Hikma has argatroban 100 mg/mL 2.5 mL vials on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=521

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