



July 2017

Drug Information Update

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NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
SEVELAMER CARBONATE	0.8 GRAM POWD PACK	GENYME	REVELA
SEVELAMER CARBONATE	0.8 GRAM POWD PACK	AUROBINDO PHARM	REVELA
SEVELAMER CARBONATE	2.4 GRAM POWD PACK	GENZYME	REVELA
SEVELAMER CARBONATE	2.4 GRAM POWD PACK	AUROBINDO PHARM	REVELA
BUPRENORPHINE	7.5 MCG/HOUR PATCH	RHODES PHARMACE	BUSTRANS
BUPRENORPHINE	7.5 MCG/HOUR PATCH	PURDUE PHARMA L	BUSTRANS
OLOPATADINE HCL	0.2% DROPS	ALCON/NOVARTIS	PATADAY
OLOPATADINE HCL	0.2% DROPS	TEVA USA	PATADAY
OLOPATADINE HCL	0.2% DROPS	QUALITY CARE	PATADAY
OLOPATADINE HCL	0.2% DROPS	A-S MEDICATION	PATADAY
OLOPATADINE HCL	0.2% DROPS	PHYSICIANS TC.	PATADAY
OLOPATADINE HCL	0.2% DROPS	SANDOZ	PATADAY
DOXYCYCLINE HYCLATE	75 MG TABLET	ACTAVIS PHARMA/	ACTICLATE
DOXYCYCLINE HYCLATE	75 MG TABLET	AQUA PHARMACEUT	ACTICLATE
DOXYCYCLINE HYCLATE	75 MG TABLET	MAYNE PHARMA IN	ACTICLATE
DOXYCYCLINE HYCLATE	150 MG TABLET	ACTAVIS PHARMA/	ACTICLATE
DOXYCYCLINE HYCLATE	150 MG TABLET	AQUA PHARMACEUT	ACTICLATE
DOXYCYCLINE HYCLATE	150 MG TABLET	MAYNE PHARMA IN	ACTICLATE
MELPHALAN	2 MG TABLET	ALVOGEN INC	ALKERAN
MELPHALAN	2 MG TABLET	AOPHARMA USA I	ALKERAN
TESTOSTERONE	30 MG/1.5 ML SOL MD PMP	ELI LILLY & CO.	AXIRON
TESTOSTERONE	30 MG/1.5 ML SOL MD PMP	PERRIGO CO.	AXIRON
TESTOSTERONE	30 MG/1.5 ML SOL MD PMP	PRASCO LABS	AXIRON

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
EPINEPHRINE HCL IN 0.9 % NACL	1 MG/10 ML SYRINGE	PHARMEDIUM/OF	EPINEPHRINE HCL-0.9% NACL
MOXIFLOXACIN HCL	0.5% DROPS	ALCON/NOVARTIS	VIGAMOX
MOXIFLOXACIN HCL	0.5% DROPS	SANDOZ	VIGAMOX
MOXIFLOXACIN HCL	0.5% DROPS	PHARMA PAC	VIGAMOX
MOXIFLOXACIN HCL	0.5% DROPS	A-S MEDICATION	VIGAMOX
MOXIFLOXACIN HCL	0.5% DROPS	PHYSICIANS TC.	VIGAMOX
MOXIFLOXACIN HCL	0.5% DROPS	APOTEX CORP	VIGAMOX
MOXIFLOXACIN HCL	0.5% DROPS	LUPIN PHARMACEU	VIGAMOX
BUPIVACAINE/PF/NORFLU/HFC245FA	5 MG/ML KIT	RX PHARMA PACK	P-CARE MG
BUPIVACAINE/PF/NORFLU/HFC245FA	5 MG/ML KIT	ENOVACHEM MANUF	MARVONA SUIK
TRIAMCIN/NORFLURANE/HFC 245FA	40 MG/ML KIT	RX PHARMA PACK	POD-CARE 100KG
TRIAMCIN/NORFLURANE/HFC 245FA	40 MG/ML KIT	ENOVACHEM MANUF	TRILOAN SUIK
TRIAMCINOLONE ACETONIDE	40 MG/ML KIT	RX PHARMA PACK	POD-CARE 100K
TRIAMCINOLONE ACETONIDE	40 MG/ML KIT	TERRAIN PHARMAC	READYSHARP TRIAMCINOLONE

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANDROGENIC AGENTS	INTRAROSA	PRASTERONE (DHEA)	6.5 MG	NEW STRENGTH, ROUTE AND DOSAGE FORM
PULMONARY ANTIHYPERTENSIVES, PROSTACYCLIN-TYPE	ORENITRAM ER	TREPROSTINIL DIOLAMINE	5 MG	NEW STRENGTH
ANTIEMETIC/ANTIVERTIGO AGENTS	SYNDROS	DRONABINOL	5 MG/ML ORAL SOLN	NEW DOSAGE FORM
ANTIVIRALS, HIV-SPECIFIC, CCR5 CO-RECEPTOR ANTAG.	SELZENTRY	MARAVIROC	20MG/ML ORAL SOLUTION	NEW STRENGTH AND DOSAGE FORM
ANTIVIRALS,HIV-1 INTEGRASE STRAND TRANSFER INHIBTR	ISENTRESS HD	RALTEGRAVIR POTASSIUM	600 MG	NEW STRENGTH
INSULINS	AFREZZA	INSULIN REGULAR, HUMAN	12 UNIT CART INHAL	NEW STRENGTH
INSULINS	AFREZZA	INSULIN REGULAR, HUMAN	8 UNIT CART INHAL	NEW STRENGTH
PRENATAL VITAMIN PREPARATIONS	ELITE-OB	PRENATAL NO.123/IRON/FOLIC AC	50MG IRON-1.25MG	NEW COMBINATION
METALLIC POISON,AGENTS TO TREAT	JADENU SPRINKLE	DEFERASIROX	90 MG GRAN PACK	NEW STRENGTH AND DOSAGE FORM
METALLIC POISON,AGENTS TO TREAT	JADENU SPRINKLE	DEFERASIROX	180 MG GRAN PACK	NEW STRENGTH AND DOSAGE FORM
METALLIC POISON,AGENTS TO TREAT	JADENU SPRINKLE	DEFERASIROX	360 MG GRAN PACK	NEW STRENGTH AND DOSAGE FORM
LOCAL ANESTHETICS	D-CARE 100X	LIDOCAINE HCL/EPINEPHRINE/PF	10 mg/mL (1 %)-1:200,000 INJ KIT	NEW DOSAGE FORM
ADRENERGICS, AROMATIC, NON-CATECHOLAMINE	MYDAYIS	DEXTROAMPHETAMINE/AMPHETAMINE	12.5 MG	NEW DOSAGE FORM
ADRENERGICS, AROMATIC, NON-CATECHOLAMINE	MYDAYIS	DEXTROAMPHETAMINE/AMPHETAMINE	25 MG	NEW DOSAGE FORM
ADRENERGICS, AROMATIC, NON-CATECHOLAMINE	MYDAYIS	DEXTROAMPHETAMINE/AMPHETAMINE	37.5 MG	NEW DOSAGE FORM
ADRENERGICS, AROMATIC,	MYDAYIS	DEXTROAMPHETAMINE/AMPHETA-	50 MG	NEW DOSAGE

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
NON-CATECHOLAMINE		MINE		FORM
ANTIPORPHYRIA FACTORS	PANHEMATIN	HEMIN	350 MG IV VIAL	NEW STRENGTH
TOPICAL LOCAL ANESTHETICS	LIDTOPIC MAX	LIDOCAINE HCL	10% CREAM	NEW DOSAGE FORM
ANTI-CD20 (B LYMPHOCYTE) MONOCLONAL ANTIBODY	RITUXAN HYCELA	RITUXIMAB/HYALURONIDASE,HUMAN	1,400 MG/11.7 ML (120 MG/ML) SUB-Q VIAL	NEW ENTITY
ANTI-CD20 (B LYMPHOCYTE) MONOCLONAL ANTIBODY	RITUXAN HYCELA	RITUXIMAB/HYALURONIDASE,HUMAN	1,600 MG/13.4 ML (120 MG/ML) SUB-Q VIAL	NEW ENTITY
TOPICAL ANTI-INFLAMMATORY, NSAIDS	FROTEK	KETOPROFEN, MICRONIZED	10% CREAM	NEW STRENGTH, DOSE FORM, AND ROUTE
C1 ESTERASE INHIBITORS	HAEGARDA	C1 ESTERASE INHIBITOR	2,000 UNIT SUB-Q VIAL	NEW STRENGTH AND ROUTE
C1 ESTERASE INHIBITORS	HAEGARDA	C1 ESTERASE INHIBITOR	3,000 UNIT SUB-Q VIAL	NEW STRENGTH AND ROUTE
NOSE PREPARATIONS, MISCELLANEOUS (RX)	ALZAIR	HYPROMELLOSE	NASAL SPRAY	NEW ROUTE AND DOSAGE FORM
INFLUENZA VIRUS VACCINES	FLUBLOK QUAD 2017-2018	FLU VAC QV 2017(18YR UP)RCM/PF	180 MCG (45 MCG x 4)/0.5 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUZONE QUAD 2017-2018	FLU VACC QS2017-18 36MOS UP/PF	60 MCG (15 mcg x 4)/0.5 ML VIAL	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUZONE QUAD 2017-2018	FLU VACC QS2017-18 36MOS UP/PF	60 mcg (15 MCG x 4)/0.5 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUZONE HIGH-DOSE 2017-2018	FLU VACC TS2017-18(65YR UP)/PF	180 MCG/0.5 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUBLOK 2017-2018	FLU VAC TV 2017(18YR UP)RCM/PF	135 MCG (45 MCG x 3)/0.5 ML VIAL	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUZONE QUAD 2017-2018	FLU VACC QUAD 2017-18(6MOS UP)	60 MCG (15 MCG x 4)/0.5 ML VIAL	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUZONE QUAD	FLU VACC QS 2017 (6-35MOS)/PF	30 MCG (7.5	NEW ENTITY

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
	PEDI 2017-2018		MCG x 4)/0.25 ML SYRINGE	
INFLUENZA VIRUS VACCINES	FLUZONE INTRADERM QUAD 2017-18	FLU VACC QS 2017 (18-64YRS)/PF	36 MCG/0.1 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUVIRIN 2017-2018	FLU VAC TS 2017-18(4 YR UP)/PF	45 MCG (15 MCG x 3)/0.5 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUVIRIN 2017-2018	FLU VACCINE TS2017-18(4 YR UP)	45 MCG (15 MCG x 3)/0.5 ML VIAL	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUAD 2017-2018	FLU VACC TS2017(65UP)/MF59C/PF	45 MCG (15 MCG x 3)/0.5 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUCELVAX QUAD 2017-2018	FLU VAC QS 17-18(4YR UP)CEL/PF	60 MCG (15 MCG x 4)/0.5 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLUCELVAX QUAD 2017-2018	FLU VAC QS 17-18 (4YR UP) CELL	60 MCG (15 MCG x 4)/0.5 ML VIAL	NEW ENTITY
ANALGESICS, NARCOTICS	METHADONE HCL	METHADONE HCL	5 MG/0.5 ML SYRINGE	NEW STRENGTH AND DOSAGE, NO PRICING

NEW INDICATIONS (EXISTING DRUGS)

Darzalex®

June 16, 2017

Copenhagen, Denmark; June 16, 2017 — Genmab A/S (Nasdaq Copenhagen: GEN) announced today the U.S. Food and Drug Administration (FDA) has approved the use of DARZALEX® (daratumumab) in combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor. DARZALEX is being developed under an August 2012 agreement in which Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop, manufacture and commercialize the product. Genmab will receive milestone payments totaling USD 25 million from Janssen in connection with the approval and first commercial sale of DARZALEX under the newly expanded label. The sale is expected to occur quickly after the approval. The approval and related milestones do not impact the financial guidance issued by Genmab on May 10, 2017.

Source: Genmab A/S

<http://ir.genmab.com/releasedetail.cfm?ReleaseID=1030508>

Dysport®

June 16, 2017

Ipsen (Euronext: IPN; ADR: IPSEY) (Ipsen) today announced that the U.S. Food and Drug Administration (FDA) has expanded the approved use of Dysport® (abobotulinumtoxinA) for injection for the treatment of spasticity in adults, based on its supplemental Biologics License Application (sBLA) in lower limb spasticity. In July 2015, Dysport® was approved for the treatment of upper limb spasticity in adults. In July 2016, Dysport® was approved to treat pediatric patients with lower limb spasticity aged two and older, making it the first and only botulinum toxin that the FDA approved for this indication.

Source: Ipsen

<https://www.ipсен.com/media/press-relases/ipсен-announces-fda-approval-dysport-abobotulinumtoxinA-treatment-lower-limb-spasticity-adults/>

Vectibix®

June 29, 2017

THOUSAND OAKS, Calif., June 29, 2017 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has approved the supplemental Biologics License Application (sBLA) for Vectibix® (panitumumab) for patients with wild-type RAS (defined as wild-type in both KRAS and NRAS as determined by an FDA-approved test for this use) metastatic colorectal cancer (mCRC) as first-line therapy in combination with FOLFOX and as monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy. Vectibix is the first-and-only fully human monoclonal anti-epidermal growth factor receptor (EGFR) antibody approved by the FDA for this patient population.

Source: Amgen

<http://investors.amgen.com/phoenix.zhtml?c=61656&p=irol-newsArticle&ID=2284122>

Blincyto®

July 11, 2017

July 11, 2017 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has approved the supplemental Biologics License Application (sBLA) for BLINCYTO® (blinatumomab) to include overall survival (OS) data from the Phase 3 TOWER study. The approval converts BLINCYTO's accelerated approval to a full approval. The sBLA approval also included data from the Phase 2 ALCANTARA study supporting the treatment of patients with Philadelphia chromosome-positive (Ph+) relapsed or refractory Bcell precursor acute lymphoblastic leukemia (ALL). The approval expands the indication of BLINCYTO for the treatment of relapsed or refractory B-cell precursor ALL in adults and children.

Source: Amgen

<http://www.amgen.com/media/news-releases/2017/07/fda-grants-full-approval-for-blinicyto-blinatumomab-to-treat-relapsed-or-refractory-bcell-precursor-acute-lymphoblastic-leukemia-in-adults-and-children/>

Orencia®

July 11, 2017

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) today announced that the U.S. Food and Drug Administration (FDA) has approved ORENCIA® (abatacept) for reducing signs and symptoms in pediatric patients six years and older with moderately to severely active polyarticular juvenile idiopathic arthritis (JIA). ORENCIA may be used as monotherapy or concomitantly with methotrexate (MTX). ORENCIA should not be administered concomitantly with tumor necrosis factor (TNF) antagonists and is not recommended for use concomitantly with other biologic rheumatoid arthritis (RA) therapy, such as anakinra. This new indication for ORENCIA provides significant evidence of its durable efficacy and long-term safety in pediatric patients, including those initiating biologic therapy for the first time. The safety and efficacy of ORENCIA in JIA were assessed in a three-part study through one year. The approval of ORENCIA in JIA represents the ongoing commitment of Bristol-Myers Squibb in this therapeutic area.

Source: Bristol-Myers Squibb Company

<https://news.bms.com/press-release/financial-news/us-food-and-drug-administration-approves-orencia-abatacept-treatment-mo>

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Paliperidone Extended-Release Tablets 3mg by Teva Pharmaceuticals: Recall-Dissolution Test Failure June 15, 2017

ISSUE: Teva Pharmaceuticals USA, Inc. (Teva) initiated a voluntary recall to retail-level on 05/31/2017 for one lot of Paliperidone Extended-Release Tablets, 3mg, 90 count bottles, lot 1160682A, expiration 6/2018, NDC 0591-3693 19, that was distributed under the Actavis Pharma Inc. label. In coordination with FDA, Teva is extending this recall to the consumer/user level.

This recall is being carried out due to failing test results for dissolution. Teva cannot at this time exclude the potential for additional tablets to be below specification.

Taking a product for the treatment of schizophrenia and schizoaffective disorders that has failed dissolution could result in less drug being absorbed. If two or more consecutive dosing regimens are with affected product, a failure to maintain therapeutic levels could occur, which could reduce effectiveness in treating a patient's mental and/or mood symptoms, including suicidal thoughts and behavior, self-injurious behavior, mental hospitalizations, assaults, aggressive behavior, as well as vocal and motor tics. Based on Teva's investigation, the likelihood of consuming two or more consecutive doses with affected product is low. In addition, no post marketing adverse events have been received to date for lack of effectiveness for this recalled lot.

BACKGROUND: Paliperidone Extended Release Tablets, 3mg is indicated for the treatment of schizophrenia and schizoaffective disorders and was distributed nationwide in the USA to wholesalers.

RECOMMENDATION: Teva has issued an Urgent Drug Recall Letter to its direct accounts. Teva has made arrangements for impacted product to be returned to Inmar. The letter asks these consignees to notify their customers that were shipped the recalled lot informing them of this recall. Anyone with an existing inventory of the recalled lot should stop use and distribution, and follow the instructions in the letter for product returns. Teva does not expect any supply interruptions.

Consumers with questions regarding this recall can contact Teva by 1-888-838-2872, option 3, then option 4, Monday – Friday (excluding holidays), 9 am to 5 pm Eastern Time, or email druginfo@tevapharm.com. Consumers should contact their healthcare provider, physician and/or pharmacist if they have experienced any problems that may be related to this drug product.

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

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

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

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm563358.htm>

Unexpired Nitroglycerin Injection in 5 Percent Dextrose USP by Advanced Pharma in Houston: Recall-Sub Potency June 15, 2017

ISSUE: Advanced Pharma, Inc. d/b/a Avella of Houston ("Advanced Pharma") is voluntarily recalling all unexpired lots of Nitroglycerin products that were produced at Advanced Pharma's Houston location between March 3, 2017

and May 31, 2017 to the hospital/user level. The recall is being issued based on laboratory test results indicating a lower than expected potency on certain lots of compounded NitroGlycerin Injection which would lead to a lower dose being administered. While the lower than expected potency results affected only certain lots of Nitroglycerin, Advanced Pharma is recalling all unexpired lots of NitroGlycerin. To date, Advanced Pharma has not received any reports of product complaints and/or adverse events related to the products.

Although nitroglycerin is titrated based on clinical response, an extreme and unexpected reduction in dose than expected could lead to a delay in treatment, disruption of clinical care of the patient, and worsening of patient's conditions.

The recalled NitroGlycerin products include the 100 mcg per mL and 200 mcg per mL strengths available in 5 mL, 10 mL, and 20 mL sterile single dose syringes and are packaged in various sizes per carton. These products were not distributed directly to patients or consumers, but rather to healthcare facilities (e.g. hospitals) nationwide in the USA between March 9, 2017 to June 1, 2017 and have expiration dates ranging from June 9, 2017 to August 15, 2017. The issue is segregated to the Houston location and no other Avella locations are involved or affected.

BACKGROUND: Nitroglycerin Injection in 5% Dextrose, USP is indicated for treatment of high blood pressure before, during or after surgery; for control of heart failure after a heart attack; for treatment of heart related chest pain in patients who have not responded to nitroglycerin tablets taken under the tongue and other heart medicines; and to lower blood pressure during surgery.

RECOMMENDATION: Advanced Pharma has notified impacted customers of the voluntary recall by phone, email and overnight mail. Customers that have any of the affected medications that are being recalled should immediately discontinue use and return the unused portion to Avella. Customers with any of the affected medications can also reference Advanced Pharma's website for more information on the specific lot numbers affected, pictures of the product labels at issue and forms and contact information: avella.com/apnitroglycerin-recall. For a full list of products, please visit <https://www.avella.com/sourceproducts>.

Patients and healthcare providers with questions regarding this recall can contact the Advanced Pharma, Inc. recall line at (877) 292-4323, Monday through Friday, between 6am and 6pm Pacific Standard Time or via e-mail at ProductRecall@avella.com.

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

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

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

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm563381.htm>

Sodium Bicarbonate Injection 8.4 Percent USP, Neut (Sodium Bicarbonate 4 Percent Additive Solution), Quelicin (Succinylcholine Chloride Injection USP), and Potassium Phosphates Injection by Hospira: Recall - Potential For Lack Of Sterility Assurance June 16, 2017

ISSUE: Hospira, Inc., a Pfizer company, is voluntarily recalling 42 lots of 8.4% Sodium Bicarbonate Injection, USP, 50 mL vials, 5 lots of Neut™ (Sodium Bicarbonate 4% additive solution) 5 mL vials, 5 lots of QUELICIN™ (Succinylcholine Chloride Injection, USP) 200 mg/10 mL vials and 7 lots of Potassium Phosphates Injection, USP, 45 mM vials to the hospital/retail level due to microbial growth detected during a routine simulation of the

manufacturing process, which represents the potential introduction of microorganisms into the products. Please view the recall notice for a list of the affected lot numbers.

In the event that impacted product is administered to a patient, there is a reasonable probability that the patient may experience adverse events ranging from fever, chills and malaise, to severe adverse events including systemic invasive mycoses or systemic bacterial sepsis. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated. No batches of distributed product have been identified as actually containing microorganisms. To date, Hospira has not received reports of any adverse events associated with this issue.

These lots were distributed nationwide in the U.S. (including Puerto Rico), Dutch Antilles, Barbados, Canada, Philippines, Kuwait, and Singapore to wholesalers and hospitals from January to June 2017. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Pfizer is working diligently to restore supply of these products and is in communication with the FDA to address any supply issues.

BACKGROUND: Sodium Bicarbonate Injection, USP is indicated in the treatment of metabolic acidosis; in the treatment of certain drug intoxications, in poisoning by salicylates or methyl alcohol and in certain hemolytic reactions. Sodium bicarbonate is indicated in severe diarrhea, which is often accompanied by significant loss of bicarbonate. Neut™ (4% sodium bicarbonate additive solution) is indicated for use as an additive to raise the pH of acid solutions administered intravenously to reduce the incidence of chemical phlebitis and patient discomfort due to vein irritation at or near the site of infusion.

Quelicin™ (Succinylcholine Chloride Injection, USP) is indicated as an adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

Potassium Phosphates Injection, USP 3 mM P/mL (millimoles/mL) is indicated as a source of phosphorus, for addition to large volume intravenous fluids, to prevent or correct hypophosphatemia in patients with restricted or no oral intake. It is also useful as an additive for preparing specific intravenous fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions.

RECOMMENDATION: Anyone with an existing inventory of the recalled lots should stop use and distribution and quarantine immediately. Inform Healthcare Professionals in your organization of this recall. If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product from you. Further, please instruct entities that may have received the recalled product from you that if they redistributed the product, they should notify their accounts, locations or facilities of the recall to the hospital/retail level. Hospira will be notifying its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. For additional assistance, call Stericycle at 1-800-805 3093 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

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

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

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

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm563382>

Potassium Phosphate and Succinylcholine by Advanced Pharma: Recall-Potential Lack of Sterility Assurance

June 22, 2017

ISSUE: Advanced Pharma, Inc. d/b/a Avella of Houston is conducting a limited, voluntary recall due to Hospira Inc.'s June 15, 2017 recall announcement that microbial growth was detected during a routine simulation of the manufacturing process and therefore there was a lack of sterility assurance. The products being recalled by Advanced Pharma were repackaged and/or compounded at its Houston, Texas facility using certain Hospira products. The recalled products are specific lots of Potassium Phosphate and Succinylcholine Chloride. This is a secondary recall based on a Hospira's recent recall.

Per Hospira, in the event that impacted product is administered to a patient, there is a reasonable probability that the patient may experience adverse events ranging from fever, chills and malaise, to severe adverse events including systemic invasive mycoses or systemic bacterial sepsis. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated.

BACKGROUND: These products were not distributed directly to patients or consumers, but rather to healthcare facilities (e.g. hospitals).

RECOMMENDATION: Avella and Advanced Pharma are notifying customers of the voluntary recall by phone, email and overnight mail. Customers in Arizona, California, Colorado, Delaware, Georgia, Louisiana, Nebraska, New Jersey, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Utah and Washington that have any of the affected medications that are being recalled should immediately discontinue use and return the unused portion to Avella Specialty Pharmacy. Customers with any of the affected medications can also reference Advanced Pharma's website for more information on the specific lot numbers affected, product images, forms and contact information: www.avella.com/AP-Hospira-recall. For a full list of Advanced Pharma products, please visit www.avella.com/sourcecb-products.

Patients and healthcare providers with questions regarding this recall can contact Avella Specialty Pharmacy recall line at (877) 292-4323, Monday through Friday, between 6am and 6pm Pacific Standard Time or via e-mail at ProductRecall@avella.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.

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

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

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

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm564303.htm>

Succinylcholine Chloride 20mg/mL 5mL Syringe by Fagron Sterile Services: Recall- Potential Lack Of Sterility Assurance

June 23, 2017

ISSUE: Fagron Sterile Services is voluntarily recalling three (3) lots of Succinylcholine Chloride 20mg/mL 5mL syringe to the hospital/clinic level. The secondary recall of product manufactured by Hospira Inc., a Pfizer company, and repacked by Fagron Sterile Services, is due to microbial growth detected during a routine simulation of Hospira's manufacturing process, which represents the potential introduction of microorganisms into the product. To date, there have been no reports of adverse events. This secondary recall is being conducted as result of the recall initiated by the manufacturer on June 15, 2017.

Per Hospira, in the event that impacted product is administered to a patient, there is a reasonable probability that the patient may experience adverse events ranging from fever, chills and malaise, to severe adverse events including systemic invasive mycoses or systemic bacterial sepsis. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated. No microorganisms have been confirmed in any Fagron Sterile Services lot. See the press release for a list of affected Lot Numbers. The impacted lots were distributed nationwide directly to hospitals and surgical clinics.

BACKGROUND: Succinylcholine Chloride Injection is indicated as an adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

RECOMMENDATION: Fagron Sterile Services has notified its direct customers by telephone and is arranging for return and replacement of all recalled products. Hospitals or surgical clinics that have received impacted product which is being recalled, should immediately examine stock and discontinue dispensing. Promptly contact Stericycle to arrange product return at 1-888-628-0728, from Monday to Friday, 8:00am to 5:00pm EDT for instructions on how to return impacted product.

Consumers with questions regarding this recall can contact Fagron Sterile Services by phone at 1-877-405-8066 M F 8:00am – 5:00pm CDT. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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

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

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

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm564443.htm>

Potassium Phosphate and Succinylcholine Chloride by PharMEDium Services: Recall-Lack of Sterility Assurance

June 27, 2017

ISSUE: PharMEDium Services is conducting a limited, voluntary recall due to Hospira Inc.'s ("Hospira") June 15, 2017 recall announcement that microbial growth was detected during a routine simulation of the manufacturing process and therefore there was a lack of sterility assurance. The products being recalled by PharMEDium Services were compounded using certain Hospira products. The recalled products are specific lots of Potassium Phosphate and Succinylcholine Chloride. This is a secondary recall based on a Hospira's recent recall: <https://www.fda.gov/Safety/Recalls/ucm563383.htm>.

Per Hospira, in the event that impacted product is administered to a patient, there is a reasonable probability that the patient may experience adverse events ranging from fever, chills and malaise, to severe adverse events including systemic invasive mycoses or systemic bacterial sepsis. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated.

Refer to the recall notice for a list of the recalled lots and product photos.

BACKGROUND: These products were not distributed directly to patients or consumers, but rather to healthcare facilities (e.g. hospitals) in the United States.

RECOMMENDATION: PharMEDium Services is notifying customers of the voluntary recall by phone. Customers that have any of the affected medications that are being recalled should immediately quarantine the product,

discontinue use and destroy per their hospital protocol. Customers with any of the affected medications can also reference PharMEDium Services website for more information on the specific lot numbers affected and contact information:
www.pharmedium.com.

Patients and healthcare providers with questions regarding this recall can contact PharMEDium Services Clinical Pharmacist at (847) 457-2220, Monday through Friday, between 8am and 5pm Central Standard Time or via e-mail at shasan@pharmedium.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.

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

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

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

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm564962.htm>

Ultra-Sten and D-Zine Capsules by Hardcore Formulations: Recall – Contains Anabolic Steroids **July 06, 2017**

ISSUE: Hardcore Formulations is voluntarily recalling all lots and expiration dates of Ultra-Sten and D-Zine capsules to the consumer level. These products are labeled to contain methylstenbolone (Ultra-Sten) and dymethazine (D-Zine), which are considered to be derivatives of anabolic steroids. The presence of these anabolic steroids in Ultra-Sten and DZine render them unapproved drugs for which safety and efficacy have not been established and therefore subject to recall. This recall applies to all lot numbers and expiration dates of these products.

Consumption of products containing derivatives of anabolic steroids may cause serious liver injury and other adverse health consequences, including kidney injury, increased risk of heart attack and stroke, decreased high density lipoprotein (HDL) cholesterol levels, elevated blood pressure, aggressive behavior, male infertility, virilization in women (e.g., menstrual irregularities, deeper voice, increased body hair, baldness, etc.), and enlarged breasts and shrinkage of the testes in men. Patients with underlying cardiac, hepatic, or prostate conditions may be at higher risk for adverse reactions than otherwise healthy users.

BACKGROUND: Ultra-Sten and D-Zine capsules are marketed as dietary supplements for body-building and are packaged in 90-count bottles, with the bar code 7-48252-68763-0 (Ultra-Sten); 7-48252-86193-1 (D-Zine) and sold through retailers nationwide in the USA. Ultra-Sten and D-Zine capsules were distributed nationwide in the USA to retailers from August 2014 to May 2017.

RECOMMENDATION: Hardcore Formulations is notifying its retailers by a formal recall notification letter and is arranging for a return of all recalled products. Consumers who have Ultra-Sten and D-Zine products should stop using them, return them to their place of purchase or discard in accordance with state and local ordinances for disposal of drug products.

Consumers with questions regarding this recall can contact Hardcore Formulations by phone at 1-855-773-6826 or by email sales@hardcoreformulations.com on Monday through Friday from 9 am to 5 pm Central Standard Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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

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

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

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm565870.htm>

Novopen Echo Insulin Delivery Device by Novo Nordisk: Recall - May Crack or Break If Exposed To Certain Chemicals

July 06, 2017

ISSUE: Novo Nordisk is initiating a recall of insulin cartridge holders used in a small number of NovoPen Echo batches because they may crack or break if exposed to certain chemicals, like certain cleaning agents. Using a device with a cracked/broken cartridge holder may result in the device delivering a reduced dose of insulin which could potentially lead to high blood sugar.

Novo Nordisk has received numerous complaints of damaged cartridge holders and has received some reports of adverse events to date.

The affected batches were distributed between 8/1/2016 – 6/22/2017 to distributors, sales representatives and replacement programs for further distribution to pharmacies, healthcare providers and patients nationwide.

BACKGROUND: The warning signs of high blood sugar (also known as hyperglycemia) typically appear gradually and might include flushed, dry skin; feeling sleepy or tired; dry mouth, fruity (acetone) breath; urinating more often, feeling thirsty; losing your appetite, feeling or being sick (nausea or vomiting).

RECOMMENDATION: Patients using an affected pen may want to check their blood sugar level more frequently until receiving a new cartridge holder. Patients should contact their health care provider if they believe they're experiencing hyperglycemia. For questions specific to the recall, please call 1-855-419-8827.

Novo Nordisk is notifying distributors, pharmacies, healthcare professionals and patients by mail and is arranging for product replacement. See the press release for additional information.

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

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

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

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm565955.htm>

Sten Z and M1 Alpha Capsules by Andropharm: Recall - Contains Derivatives of Anabolic Steroids July 12, 2017

ISSUE: Andropharm is voluntarily recalling all lots of Sten Z and M1 Alpha capsules to the consumer level because these products contain derivatives of anabolic steroids rendering them unapproved drugs for which safety and efficacy have not been established and therefore subject to recall.

Consumption of these products may cause elevated blood pressure, aggressive behavior, male infertility, or enlarged breasts and shrinkage of the testes in men. Patients with underlying cardiac, hepatic, or prostate conditions may be at higher risk for adverse reactions than otherwise healthy users. To date, Andropharm has not received any reports of these or any illnesses or injuries related to Sten Z or M1 Alpha.

BACKGROUND: Sten Z and M1 Alpha capsules are marketed as dietary supplements and promoted to increase, sustain, and strengthen muscularity. The two products were packaged as capsules in 60 count bottles with the UPC code-642125502948 (Sten Z) and UPC code- 642125502924 (M1 Alpha) and were sold through retailers nationwide in the United States from March 2016 to April 2017. This recall applies to all lot numbers and expiration dates of these products.

RECOMMENDATION: Consumers who have purchased Sten Z and M1 Alpha products should discontinue their use and either return them to their place of purchase or discard the products in accordance with state and local ordinances for disposal of the drug products.

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

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

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

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm566712.htm>

STUDIES AND RECENT TOPICS

Mistaken Antibodies may have led Breast Cancer Research down a 20-Year Dead End.

June 15, 2017

For nearly two decades researchers have sought a way to target an estrogen receptor in the hope they could improve breast cancer survival, but an article published today in Nature Communications contends that the effort may never pan out. The reason? The target receptor does not actually appear to be where they believe it to be.

<https://medicalxpress.com/news/2017-06-mistaken-antibodies-breast-cancer-year.html>

Penn State study says statin drugs can raise the risk of Parkinson's disease

June 19, 2017

The impacts of statin drugs on other health conditions has drawn considerable attention in recent years, including studies suggesting benefits against Parkinson's disease. But a new Penn State University study published in the journal Movement Disorders has found that statin drugs actually were "associated with higher, not lower, Parkinson's disease risk," with the association more pronounced with fat-based or "lipophilic" statins that include some of the most popular brands — Lipitor, Zocor, Lescol and Livalo.

<http://www.post-gazette.com/news/health/2017/06/20/Penn-State-study-statin-drugs-Parkinson-disease/stories/201706170021>

Researchers call for paradigm shift in type 2 diabetes treatment

June 20, 2017

Heart disease is a leading cause of death worldwide and exacerbated by type 2 diabetes, yet diabetes treatment regimens tend to focus primarily on blood sugar maintenance. This common approach to type 2 diabetes management can leave patients at risk for heart attack and stroke. But results from four recent randomized clinical trials suggest that using medications that offer glucose control while reducing the risk for cardiovascular disease could improve patient outcomes.

https://www.eurekalert.org/pub_releases/2017-06/cwru-rcf062017.php

FDA to Clear Path for Drugs Aimed at Cancer-Causing Genes

June 20, 2017

For years, doctors have identified cancers by the affected body part: lung, breast, and kidney.

Now, in a long-awaited move, U.S. drug regulators will simplify the approval of treatments targeting specific gene mutations that can spur tumors in a variety of organs.

<https://www.bloomberg.com/news/articles/2017-06-20/fda-moves-to-clear-path-for-drugs-aimed-at-cancer-causing-genes>

Popular Prostate Drug Linked to Serious Side Effects

June 22, 2017

Treatment of benign prostatic hyperplasia (BPH) with the commonly prescribed Avodart (Dutasteride) may put men at an increased risk for diabetes, elevated cholesterol levels, non-alcoholic fatty liver disease (NAFLD) and worsening erectile dysfunction.

https://www.eurekalert.org/pub_releases/2017-06/bumc-ppd062217.php

From Bug to Drug – Tick Saliva Could be Key to Treating Heart Disease

June 27, 2017

Proteins found in tick saliva could be used to treat a potentially fatal form of heart disease, according to new Oxford University research.

Myocarditis can cause sudden cardiac death in young adults, and occurs when the heart muscle becomes inflamed, often as a result of an infection caused by common viruses. The study, funded by the British Heart Foundation, identified a protein within tick saliva which can bind to and neutralize several chemicals called chemokines, which are released in the heart during myocarditis. The chemokines attract cells which cause inflammation, but by neutralizing the chemicals, tick saliva could potentially prevent this inflammation.

<https://phys.org/news/2017-06-bug-drugtick-saliva-key-heart.html>

Prescription Abuse Drops when States Adopt Mandatory Monitoring

June 27, 2017

Programs that monitor doctor prescribing and pharmacist dispensing could help to fight against drug addiction, new research shows, and with an especially strong effect for young adults.

America's raging opioid epidemic sprung from the over-prescription of painkillers, and it's causing a heavy and climbing death toll and impairing labor-market readiness, so it's important that this policy response seems to be effective. The paper assessing it leads this week's economic research wrap, which also takes a look at how Europe prioritizes immigration, Americans' faith in the Federal Reserve, and how the U.S. heartland has responded to manufacturing shocks. Check back each week for recent findings from around the world.

<https://www.bloomberg.com/news/articles/2017-06-27/prescription-abuse-drops-when-states-adopt-mandatory-monitoring>

Drugmakers Are Racing to Find Alternatives to Opioids

June 28, 2017

In the wake of mounting overdoses and deaths from the opioid-addiction crisis sweeping across the U.S., drugmakers are racing to come up with safer painkillers.

Companies are highly motivated to create alternatives to the \$4 billion opioid market. The federal government is cracking down on lax prescriptions that contribute to many thousands of deaths a year and has started to block the sale of medications it considers unsafe.

<https://www.bloomberg.com/news/articles/2017-06-28/life-after-opioids-drugmakers-scramble-to-concoct-alternatives>

The Buzzy New Technology that could Make Pills Obsolete

June 28, 2017

Pills have been popped for aches, pains, and other medical problems for at least a few millennia. But are their days as the holy grail of drug delivery (and discovery) coming to an end? It's hard to imagine the \$450 billion pharmaceutical industry—which makes almost half of its sales on pills, according to QuintilesIMS—abandoning the simple medical tablet altogether, but increasingly it has competition.

<http://fortune.com/2017/06/28/implantables-pills-big-pharma/>

FDA Outlines Plan to Speed Rare Disease Drug Designation

June 29, 2017

The U.S. Food and Drug Administration plans to reorganize its drug review staff and create a SWAT team to eliminate a backlog of requests for rare disease drug designation, it said on Thursday.

The agency plans to deploy a team of senior reviewers with expertise in drugs to treat diseases with 200,000 patients or fewer, known as orphan drugs.

<http://www.reuters.com/article/us-healthcare-fda-idUSKBN19K25J>

Marijuana Treats Migraine Pain Better than Prescription Medication, Study Finds

June 29, 2017

In another win for marijuana research, a study has found that the active compounds in cannabis are more effective at reducing the frequency of acute migraine pain than prescription migraine meds, and with fewer side effects. The study included a total of 127 participants who suffered from chronic migraines and cluster headaches, severe headaches that occur on one side of the head, often around an eye. Migraine pain usually affects both sides of the head and is often accompanied by light sensitivity and nausea.

<https://www.forbes.com/forbes/welcome/?toURL=https://www.forbes.com/sites/daviddisalvo/2017/06/29/marijuana-treats-migraine-pain-better-than-prescription-medication-study-finds/&refURL=&referrer=#1712d7243700>

Seniors Miss Out on Clinical Trials

June 29, 2017

More than 60 percent of cancer patients are older adults — and that will rise to 70 percent by 2040. Yet seniors continue to be underrepresented in clinical trials, making it difficult to assess how treatments are likely to help or harm them.

<http://khn.org/news/seniors-miss-out-on-clinical-trials/>

Many U.S. Teens Still Denied 'Morning After' Pill at Pharmacies

June 30, 2017

Although the U.S. Food and Drug Administration has lifted age restrictions on the use of the "morning after" pill, new research suggests that many teens may still have a tough time trying to get the emergency contraception. In

the study, researchers posing as teenagers were often told erroneously by pharmacies that they needed a prescription for the over-the-counter pill or they were denied it altogether because of their age.

<https://consumer.healthday.com/sexual-health-information-32/morning-after-pill-plan-b-news-765/many-u-s-teens-still-denied-morning-after-pill-at-pharmacies-724190.html>

Some Heartburn Drugs Linked with Higher Risk of Death

July 3, 2017

Some heartburn drugs used by millions of Americans are associated with a higher risk of death, a new study suggests, but people on the drugs should talk with their doctor first before stopping the medicines, experts say.

<http://www.cbsnews.com/news/heartburn-drugs-proton-pump-inhibitors-ppi-risks-prilosec-nexium-prevacid/>

Antibody could be First New Mechanism of Action for HIV Treatment in 10 Years

July 3, 2017

Theratechnologies (TSE:TH) said today that the FDA granted priority review to the biologics license application for ibalizumab as a treatment for multi-drug resistant HIV-1. If the monoclonal antibody is approved, it will be the first antiretroviral treatment with a new mechanism of action to be introduced in a decade. It would also be the only available therapy that doesn't necessitate daily dosing.

<http://www.drugdeliverybusiness.com/antibody-first-new-mechanism-action-hiv-treatment-10-years/>

Proper Tools may Help Prevent Medicine Errors at Home

July 4, 2017

Providing parents with picture-based instructions - and with dosing tools that closely match the amount of medication needed - may help reduce cases of medication overdoses in children, researchers say.

Poorly designed medication labels and dosing tools lead to dosing errors, especially when parents are given large cups for small doses, the study team writes in Pediatrics, June 27.

<http://www.reuters.com/article/us-children-dosing-errors-idUSKBN19P23G>

Bring on the Exercise, Hold the Painkillers

July 5, 2017

Taking ibuprofen and related over-the-counter painkillers could have unintended and worrisome consequences for people who vigorously exercise. These popular medicines, known as nonsteroidal anti-inflammatory drugs, or NSAIDs, work by suppressing inflammation. But according to two new studies, in the process they potentially may also overtax the kidneys during prolonged exercise and reduce muscles' ability to recover afterward.

<https://www.nytimes.com/2017/07/05/well/move/bring-on-the-exercise-hold-the-painkillers.html>

Pain-free Microneedle Patch could Help Boost Flu Vaccination Rates

July 5, 2017

Lagging flu vaccination rates in the U.S., especially among children, have scientists working to take the "Ow!" out of immunization. Enter an experimental patch with dissolvable microneedles. The Band-Aid-like vaccine patch is the size of a dime and contains 100 tiny, water-soluble spinules just long enough to penetrate the skin and deliver the vaccine.

<http://www.fiercepharma.com/vaccines/new-pain-free-microneedle-patch-could-help-boost-vaccination-rate>

The Opioid Opana ER is being Taken Off the Market

July 7, 2017

The opioid medication Opana ER is being voluntarily withdrawn from the market, its manufacturer Endo Pharmaceuticals said in a statement Thursday. The decision comes less than a month after the U.S. Food and Drug Administration (FDA) requested that drug sales be halted, due to concerns over its potential for misuse and abuse.

<http://time.com/4849361/opioid-opana-er-fda/>

From Viagra to Valium, the Drugs that were Discovered by Accident

July 10, 2017

When scientists in New Zealand discovered that a meningitis vaccine fortuitously protects against gonorrhea, they were benefiting from an unpredictable force responsible for some of history's most striking medical breakthroughs: serendipity.

<https://www.theguardian.com/lifeandstyle/2017/jul/11/from-viagra-to-valium-the-drugs-that-were-discovered-by-accident>

Widely Used Malaria Drug may Shield Fetuses from Zika Infection

July 10, 2017

The neurological damage caused by the mosquito-born virus Zika occurs when babies are in the womb, so it's no surprise scientists have been searching for ways to create barriers that shield fetuses from infection. Toward that end, a team of researchers at the Washington University School of Medicine in St. Louis has been focusing on a key element of fetal development called autophagy, which is the process by which cells dispose of waste and unwanted microbes to create a placental barrier that keeps infectious invaders away from developing infants.

http://www.fiercebiotech.com/research/widely-used-malaria-drug-may-shield-babies-from-zika-infection?utm_medium=nl&utm_source=internal&mrkid=696991&mkt_tok=eyJpIjoiWkRjeE16RXhOakV6TkRBNSIsInQiOiJnV0ZcL29Vdm5kdFhyWGJlanRJQmoxU2drcUxWZEdUWXNvT2JxTUxod3ZRcHlj

Medication Mistakes are on the Rise, Leading to More Serious Health Problems

July 10, 2017

Every minute of every day, three Americans call a poison control center because they've made a major mistake with their medication. Some have taken the wrong dose. Some have double-dosed, and others have taken the wrong medicine altogether.

<http://www.cbsnews.com/news/medication-mistakes-causing-more-health-problems-overdoses/>

Med Switch Not Always Best Choice with Tough Depression

July 11, 2017

Switching to another antidepressant may not be the best way to help depression patients who don't respond to the first antidepressant they take, a new study indicates. Among more than 1,500 depression patients at 35 U.S. Veterans Health Administration medical centers, better symptom relief was achieved when people were prescribed an antipsychotic medication or a second antidepressant rather than being switched to another antidepressant, the researchers found.

<https://consumer.healthday.com/mental-health-information-25/depression-news-176/med-switch-not-always-best-choice-with-tough-depression-724469.html>

Updating Drug Labels would Greatly Help Patients – but few companies do it

July 11, 2017

Do you ever look at the labels of the prescription medications you take? Or do you simply rely on your physician to read them to understand the medications' appropriate uses and side effects? Either way, there's a good chance that these labels — the detailed instructions for use that accompany every drug approved by the Food and Drug Administration — are out of date and lacking essential new information for appropriate use and safety.

<https://www.statnews.com/2017/07/11/drug-labels-update/>

More Doctors are using Apps to Help Manage Chronic Disease

July 12, 2017

About half of all adults suffer from one or more chronic diseases, which account for seven of 10 deaths and 86% of U.S. health-care costs. But preventing and treating such ailments requires time that doctors don't have in brief office visits, and a degree of daily self-management that many patients have been unable to handle. They often become overwhelmed by the demands of their daily regimens, slip back into poor health habits, fail to take their medications correctly—and end up in the emergency room.

<http://www.marketwatch.com/story/apps-help-patients-manage-diabetes-blood-pressure-copd-2017-07-12>

Hormone Replacement Therapies Help Breast Cancer Grow and Spread

July 12, 2017

Hormone replacement therapies or medications containing female hormones that substitute those no longer produced by the body, often are prescribed to reduce the effects of menopausal symptoms in women. Research has indicated that women who take hormone replacement therapies have a higher incidence of breast cancer. Now, researchers at the University of Missouri have linked natural and synthetic progestins to the body's production of specialized cancer cells that act like stem cells in humans. Findings could help scientists target these rare cells that proliferate in breast cancers and metastasize elsewhere, and may help clinicians identify immunotherapies to combat the spread of the disease.

https://www.eurekalert.org/pub_releases/2017-07/uom-hrt071217.php

Antidepressants in Pregnancy not Tied to Intellectual Disability in Kids

July 12, 2017

Pregnant women's use of antidepressants does not increase their babies' risk of intellectual disability, a new study suggests. Researchers analyzed data from a large sample of children and found those whose mothers took antidepressant medications while pregnant were no more likely to be diagnosed with intellectual disability than those who weren't exposed to antidepressants in the womb.

<http://www.reuters.com/article/us-health-pregnancy-depression-idUSKBN19X2XZ>

Painkiller Prescriptions More Prone to Errors if Handwritten

July 12, 2017

Mistakes are much more likely to occur with handwritten prescriptions for opioid painkillers than with electronic ones, a new study finds. Researchers analyzed 510 prescriptions for opioids -- such as oxycodone (Oxycontin, Percocet) and hydrocodone (Vicoprofen) -- filled at a Johns Hopkins Medicine outpatient pharmacy. The investigators found that 42 percent of the prescriptions contained an error.

<https://consumer.healthday.com/public-health-information-30/drug-safety-news-741/painkiller-prescriptions-more-prone-to-errors-if-handwritten-724450.html>

More People are Making Mistakes with Medicines at Home

July 12, 2017

When people take medicine at home, mistakes happen. Some people end up taking the wrong dose of a medication or the wrong pill. Sometimes, they don't wait long enough before taking a second dose. Other times, it's a health professional who's at fault. A pharmacist might have dispensed a medication at the wrong concentration, for example.

<http://www.npr.org/sections/health-shots/2017/07/12/536519077/took-the-wrong-medicine-by-mistake-study-finds-such-errors-are-on-the-rise>

RECALLS

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Human Chorionic Gonadotropin, 125 IU HCG, in 0.5 ml syringe, subcutaneous administration, Rx only, Complete Pharmacy & Medical Solutions, Miami Lakes, FL 33014	Class I	Lot # 2079ps5, Exp 02/01/2016	Non-sterility: presence of mold confirmed by outside laboratory at the 14 day culture.	Complete Pharmacy and Medical Solutions LLC 5829 Nw 158th St Miami Lakes, FL 33014-6721
Drugs	Human Chorionic Gonadotropin, 15,000 IU per vial, lyophilized for injection, Rx only, Complete Pharmacy & Medical Solutions, Miami Lakes, FL 33014	Class I	Lot # 22016, Exp 1/30/2017	Non-sterility - presence of bacteria confirmed by outside laboratory after day 14.	Complete Pharmacy and Medical Solutions LLC 5829 NW 158th St Miami Lakes, FL 33014-6721
Drugs	Acetaminophen 325mg tablets, 120-count bottles, Pk By Safecor Health Woburn, MA 01801, NDC 00904198280.	Class II	Lot #: A18688, Exp. 09/30/2018	CGMP Deviations	Safecor Health, LLC 317 New Boston St Woburn, MA 01801-6231
Drugs	Atorvastatin Calcium 40mg Tablet, 30-count bottles, Rx only, Pk By Safecor Health Woburn, MA 01801, NDC 60505258009	Class II	Lot # A18661, Exp. 10/31/2017	CGMP Deviations	Safecor Health, LLC 317 New Boston St Woburn, MA 01801-6231
Drugs	Calcium Carbonate 600mg/Vitamin D3 400 International Units tablets, 60-count bottles, Pk By Safecor Health Woburn, MA 01801, NDC 00904323392.	Class II	Lot # A18705, Exp. 09/30/2017	CGMP Deviations	Safecor Health, LLC 317 New Boston St Woburn, MA 01801-6231
Drugs	Acyclovir 400mg Tablet, 15-count bottles, Rx only, Packaged by Safecor Health, LLC. Woburn, MA 01801, NDC 0093894305	Class II	Lot # A25591, Exp. 02/22/2017	CGMP Deviations	Safecor Health, LLC 317 New Boston St Woburn, MA 01801-6231

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Doxycycline 100mg Tablets, 14-count bottles, Rx only, Packaged By Safecor Health LLC Woburn, MA 01801, NDC 0143314205	Class II	Lot # A25593, Exp. 2/22/2017	CGMP Deviations	Safecor Health, LLC 317 New Boston St Woburn, MA 01801-6231
Drugs	Metronidazole 500mg Tablet, 50-count bottles, Rx only, Packaged By Safecor Health LLC Woburn, MA 01801, NDC 5011133402	Class II	Lot # A25593, Exp. 02/22/2017	CGMP Deviations	Safecor Health, LLC 317 New Boston St Woburn, MA 01801-6231
Drugs	Potassium PHOSphate in 0.5% Dextrose, 7.5 mMol in 100 mL, Service Code 2K5299, NDC# 61553-0299-48, Total Volume 100.00 mL incorrectly labeled as 150.00 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478	Class II	Lot Numbers: 170020074D, 4/3/2017; 170050071D, 4/6/2017; 170270036D, 4/30/2017	Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	VANCOMYCIN HCl 1.5g in 300 mL 0.9% Sodium Chloride Injection USP, Service Code 2K2243, NDC# 61553-043-34, Total Volume 300.00 mL incorrectly labeled as 500.00 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478	Class II	Lot Numbers: 170200039S, 2/22/2017; 170230182S, 170230137S, 2/23/2017; 170260122S, 2/26/2017; 170300085S, 3/2/2017; 170320048S, 3/4/2017; 170340152S, 3/8/2017; 170380097S, 3/10/2017	Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	VANCOMYCIN HCl 1.75g in 300 mL 0.9% Sodium Chloride Injection USP, Service Code 2K2237, NDC# 61553-037-34, Total Volume 300.00 mL incorrectly labeled as 500.00 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478	Class II	Lot Numbers: 170160016S, 2/20/2017; 170240147S, 3/1/2017; 170380016S, 3/15/2017; 170450010S, 3/22/2017	Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	VANCOMYCIN HCl 1.5g in 300 mL 5% Dextrose Injection USP, Service Code 2K2227, NDC# 61553-027-34, Total Volume 300.00 mL incorrectly labeled as 500.00 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478	Class II	Lot Numbers: 170250124S, 2/25/2017; 170270018S, 2/28/2017; 170380015S, 3/10/2017	Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	Levophed norepinephrine bitartrate, injection, USP, 4 mg /4 mL (1 mg/mL), Rx only, Hospira, Inc. Lake Forest, IL --- NDC 0409-3375-04	Class II	720503A, 720603A (Canada only)	GMP Deviation; A foreign stopper was observed during packaging of a lot of product.	Hospira Inc., A Pfizer Company 275 N Field Dr Lake Forest, IL 60045-2579
Drugs	NasalCrom (cromolyn sodium) Nasal Spray, USP, 5.2 mg per spray, 200 metered sprays, 0.88 FL OZ (26 mL) metered spray pump bottle, Distributed by: Medtech Products, Inc., Tarrytown, NY 10591, UPC 8 148332 01101 7.	Class II	Lot: 253211, Exp 12/18	CGMP Deviations: Possibility of the presence of microbial contamination in the water used to manufacture this product lot.	Bausch & Lomb, Inc. 8500 Hidden River Pkwy Tampa, FL 33637-1014
Drugs	ESTRONE USP, packaged in a) 1g bottle (NDC: 58597-8049-2), c) 5g bottle (NDC: 58597-8049-3), d) 25g bottle (NDC: 58597-8049-4), For Prescription Compounding, RX Only, Packed under cGMP conditions by American Pharmaceutical Ingredients, LLC, 6650 Highland Road, Waterford,	Class II	Lots: 052915-1, 052915-2, exp 5/5/2017	cGMP Deviations; lack of quality assurance.	American Pharmaceutical Ingredients LLC 6650 Highland Rd Ste 302 Waterford, MI 48327-1665

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	MI 48327				
Drugs	Venlafaxine Hydrochloride Extended-Release Capsules USP, 75 mg, packaged in a) 30-count bottles (NDC 52343-132-30) and b) 90-count bottles (NDC 52343-132-90), Rx only, Distributed by: Lucid Pharma LLC, 2 Tower Center Blvd, Suite-1101-B, East Brunswick, NJ 08816 USA.	Class II	Lot #: a) V17516045-A, Exp 08/18; b) V17516047-A 09/18	Failed Tablet/Capsules Specifications: pharmacists complaints for bottles containing melted capsules.	Lucid Pharma LLC 2 Tower Center Blvd Suite 1101B East Brunswick, NJ 08816-1100
Drugs	Magnesium Citrate Saline Laxative Cherry Flavored, packaged in a) 10 fl. oz. (296 mL) bottle UPC: 072785104556 (Rexall's label), b) 10 fl. oz. (296 mL) bottle UPC: 041163254138 (Equaline's label), OTC, Distributed by a) Dolgencorp, LL, Goodlettsville, TN 37072 b)Supervalu, Inc. Eden Prairie, MN 55344	Class II	Lot: 0313246	Presence of foreign substance: glass particle	Vi-Jon, Inc. 1 Swan Dr Smyrna, TN 37167-2099
Drugs	Blephamide (sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2% sterile, 3.5 g tube, RX only, Manufactured by Allergan, Irvine, California, 92612, U.S.A., NDC: 0023-0313-04.	Class II	Lot: 93802, EXP NOV 2019	Failed Impurities/Degradation Specifications: stability testing results did not meet the specification for impurities.	Allergan Sales, LLC 8301 Mars Dr Waco, TX 76712-6578
Drugs	Doxycycline Hyclate USP, active pharmaceutical ingredient, a) 25 g packaged in a 500 cc container (NDC: 58597-8082-4), b) 100 g packaged in 16 oz container (NDC: 58597-8082-6), c) 500 g packaged in a 2500 cc container (NDC: 58597-8082-7) and a 1,000 g packaged in 1 gallon container (NDC: 58597-8082-8). For Prescription Compounding RX Only. Packed under cGMP conditions by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot: 082815-1, EXP 06/04/2019	Labeling: Not Elsewhere Classified. Manufacturer and product were discovered to be on FDA Import Alert 66-66 for misbranding of active pharmaceutical ingredient.	American Pharmaceutical Ingredients LLC 6650 Highland Rd Ste 302 Waterford, MI 48327-1665
Drugs	Progesterone Injection in Olive Oil With Benzyl Alcohol 10%, 50mg/mL, 10mL Multi-Dose Vial, Rx only, Apothecary by Design,	Class II	Lot #: 04192017@1, Exp 09/30/2017	CGMP Deviations: The metal container closure adheres to the rubber stopper on some of the units of the batch which can impact the	Apothecary By Design 141 Preble St Portland, ME 04101-

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	141 Preble Street, Portland, ME.			integrity of the container closure.	2440
Drugs	Methocarbamol, USP, packaged in a) 100 g container (NDC: 58597-8023-6, b) 500 g container (NDC: 58597-8023-7), c) 1,000 g container (NDC: 58597-8023-8). For Prescription Compounding RX Only. Packed under cGMP conditions by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lots: MCMR1308029NS, MC MR1308029NS-4202015; Exp. 08/18	CGMP Deviations: Lack of quality assurance at the API manufacturer.	American Pharmaceutical Ingredients LLC 6650 Highland Rd Ste 302 Waterford, MI 48327-1665
Drugs	Chlorhexidine Gluconate 0.12% Oral Rinse, USP, 1 Pint (473 ml), Rx Only, Distributed by: Xttrium Laboratories, Inc., Mount Prospect, IL 60056, NDC 0116-2001-16	Class II	1999CHG16MC-Lot number 704-201 (full lot # 704-1999-201), Exp 03/20 1999CHG16 MC-Lot number 705-208 (full lot # 705-1999-208), Exp 04/20	CGMP Deviations	Xttrium Laboratories Inc 415 W Pershing Rd Chicago, IL 60609-2788
Drugs	Tetracycline-ABC Brand Topical ointment First Aid Antibiotic, tetracycline (3%), 3 mL in a 5 mL bottle, sold over the counter Phillips Company, Millerton, OK -- NDC 4307410201	Class II	All lots remaining within expiry.	GMP Deviations; FDA inspection found significant manufacturing practices that call into question the safety, identity, strength, quality and purity of unexpired drug products manufactured by the firm.	Phillips Co. 311 Chikasaw Street Millerton, OK 74750
Drugs	Clindamycin Injection USP; 300 mg/2 mL (150 mg/mL). 2 mL Single-dose ADD-VANTAGE Vial, Rx Only, Manufactured for Alvogen, Inc., Pine Brook, NJ 07058, NDC 47781-462-69	Class II	Lot: 73-154-EV; Exp. 12/31/17	Lack of Assurance of Sterility	Alvogen, Inc 10 Bloomfield Ave Bldg B Ste 2 Pine Brook, NJ 07058-9743
Drugs	TetraStem brand Topical Ointment First Aid Antibiotic, tetracycline (3%), 3 mL in a 5 mL bottle, sold over the counter Phillips Company, Millerton, OK -- NDC 04307-301-11	Class II	All lots remaining within expiry.	GMP Deviations; FDA inspection found significant manufacturing practices that call into question the safety, identity, strength, quality and purity of unexpired drug products manufactured by the firm.	Phillips Co. 311 Chikasaw Street Millerton, OK 74750

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Diabecline brand Topical Ointment First Aid Antibiotic, tetracycline (3%), 3 mL in a 5 mL bottle, sold over the counter Phillips Company, Millerton, OK -- NDC 04307-100-11	Class II	All lots remaining within expiry.	GMP Deviations; FDA inspection found significant manufacturing practices that call into question the safety, identity, strength, quality and purity of unexpired drug products manufactured by the firm.	Phillips Co. 311 Chikasaw Street Millerton, OK 74750
Drugs	StingMed Insect bites Skin Protectant. Zinc acetate (.1% by volume), 0.3 fl. oz. (3 mL) bottle, Phillips Company, Millerton, OK -- NDC 04307-100-11	Class II	All lots remaining within expiry.	GMP Deviations; FDA inspection found significant manufacturing practices that call into question the safety, identity, strength, quality and purity of unexpired drug products manufactured by the firm.	Phillips Co. 311 Chikasaw Street Millerton, OK 74750
Drugs	StaphWash+Plus+ Skin Protectant, Zinc acetate (.1% by volume), 0.3 fl. oz. (3 mL) bottle, Phillips Company, Millerton, OK -- NDC 43074-101-01	Class II	All lots remaining within expiry.	GMP Deviations; FDA inspection found significant manufacturing practices that call into question the safety, identity, strength, quality and purity of unexpired drug products manufactured by the firm.	Phillips Co. 311 Chikasaw Street Millerton, OK 74750
Drugs	VenomX, Zinc acetate (.1% by volume), 0.3 fl. oz. (3 mL) bottles, Skin Protectant Phillips Company, Millerton, OK -- NDC 43074-207-01	Class II	All lots remaining within expiry.	GMP Deviations; FDA inspection found significant manufacturing practices that call into question the safety, identity, strength, quality and purity of unexpired drug products manufactured by the firm.	Phillips Co. 311 Chikasaw Street Millerton, OK 74750
Drugs	Succinylcholine Chloride, 100 mg per 5mL, 20 mg per mL syringe. IV Use Only. JCB Laboratories, 8710 E 34th St., N. Wichita, KS 67226 UPC 7335968405	Class II	Lot #: C274-000000331, BU D 08/30/2017; C274-000001274, BUD 09/07/2017; C274-000001326, BUD 09/14/2017	Lack Of Assurance Of Sterility: voluntary recall initiated by the commercial supplier	Fagron Compounding Services LLC dba Fagron Sterile Services 8710 E 34th St N Wichita, KS 67226-2636
Drugs	Clindamycin Injection USP; 600 mg/4 mL (150 mg/mL). 4 mL Single-dose ADD-VANTAGE Vial, Rx Only, Manufactured for Alvogen, Inc., Pine Brook, NJ 07058, NDC 47781-463-69	Class II	Lots: 68-104-EV; Exp 07/31/18, 73-155-EV; Exp. 12/31/18, 73-156-EV; Exp.12/31/18	Lack of Assurance of Sterility	Alvogen, Inc 10 Bloomfield Ave Bldg B Ste 2 Pine Brook, NJ 07058-9743

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Clindamycin Injection USP; 900 mg/6 mL (150 mg/mL). 6 mL Single-dose ADD-VANTAGE Vial, Rx Only, Manufactured for Alvogen, Inc., Pine Brook, NJ 07058, NDC 47781-464-69	Class II	Lots: 68-105-EV; Exp. 07/31/18, 68-106-EV; Exp. 07/31/18, and 73-157-EV; Exp. 12/31/18	Lack of Assurance of Sterility	Alvogen, Inc 10 Bloomfield Ave Bldg B Ste 2 Pine Brook, NJ 07058-9743
Drugs	parodontax WHITENING (Stannous fluoride) Daily Fluoride Anticavity and Antigingivitis Toothpaste, 0.454% (0.15% w/v fluoride ion), 3.4 OZ (96.4 g) tube, Distributed by: GSK Consumer Healthcare, Warren, NJ 07059, NDC 0135-0601-01.	Class II	G7E101, Exp 04/19 G7E101, Exp 04/19	Presence of Foreign Substance: possibility of the presence of metal in the product.	GSK Consumer Healthcare 184 Liberty Corner Rd Ste 200 Warren, NJ 07059-6868
Drugs	Potassium CHLORide added to 0.9% Sodium Chloride, 30mEq 100 mL Bag, Service Code 2K5824, NDC# 61553-0824-48, Total Volume 100.00 mL incorrectly labeled as 115.00 mL, Rx Only, PharMEDium Services, LLC, 6100 Global Drive, Memphis, TN 38141	Class III	Lot Numbers: 70090135M, 2/27/2017; 170250101M, 3/15/2017; 170030011D, 4/4/2017; 170040078D, 4/5/2017; 170310012D, 5/2/2017; 170400046D, 5/11/2017;	Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	Potassium CHLORide added to 0.9% Sodium Chloride, 10mEq 100 mL Bag, Service Code 2K5856, NDC# 61553-0856-48, Total Volume 100.00 mL incorrectly labeled as 105.00 mL, Rx Only, PharMEDium Services, LLC, 6100 Global Drive, Memphis, TN 38141	Class III	Lot Numbers: 163640167M, 3/21/2017; 170050171M, 3/28/2017; 170070172M, 3/31/2017; 170190235M, 4/11/2017; 170200120M, 4/14/2017; 170230115M, 4/15/2017; 170390059D, 5/10/2017 ;	Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	Potassium PHOSphate added to 0.9% Sodium Chloride, 7.5 mMol 100 mL Bag, Service Code 2K5298, NDC# 61553-0298-48, Total Volume 100.00 mL incorrectly labeled as 102.50 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478	Class III	Lot Numbers: 163640146S, 3/30/2017; 170020187S, 4/3/2017; 170100120S, 4/11/2017; 170200117S, 4/23/2017; 170340009S, 5/6/2017	Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	Potassium PHOSphate added to 0.9% Sodium Chloride, 15 mMol 100 mL Bag, Service Code 2K5295, NDC# 61553-0295-48, Total Volume 100.00 mL incorrectly labeled as 105.00 mL, Rx Only, PharMEDium Services, LLC, 12620	Class III	Lot Numbers: 170050001D, 4/5/2017; 170040025D, 4/5/2017; 170060046D, 4/9/2017; 170090062D, 4/10/2017; 170110125S, 4/12/2017; 170170016S, 4/18/2017; 170200120S, 4/23/2017; 17038	Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	W. Airport Blvd #130, Sugar Land, TX 74478		0108S, 5/9/2017;		
Drugs	Potassium PHOSphate added to 0.9% Sodium Chloride, 10 mMol 100 mL Bag, Service Code 2K5288, NDC# 61553-0288-48, Total Volume 100.00 mL incorrectly labeled as 103.33 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478	Class III	Lot Numbers: 163640076D, 3/30/2017; 170040009D, 4/5/2017; 170040224S, 4/5/2017; 170040065S, 4/5/2017; 170050068D, 4/6/2017; 170060353S, 4/9/2017; 170100076D, 4/11/2017; 170100111S, 4/11/2017; 170120090D, 4/13/2017; 170120154S, 4/13/2017; 170160150S, 4/17/2017; 170260005D, 4/27/2017; 170380110S, 5/9/2017; 170400085S, 5/11/2017	Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	Potassium PHOSphate added to 0.9% Sodium Chloride, 20 mMol 100 mL Bag, Service Code 2K5287, NDC# 61553-0287-48, Total Volume 100.00 mL incorrectly labeled as 106.67 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478	Class III	Lot Numbers: 170100124S, 4/11/2017; 170390015S, 5/10/2017	Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	Potassium PHOSphate added to 0.9% Sodium Chloride, 7 mMol 100 mL Bag, Service Code 2K5284, NDC# 61553-0284-48, Total Volume 100.00 mL incorrectly labeled as 102.33 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478	Class III	Lot Numbers: 163640084D, 3/30/2017; 170120081D, 4/13/2017; 170160062D, 4/17/2017; 170200066D, 4/23/2017; 170370011D, 5/8/2017	Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	Montelukast Sodium Oral Granules, 4 mg pouch, Rx only, Mylan Pharmaceuticals Inc., Morgantown, WV --- NDC 0378-6040-93	Class III	Batch 3074707, exp 02/2018	Failed Impurities/Degradation Specifications; out of specification results for Sulphoxide Impurity and Total Impurities	Mylan Pharmaceuticals Inc. 781 Chestnut Ridge Rd Morgantown, WV 26505-2730

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	BuPROPion HCL Tablets, USP, 75 mg, packaged as UD 100 tablets (10x10), Rx Only, Mfg by: Sandoz Inc., 508 Carnegie Center, Suite 400, Princeton, NJ 08805, NDC: 63739-706-10	Class III	Lot # 0113148, 0113149, 0113150, Exp: 04/18; 0113636, Exp: 06/18; 0114513, Exp: 10/18	Failed Moisture Limits: Product tested out-of-specification for moisture content.	Mckesson Packaging Services 7101 Weddington Rd NW Concord, NC 28027-3412
Drugs	Walgreens Daytime and Nighttime Cold & Flu, packaged in combo pack of two plastic 12FL OZ (355 mL) bottles connected by one paper sleeve, TOTAL 24 FL OZ (1.5 pt)(710 mL), OTC, Distributed by: Walgreen CO., 200 Wilmot Rd., Deerfield, IL 60015	Class III	Lot #: 6MV0944, Exp 10/18	Labeling: Label Mix-Up - This product is being recalled due to an incorrect product sleeve on the product twin pack. The incorrect product sleeve is for Day-Night Cold and Flu whereas the batch contains Day-Night Cough Liquid.	L. Perrigo Company 515 Eastern Ave Allegan, MI 49010-9070
Drugs	Minivelle (estradiol Transdermal System) 0.1 mg per day, pack of 8 systems per carton, Rx only, Dist. by: Noven Therapeutics, LLC. Miami, Florida 33186. NDC: 68968-6610-8	Class III	Lot #: 78618, Exp. 05/2017	Defective Delivery System: Out of specification for peel force from the release liner specification during stability testing at 18M 25C/60%RH.	Noven Pharmaceuticals, Inc. 11960 SW 144th St Miami, FL 33186-6109
Drugs	Gaviscon (Alumina & Magnesium Trisilicate) Regular Strength Original Flavor Chewable Tablets, 80 mg & 14.2 mg, 100-count bottles, Distributed by: GlaxoSmithKline Consumer Healthcare, L.P., Moon Twp, PA 15108, UPC 3 0088-1175-47 8.	Class III	Lot #: 5J69A, Exp 02/19; 6GF2A, 6GF3A, Exp 08/19	Superpotent Drug: high out-of-specification result for magnesium.	Sanofi-Aventis U.S. LLC 55 Corporate Dr Bridgewater, NJ 08807-1265
Drugs	Ropivacaine HCl 0.2% 400 mL Total Volume in an ON-Q Pump in 0.9% Sodium Chloride Injection in 400 mL, Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478, NDC: 61553-256-09	Class III	Lot: 170340164s Lot: 170380152s Ex.: 01/1/1900	Labeling: Incorrect or Missing Lot and/or Exp Date	Pharmedium Services Llc 150 N Field Dr Lake Forest, IL 60045-4847

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Ropivacaine HCl 0.2% 500 mL Total Volume in an ON-Q Pump in 0.9% Sodium Chloride Injection in 400 mL, Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478, NDC: 61553-258-03	Class III	Lot: 170340167s; Exp. 01/01/1900	Labeling: Incorrect or Missing Lot and/or Exp Date	Pharmedium Services Llc 150 N Field Dr Lake Forest, IL 60045-4847
Drugs	Ropivacaine HCl 0.2% 500 mL Total Volume in an ON-Q Pump in 0.9% Sodium Chloride Injection in 400 mL, Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478, NDC: 61553-258-25	Class III	Lot: 170270192s Lot: 170330167s Lot: 170320087s Ex.: 01/01/1900	Labeling: Incorrect or Missing Lot and/or Exp Date	Pharmedium Services Llc 150 N Field Dr Lake Forest, IL 60045-4847
Drugs	Ropivacaine HCl 0.2% 750 mL Total Volume in an ON-Q Pump in 0.9% Sodium Chloride Injection in 600 mL, Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478, NDC: 61553-279-33	Class III	Lot: 170170204s; Exp. 01/01/1900	Labeling: Incorrect or Missing Lot and/or Exp Date	Pharmedium Services Llc 150 N Field Dr Lake Forest, IL 60045-4847
Drugs	Ropivacaine HCl 0.2% 550 mL Total Volume in an AutoFuser Pump in 0.9% Sodium Chloride Injection, Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478, NDC: 61553-100-13	Class III	Lot: 170310113s; Exp. 01/01/1900	Labeling: Incorrect or Missing Lot and/or Exp Date	Pharmedium Services Llc 150 N Field Dr Lake Forest, IL 60045-4847
Drugs	Bupivacaine HCl 0.25% 270 mL Total Volume in an ON-Q Pump in 0.9% Sodium Chloride Injection in 270 mL, Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478, NDC: 61553-044-57	Class III	Lot: 170320107s; Exp. 01/01/1900	Labeling: Incorrect or Missing Lot and/or Exp Date	Pharmedium Services Llc 150 N Field Dr Lake Forest, IL 60045-4847
Drugs	Bupivacaine HCl 0.25% 400 mL Total Volume in an ON-Q Pump in 0.9% Sodium Chloride Injection in 400 mL, Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478, NDC: 61553-023-09	Class III	Lot: 170300146s; Exp. 01/01/1900	Labeling: Incorrect or Missing Lot and/or Exp Date	Pharmedium Services Llc 150 N Field Dr Lake Forest, IL 60045-4847

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	G & W Clobetasol Propionate Ointment 0.05%, packaged in a) 15 g tube (NDC 0713-0656-15), b) 30 g tube (NDC 0713-0656-31), c) 45 g tube (NDC 0713-0656-37), d) 60 g tube (NDC 0713-0656-60), Rx Only, Manufactured by G & W Laboratories, Inc. 111 Coolidge Street, South Plainfield, NJ 07080	Class III	Lot #: a) 1001090, Exp 8/ 17; 1002881, Exp 2/18; b) 1001086, Exp 8/ 17; 1001154, Exp 11/ 17; 1001156, Exp 9/17 ; 1002882, Exp 2/18, 1004564, Exp 7/18; c) 1001155, Exp 9/17; 1004572, Exp 7/18; d) 1001158, Exp 9/17; 1001159 , Exp 10/17; 1002884, Exp 4/ 18	Failed impurities/degradation specifications: This product is being recalled due to out of specification results for Clobetasol Related Compound A, a known impurity which is a degradation product.	G & W Laboratories, Inc. 111 Coolidge St South Plainfield, NJ 07080-3895
Drugs	Fludeoxyglucose F 18 Injection, 20mCi/mL to 200 mCi/mL at EOS, 30 mL Multiple-Dose Vial, Rx Only, Manufactured by: Lantheus MI Radiopharmaceuticals, Inc., San Juan, PR --- NDC 11994-015-01	Class III	Lot: FDG170518-01, exp 5/18/2017	Failed Impurities/Degradation Specifications; out of specification result for Acetonitrile residual solvent	Lantheus MI Radiopharmaceuticals Inc. 150 Calle Federico Costa Ste 1 San Juan, PR 00918- 1339
Drugs	Amitriptyline HCl Tablets, USP 25 mg, Packaged in a)100-count bottles (NDC 0781-1487-01) and b) 1000-count bottles (NDC 0781-1487-10), Rx only, Manufactured by Sandoz Inc., Princeton, NJ 08540	Class III	Lot #: a) GR3831, GS9690, Exp. 08/2019; b) GR3832, Exp . 08/2019.	Cross Contamination With Other Product: Imipramine	Sandoz Incorporated 2555 W Midway Blvd Broomfield, CO 80020-1632

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

CURRENT DRUG SHORTAGES

Methylphenidate Hydrochloride Chewable Tablets

June 19, 2017

Reason for the Shortage

- Shionogi Pharma has Methylin chewable tablets on shortage due to manufacturing issues.
- Gavis launched methylphenidate chewable tablets in April 2015.

Estimated Resupply Dates

- Shionogi Pharma has all Methylin chewable tablets 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=1163>

Lidocaine Topical 4% Solution

June 20, 2017

Reason for the Shortage

- Amphastar did not provide a reason for the shortage.
- Teligent did not provide a reason for the shortage.
- West-Ward did not provide a reason for the shortage.

Estimated Resupply Dates

- Teligent has lidocaine topical 4% solution in 50 mL bottles on back order and the company cannot estimate a release date.
- West-Ward has lidocaine topical 4% solution in 50 mL bottles on allocation.
- Amphastar has Laryng-O-Jet syringes on back order and the company estimates a release date in late-June 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1128>

Hepatitis A Virus Vaccine Inactivated

June 20, 2017

Reason for the Shortage

- Merck did not provide a reason for the Vaqta shortage.
- GlaxoSmithKline has Havrix available.

Estimated Resupply Dates

- Merck has Vaqta pediatric/adolescent formulation 25 U/0.5 mL prefilled syringes in 10 count on back order and the company estimates a release date of 3rd quarter 2017.
- Merck has Vaqta adult formulation 50 U/1 mL vials in 1 count on back order and the company estimates product will not be available in 2017. Vaqta 50 U/1 mL prefilled syringes are on back order and the company estimates a release date of 3rd quarter 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=180>

Ethiodized Oil

June 20, 2017

Reason for the Shortage

- MGuerbet states their Lipiodol product is in short supply due to manufacturing problems at Jubliant HollisterStier, the manufacturing site in Canada that supplies Lipiodol for Guerbet. The company estimates the shortage will last at least one year.^{1,2}

Estimated Resupply Dates

- Guerbet is shipping supplies of Lipiodol Ultra-Fluide.² Lipiodol Ultra-Fluide is not FDA approved. In order to prevent a drug shortage, FDA is allowing Guerbet to import Lipiodol Ultra-Fluide, a product manufactured for Guerbet in France by Delpharm Tours.²
- Customers must order Lipiodol Ultra-Fluide directly from Guerbet by calling 1-877-729-6679. Lipiodol Ultra-Fluide is non-refundable and may not be resold.²

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=618>

Doxorubicin Injection

June 20, 2017

Reason for the Shortage

- West-Ward has Adriamycin available.¹
- Teva has doxorubicin solution for injection available.²
- Fresenius Kabi has doxorubicin solution for injection available.³
- Caraco has discontinued doxorubicin solution for injection 25 mL and 100 mL vials.⁴
- Pfizer has doxorubicin solution for injection available.⁵
- Sagent has doxorubicin solution for injection on back order due to manufacturing delays.⁶
- Mylan Institutional has doxorubicin lyophilized powder for injection available.⁷
- Actavis has doxorubicin injection available.⁸
- FDA is 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.^{10,9}

Estimated Resupply Dates

- Sagent has doxorubicin 2 mg/mL 5 mL, 25 mL, and 100 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=464>

Dopamine Hydrochloride Injection

June 21, 2017

Reason for the Shortage

- American Regent has dopamine on shortage due to manufacturing delays.
- Baxter could not provide a reason for the shortage.
- Pfizer states the shortage is due to manufacturing delays.

Estimated Resupply Dates

- American Regent has all dopamine presentations on back order and the company cannot estimate a release date.
- Pfizer has dopamine 40 mg/mL 10 mL vials on back order and the company estimates a release date of 2018. The dopamine 200 mg/250 mL premixed bags are on back order and the company estimates a release date of mid-September 2017. The 400 mg/250 mL, 800 mg/250 mL, and 800 mg/500 mL premixed bags are on back order and the company estimates a release date of mid-August 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1243>

Trace Elements Injection

June 25, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- American Regent has Multitrace-4 Concentrate 10 mL vials and trace elements-4 pediatric vials on back order and the company cannot estimate a release date. The Multitrace-5 Concentrate 1 mL vials are available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=785>

Torseamide Injection

June 25, 2017

Reason for the Shortage

- Roche discontinued Demadex injection for business reasons. Demadex tablets are not affected by this shortage.
- American Regent has toseamide on shortage due to manufacturing delays.

Estimated Resupply Dates

- American Regent has toseamide injection 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=344>

Theophylline Extended-Release Tablets

June 25, 2017

Reason for the Shortage

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

Estimated Resupply Dates

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

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1221>

Penicillin G Procaine Injection

June 25, 2017

Reason for the Shortage

- Pfizer has penicillin G procaine on shortage due to manufacturing delays.
- Pfizer is the sole supplier of penicillin G procaine.

Estimated Resupply Dates

- Pfizer has penicillin G procaine 600,000 unit/mL 1 mL and 2 mL vials on back order and the company estimates a release date of 4th quarter 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1238>

Penicillin G Benzathine/Penicillin G Procaine

June 25, 2017

Reason for the Shortage

- Pfizer has Bicillin C-R and Bicillin C-R 900/300 on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Bicillin C-R 1,200,000 units/2 mL prefilled syringes and 1,200,000 units/2 mL pediatric prefilled syringes on allocation.
- Pfizer has Bicillin C-R 900/300 2 mL pediatric prefilled syringes on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1249>

Penicillin G Benzathine

June 25, 2017

Reason for the Shortage

- Pfizer states the shortage is due to a delay in the manufacturing process.

Estimated Resupply Dates

- Pfizer has Bicillin L-A 600,000 unit/ 1 mL syringes, 1,200,000 unit/ 2 mL syringes, and 2,400,000 unit/ 4 mL syringes on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1232>

Morrhuate Sodium Injection

June 25, 2017

Reason for the Shortage

- American Regent has morrhuate sodium injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- American Regent has morrhuate sodium 50 mg/mL 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=903>

Methyldopate Injection

June 25, 2017

Reason for the Shortage

- American Regent has methyldopate injection on shortage due to manufacturing delays.
- There are no other suppliers of methyldopate injection.

Estimated Resupply Dates

- American Regent has methyldopate injection on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=844>

Electrolyte Concentrate

June 25, 2017

Reason for the Shortage

- American Regent has Nutrilite and Nutrilite II on back order due to manufacturing delays.

Estimated Resupply Dates

- American Regent has Nutrilite and Nutrilite II 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=1054>

Cefotaxime Injection

June 25, 2017

Reason for the Shortage

- Hospira has discontinued Claforan. Sanofi-Aventis manufactured Claforan for Hospira and is no longer making the product.
- Baxter discontinued Claforan in late-2015.
- West-Ward has cefotaxime on shortage due to manufacturing and issues with raw material.

Estimated Resupply Dates

- West-Ward has cefotaxime 500 mg, 1 gram, 2 gram, and 10 gram vials 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=826>

Ammonium Molybdate Injection

June 25, 2017

Reason for the Shortage

- American Regent has ammonium molybdate injection on shortage due to manufacturing delays.
- American Regent is the sole supplier of ammonium molybdate injection.

Estimated Resupply Dates

- American Regent has ammonium molybdate injection on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1003>

Thiotepa for Injection

June 26, 2017

Reason for the Shortage

- West-Ward launched thiotepa in August 2015.
- FDA was allowing temporary importation of Tepadina (thiotepa), from Adienne SA in Italy. There may still be product available at some healthcare centers but importation stopped in December 2015.

Estimated Resupply Dates

- West-Ward has thiotepa available with an expiration date of < May 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=589>

Procainamide Hydrochloride Injection

June 26, 2017

Reason for the Shortage

- Pfizer did not provide a reason for the shortage.

Estimated Resupply Dates

- Pfizer has procainamide 500 mg/mL 2 mL vials on back order and the company estimates a release date of 3rd quarter 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=868>

Multiple Vitamins for Infusion

June 26, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has M.V.I. adult 5 mL and 50 mL Dual vials on back order and the company estimates a release date of August 2017 for the 5 mL vials and mid-July 2017 for the 50 mL vials.
- Pfizer has M.V.I. pediatric 5 mL vials on back order and the company estimates a release date of December 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=831>

Hydroxyzine Hydrochloride Injection

June 26, 2017

Reason for the Shortage

- American Regent would not provide a reason for the shortage. They are the sole supplier of hydroxyzine injection.

Estimated Resupply Dates

- American Regent has hydroxyzine 50 mg/mL 10 mL vials on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1185>

Fludarabine Injection

June 26, 2017

Reason for the Shortage

- Actavis has fludarabine available.¹
- Fresenius Kabi had fludarabine on shortage due to increased demand.²
- Pfizer has fludarabine on shortage due to increased demand.³
- Sagent had fludarabine 25 mg/mL 2 mL vials on shortage due to manufacturing delays.⁴

Estimated Resupply Dates

- pfizer has fludarabine lyophilized powder 50 mg vials on back order and the company estimates a release date of late-July 2017.³

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=648>

Yellow Fever Vaccine Injection

June 27, 2017

Reason for the Shortage

- Sanofi Pasteur states the shortage is due to production delays.¹
- There are no other suppliers of yellow fever vaccine.
- [Additional information](#) on the yellow fever shortage.
- 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 [initial rollout](#) began in April 2017.
- [Information](#) on countries that require yellow fever vaccination.

Estimated Resupply Dates

- Sanofi Pasteur has YF-Vax multi-dose vials and single dose vials available in limited supply but product is expected to be depleted soon. Customers can call Sanofi Pasteur to order product for patients traveling in the next 30 days.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=383>

Sincalide Injection

June 27, 2017

Reason for the Shortage

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

Estimated Resupply Dates

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

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1032>

Indomethacin Capsules

June 27, 2017

Reason for the Shortage

- Glenmark had indomethacin 25 mg 100 count on shortage due to manufacturing delays.
- Heritage did not provide a reason for the shortage.
- Mylan did not provide a reason for the shortage.
- Sandoz discontinued indomethacin in mid-2016.
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates

- Glenmark has indomethacin 25 mg capsules in 100 count on back order and the company cannot estimate a release date.
- Heritage has indomethacin 50 mg capsules in 100 count and 500 count on back order and the company cannot estimate a release date. Heritage has short-dated indomethacin 25 mg capsules in 100 count and 1000 count available.
- Mylan has indomethacin 50 mg capsules in 100 count on back order and the company estimates a release date of late-July 2017.
- Teva has all indomethacin presentations temporarily unavailable and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1236>

Hyoscyamine Sulfate Injection

June 27, 2017

Reason for the Shortage

- Mylan did not provide a reason for the shortage.

Estimated Resupply Dates

- Mylan has Levsin injection on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1094>

Hepatitis B Vaccine Recombinant

June 27, 2017

Reason for the Shortage

- Merck did not provide a reason for the shortage.

Estimated Resupply Dates

- Merck has Recombivax HB adult formulation vials and syringes on back order and the company does not anticipate these products will be available in 2017.
- Merck has Recombivax HB pediatric/adolescent formulation syringes on intermittent back order and the company estimates this will continue through 3rd quarter 2017.

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

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

June 27, 2017

Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has 0.9% sodium chloride preservative free vials available.

Estimated Resupply Dates

- Fresenius Kabi has 0.9% sodium chloride 10 mL single dose vials on back order and the company estimates a release date in late-June 2017. The 20 mL single dose vials are available with short expiration dating (< 5 months). The company estimates the 20 mL vials with regular dating will be released in early-July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1276>

Sodium Acetate Injection

July 3, 2017

Reason for the Shortage

- American Regent has had sodium acetate on long-term back order for several years.
- Fresenius Kabi has sodium acetate on shortage due to increased demand.
- Pfizer has sodium acetate 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 mid-July 2017.
- Pfizer has sodium acetate 2 meq/mL 20 mL, 50 mL and 100 mL vials on back order and the company estimates a release date of August 2017 for the 20 mL vials and late-July 2017 for the 50 mL and 100 mL vials.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=762>

Dextrose (25%) Injection

July 3, 2017

Reason for the Shortage

- Pfizer has 25% dextrose injection 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 mid-September 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1011>

Clindamycin Injection

July 3, 2017

Reason for the Shortage

- Akorn did not provide a reason for the shortage.
- Alvogen has clindamycin injection available.
- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has Cleocin available.
- Sagent has clindamycin injection available.
- Sandoz has clindamycin injection available.

Estimated Resupply Dates

- Alvogen has clindamycin 150 mg/mL 2 mL, 4 mL, and 6 mL ADD-Vantage vials on back order and the company estimates a release date of 3rd quarter 2017.
- Fresenius Kabi has clindamycin 150 mg/mL 2 mL, 6 mL, and 60 mL vials on back order and the company cannot estimate a release date.
- Sagent has clindamycin 150 mg/mL 2 mL vials available with an expiration date of October 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1029>

Cisplatin Injection

July 3, 2017

Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.¹
- Mylan Institutional could not provide a reason for the shortage.²
- Teva has cisplatin available.³
- WG Critical Care did not provide a reason for the shortage.⁴

Estimated Resupply Dates

- Fresenius Kabi has cisplatin 200 mL vials on back order and the company estimates a release date of late-July 2017.¹
- Mylan Institutional has cisplatin 50 mL and 100 mL vials temporarily unavailable and the company cannot estimate a release date.²
- Teva has cisplatin 100 mL vials on allocation.³
- WG Critical Care has cisplatin 50 mL and 100 mL vials on back order and the company estimates a release date of July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=57>

Cefuroxime Sodium Injection

July 3, 2017

Reason for the Shortage

- Teligent has Zinacef on shortage due to increased demand.
- West-Ward did not provide a reason for the cefuroxime injection shortage.

Estimated Resupply Dates

- Sagent has cefuroxime 1.5 gram and 7.5 gram vials on back order and the company cannot estimate a release date.
- Teligent has Zinacef 750 mg ADD-Vantage vials and 7.5 gram vials on long-term back order and the company cannot estimate a release date.
- West-Ward has cefuroxime 750 mg vials available with an expiration date of March 2018. The cefuroxime 7.5 gram vials are available with an expiration date of < March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=990>

Cefoxitin Sodium Injection

July 3, 2017

Reason for the Shortage

- Fresenius Kabi and West-Ward did not provide a reason for the shortage.
- Sagent has cefoxitin on shortage due to manufacturing delays.
- BBraun has cefoxitin on allocation due to increased demand.

Estimated Resupply Dates

- Fresenius Kabi has cefoxitin 1 gram vials and 2 gram vials on back order and the company estimates a release date of late-July 2017. The 10 gram vials are available with an expiration date of <9 months.
- Sagent has cefoxitin 1 gram and 10 gram vials on back order and the company estimates a release date of July 2017. The 2 gram vials are on back order and the company cannot estimate a release date.
- West-Ward has cefoxitin 10 gram vials on back order and the company cannot estimate a release date. The 2 gram vials are on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1256>

Cefepime Injection

July 3, 2017

Reason for the Shortage

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

- WG Critical Care had cefepime injection on shortage due to increased demand

Estimated Resupply Dates

- Apotex has cefepime 2 gram vials in 10 count on back order and the company estimates a release date in mid-July 2017.
- BBraun has cefepime 1 gram premixed bags on back order and the company cannot estimate a release date.
- Pfizer has Maxipime 1 gram ADD-Vantage vials on back order and the company estimates a release date of July 2017. The 2 gram ADD-Vantage vials are on back order and the company estimates a release date of August 2017.
- Sagent has cefepime 1 gram vials on allocation. The 2 gram vials are on back order and the company estimates a release date of July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1176>

Bupivacaine Injection

July 3, 2017

Reason for the Shortage

- AuroMedics has not provided a reason for the shortage.
- Fresenius Kabi has Sensorcaine on shortage due to increased demand for the product.
- Pfizer has bupivacaine on shortage due to manufacturing delays.

Estimated Resupply Dates

- Fresenius Kabi has 0.25% Sensorcaine preservative-free 30 mL vials in sterile packs on intermittent back order and the company is releasing product as it becomes available.
- Pfizer has 0.25% Marcaine 50 mL vials and 0.5% Marcaine 50 mL vials available in limited supply. The 0.5% Marcaine 10 mL preservative-free vials are on back order and the company estimates a release date of 2nd quarter 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=864>

Atenolol Tablets

July 5, 2017

Reason for the Shortage

- Mylan, Sandoz, and Teva did not provide a reason for the back order.
- Zydus states increased demand as the reason for the back order.
- Ranbaxy refuses to provide us with any information regarding drug availability.

Estimated Resupply Dates

- Mylan has atenolol 50 mg tablets in 100 count bottles and 100 mg tablets in 100 count and 1,000 count bottles on back order. Atenolol 100 mg tablets in 1,000 count bottles have an estimated release date in early-October 2017. The company cannot estimate a release date for atenolol 50 mg tablets or 100 mg tablets in 100 count bottles.
- Sandoz has atenolol 25 mg and 50 mg tablets in 100 count bottles and 100 mg tablets in 1,000 count bottles on back order, and the company estimates a release date in mid-August 2017.
- Teva has all presentations of atenolol 50 mg and 100 mg tablets on back order, and the company cannot estimate a release date.
- Zydus has all presentations of atenolol 25 mg, 50 mg, and 100 mg tablets on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1127>

Succinylcholine Injection

July 6, 2017

Reason for the Shortage

- Pfizer has Quelicin on shortage due to manufacturing delays

Estimated Resupply Dates

- Pfizer has Quelicin 20 mg/mL 10 mL vials available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1267>

Sodium Phosphate Injection

July 6, 2017

Reason for the Shortage

- American Regent has sodium phosphate injection on shortage due to manufacturing delay.¹
- Fresenius Kabi states the reason for the shortage was increased demand.²
- Pfizer has sodium phosphate injection on shortage due to manufacturing delay.³

Estimated Resupply Dates

- American Regent has sodium phosphate 3 mmol/mL 5 mL, 15 mL, and 50 mL vials on back order and the company cannot estimate a release date.¹
- Pfizer has sodium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of mid-July 2017.³

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=770>

Magnesium Sulfate Injection

July 6, 2017

Reason for the Shortage

- American Regent has had magnesium sulfate unavailable since late 2012.
- Fresenius Kabi has magnesium sulfate injection on shortage due to increased demand for the product.
- Pfizer has magnesium sulfate injection on shortage due to manufacturing delays.
- X-Gen has magnesium sulfate injection available.

Estimated Resupply Dates

- Fresenius Kabi has magnesium sulfate 40 mg/mL 50 mL premixed bags on back order and the company estimates a release date of mid-July 2017.
- Pfizer has magnesium sulfate 500 mg/mL 20 mL vials on back order and the company estimates a release date of 1st quarter 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=757>

Fentanyl Citrate Injection

July 6, 2017

Reason for the Shortage

- Akorn has fentanyl injection on shortage due to increased demand.
- West-Ward has fentanyl injection on shortage due to supply and demand issues.
- Pfizer has fentanyl injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Akorn has fentanyl 50 mcg/mL 2 mL and 5 mL ampules on allocation.
- Pfizer has fentanyl 50 mcg/mL 5 mL ampules and 2 mL Carpuject syringes are on allocation. The 2 mL ampules are on back order and the company estimates a release date of early-July 2017. The 5 mL and 10 mL vials are on back order and the company estimates a release date of early-August 2017. The 20 mL and 50 mL vials are on back order and the company estimates a release date of late-July 2017.
- West-Ward has fentanyl 50 mcg/mL 2 mL and 50 mL vials on allocation. The 2 mL, 5 mL, and 20 mL ampules, and 5 mL vials are on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1273>

Epinephrine Injection

July 6, 2017

Reason for the Shortage

- Amphastar stopped distributing epinephrine 1 mg/mL 30 mL vials on May 10, 2017. They are continuing to supply 0.1 mg/mL 10 mL syringes. These are on shortage due to increased demand.¹
- Pfizer stopped distributing epinephrine 1 mg/mL presentations on May 10, 2017.²
- BPI has epinephrine 1 mg/mL 2 mL ampules available.³
- Par has Adrenalin 1 mg/mL 1 mL and 30 mL vials available.⁴

Estimated Resupply Dates

- Amphastar has epinephrine 0.1 mg/mL 10 mL syringes on allocation.¹
- Pfizer has epinephrine 0.1 mg/mL 10 mL syringes on back order and the company estimates a release date of late-July 2017.²

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=685>

Diltiazem Hydrochloride Injection

July 6, 2017

Reason for the Shortage

- Akorn states the reason for the shortage was increased demand due to market conditions.
- Pfizer states the reasons for the shortage is manufacturing delays and increases in demand.
- West-Ward has diltiazem injection on shortage due to manufacturing delays caused by increased demand due to current market conditions.

Estimated Resupply Dates

- Pfizer has 100 mg ADD-Vantage vials on back order and the company estimates a release date of late-July 2017. The 5 mg/mL 5 mL and 10 mL vials are on back order and the company estimates a release date of 3rd quarter 2017 for the 5 mL vials and 2018 for the 10 mL vials.
- West-Ward has diltiazem 5 mg/mL 25 mL vials on a weekly allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1271>

Dihydroergotamine Mesylate Injection

July 6, 2017

Reason for the Shortage

- Perrigo has dihydroergotamine injection available.
- Valeant 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=1050>

Dextrose (50%) Injection

July 6, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Amphastar has 50% dextrose 50 mL syringes on allocation and is regularly releasing product.
- Pfizer has 50% dextrose 50 mL LifeShield syringes, Ansyr syringes, and vials on back order and the company estimate a release date of July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1012>

Calcium Gluconate Injection

July 6, 2017

Reason for the Shortage

- American Regent has calcium gluconate on shortage due to manufacturing delays.
- Fresenius Kabi has calcium gluconate available with alternating short-dating due to manufacturing process of the vials.
- American Regent has [issued a statement](#) that all lots of calcium gluconate may contain glass particles and filters must be used. Do not use if there are visible glass particles and filter all other product.

Estimated Resupply Dates

- American Regent has calcium gluconate 100 mg/mL 50 mL and 100 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has calcium gluconate 100 mg/mL 100 mL vials on back order and the company estimates a release date of mid-July 2017.

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

Belatacept Injection

July 6, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Bristol-Myers Squibb has limited the distribution of Nulojix. They have product only for existing patients available through the US Nulojix Distribution Program. They have no estimated recovery date, but do not expect full recovery before the end of 2017. Nulojix is distributed by McKesson Plasma Biologics.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1265>

Bupivacaine with epinephrine Injection

July 6, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 10 mL and 30 mL vials on back order and the company estimates a release date of mid-August 2017 for the 10 mL vials and mid-July 2017 for the 30 mL vials. The 0.25% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of mid-July 2017. The 0.5% Sensorcaine-MPF with epinephrine 10 mL and 30 mL vials are on back order and the company estimates a release date of mid-July 2017. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials sterile packs are on back order and the company estimates a release date of early-August 2017. The 0.5% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of late-July 2017.
- Pfizer has 0.25% bupivacaine with epinephrine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of mid-July 2017 for the 10 mL vials and October 2017 for the 30 mL vials. The 0.25% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 2018. The 0.5% bupivacaine with epinephrine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of early-July 2017 for the 10 mL vials and early-August 2017 for the 30 mL vials. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of October 2017.
- Pfizer has 0.25% Marcaine with epinephrine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of October 2017 for the 10 mL vials and early-July 2017 for the 30 mL vials. The 0.25% Marcaine with epinephrine 50 mL vials are available in limited supply. The 0.5% Marcaine with epinephrine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of 1st quarter 2018 for the 10 mL vials and late-July 2017 for the 30 mL vials. The 0.5% Marcaine with epinephrine 50 mL vials are available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=937>

Topotecan Capsules

July 7, 2017

Reason for the Shortage

- Novartis did not provide a reason for the current shortage.

Estimated Resupply Dates

- Novartis has Hycamtin 0.25 mg capsules available with an expiration date of December 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1266>

Tolmetin Capsules and Tablets

July 7, 2017

Reason for the Shortage

- Mylan did not provide a reason for the shortage.
- Sun Pharma has not had tolmetin available since 2015. They refuse to provide availability information on any product.

Estimated Resupply Dates

- Mylan has tolmetin 400 mg capsules and 600 mg tablets on back order and the company estimates a release date of late-August 2017 for the 400 mg capsules and mid- to late-September 2017 for the 600 mg tablets.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1278>

Tetanus and Diphtheria Toxoids Adsorbed

July 7, 2017

Reason for the Shortage

- Grifols has tetanus and diphtheria toxoids adsorbed (Td) available.¹
- Sanofi Pasteur has Tenivac on shortage due to manufacturing delays.²
- Adult tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccines are not affected by this shortage.
- Pediatric diphtheria and tetanus toxoids adsorbed (DT) and diphtheria and tetanus toxoids and acellular pertussis vaccines (DTaP) are not affected by this shortage.

Estimated Resupply Dates

- Sanofi Pasteur has Tenivac on back order and the company estimates a release date of July 2017.²

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1260>

Promethazine Injection

July 7, 2017

Reason for the Shortage

- Teva is not marketing promethazine injection at this time.
- West-Ward states the shortage is due to manufacturing delays.
- Hospira discontinued promethazine in 2016.

- X-Gen has promethazine available.

Estimated Resupply Dates

- West-Ward has promethazine 25 mg/mL 1 mL vials and ampules on a weekly allocation. The 50 mg/mL 1 mL vials and ampules are on a weekly allocation.
- West-Ward has Phenergan 25 mg/mL 1 mL vials on back order and the company estimates a release date of July or August 2017. Phenergan 25 mg/mL 1 mL ampules and 50 mg/mL 1 mL vials are on a weekly allocation.
- X-Gen has promethazine 25 mg/mL 1 mL ampules on back order and the company estimates a release date of mid-August 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=654>

Olanzapine Injection

July 7, 2017

Reason for the Shortage

- Sandoz did not provide a reason for the shortage of olanzapine intramuscular injection.

Estimated Resupply Dates

- Sandoz has olanzapine 10 mg vials on back order and the company estimates a release date of mid-July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1093>

Octreotide Injection

July 7, 2017

Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Mylan Institutional has octreotide available.
- Sagent has octreotide on shortage due to manufacturing delays.
- Sun Pharma refuses to provide availability information for any of their products including octreotide.
- Teva has octreotide available.
- Novartis has Sandostatin available.

Estimated Resupply Date

- Fresenius Kabi has octreotide 50 mcg/mL 1 mL vials on back order and the company estimates a release date of 1st quarter 2018.
- Sagent has octreotide 50 mcg/mL 1 mL vials on back order and the company estimates a release date of July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=803>

Norepinephrine Bitartrate Injection

July 7, 2017

Reason for the Shortage

- Claris has norepinephrine injection available.

- Pfizer has Levophed on shortage due to manufacturing delays.
- Teva has norepinephrine injection on shortage due to increased demand.

Estimated Resupply Dates

- Teva has norepinephrine 1 mg/mL 4 mL vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1262>

Metronidazole Hydrochloride Injection

July 7, 2017

Reason for the Shortage

- Pfizer has metronidazole injection on shortage due to manufacturing delay.
- Baxter, BBraun, and Claris did not provide a reason for the metronidazole injection shortage.

Estimated Resupply Dates

- Baxter has metronidazole injection available in limited quantities.
- BBraun has metronidazole injection on intermittent back order and the company is releasing product regularly.
- Claris has metronidazole injection on long-term back order and the company cannot estimate a release date.
- Pfizer has metronidazole injection in 24 count and 80 count on back order and the company estimates a release date of August 2017 for the 24 count size and October 2017 for the 80 count size.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1272>

Lidocaine with Epinephrine Injection

July 7, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has 1% lidocaine with epinephrine (1:100,000) 20 mL on back order and the company estimates a release date of 2nd quarter 2018. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are on back order and the company estimates a release date of mid-August 2017. The 1% lidocaine with epinephrine (1:100,000) 50 mL vials are on back order and the company estimates a release date of late-August 2017. The 0.5% lidocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates a release date of 1st quarter 2018. The 1.5% lidocaine with epinephrine (1:200,000) 30 mL vials are on back order and the company estimates a release date of October 2017. The 2% lidocaine with epinephrine (1:200,000) 20 mL vials are on back order and the company estimates a release date of mid-August 2017. The 2% lidocaine with epinephrine (1:100,000) 20 mL, 30 mL, and 50 mL vials are on back order and the company estimates a release date of October 2017 for the 20 mL and 50 mL vials and 1st quarter 2018 for the 30 mL vials.
- Fresenius Kabi has 0.5% Xylocaine with epinephrine (1:200,000) 50 mL vials on back order and the company estimates a release date of late-July to early-August 2017. The 1% Xylocaine with epinephrine (1:200,000) 10 mL, 20 mL, and 50 mL vials are on back order and the company estimates a release date of early-August 2017 for the 10 mL vials and mid-July 2017 for the 20 mL and 50 mL vials. The 1% Xylocaine-

MPF with epinephrine (1:200,000) 10 mL and 30 mL vials are on back order and the company estimates a release date of early-August 2017 for the 10 mL vials and mid-July 2017 for the 30 mL vials. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company estimates a release date of mid-July 2017. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are available with an expiration date of <8 months. The 2% Xylocaine with epinephrine (1:200,000) 20 mL and 50 mL vials are on back order and the company estimates a release date of late-July 2017 for the 20 mL vials and mid-July 2017 for the 50 mL vials. The 2% Xylocaine-MPF with epinephrine (1:200,000) 10 mL and 20 mL vials are on back order and the company estimates a release date of late-July 2017 for the 10 mL vials and late-July to early-August 2017 for the 20 mL vials. The 2% Xylocaine-MPF with epinephrine (1:200,000) 20 mL vials in sterile packs are on back order and the company estimates a release date of late-August 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=860>

Lidocaine Injection

July 7, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- AuroMedics has 1% lidocaine 2 mL and 5 mL vials on intermittent back order and the company is releasing product as it becomes available. AuroMedics has 2% lidocaine 2 mL and 5 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has 1% Xylocaine 20 mL and 50 mL vials on back order and the company estimates a release date of late-July 2017 for the 20 mL vials and mid-July 2017 for the 50 mL vials. The 2% Xylocaine 20 mL vials are on back order and the company estimates a release date of mid-July 2017. The 2% Xylocaine-MPF 10 mL ampules are on intermittent back order and the company is releasing product as it becomes available.
- Pfizer has 1% lidocaine 5 mL preservative-free ampules on back order and the company estimates a release date of early-July 2017. The 2% lidocaine 5 mL Ansyf syringes and 5 mL LifeShield syringes are on back order and the company estimates a release date of early-July 2017 for the Ansyf syringes and mid-August 2017 for the LifeShield syringes.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=859>

Levetiracetam Injection

July 7, 2017

Reason for the Shortage

- American Regent has product available.
- AuroMedics did not provide a reason for the shortage.
- Caraco will not provide availability information on levetiracetam.
- Fresenius Kabi had levetiracetam injection on shortage due to manufacturing delays.
- Mylan has product available.
- Pfizer has product available.

- Sagent has levetiracetam injection on shortage due to manufacturing delays.
- UCB has product available.
- West-Ward has product available.
- X-Gen has product available.

Estimated Resupply Dates

- AuroMedics has levetiracetam 100 mg/mL 5 mL vials and 15 mg/mL 100 mL premixed bags on intermittent back order and the company is releasing product as it becomes available.
- Sagent has levetiracetam 100 mg/mL 5 mL vials on back order and the company estimates a release date of July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1183>

Leucovorin Calcium Injection

July 7, 2017

Reason for the Shortage

- Fresenius Kabi has leucovorin available.
- Sagent has leucovorin on shortage due to manufacturing delay.
- Teva had leucovorin on allocation due to increased demand.
- West-Ward did not provide a reason for the current shortage.

Estimated Resupply Dates

- Fresenius Kabi has leucovorin 500 mg vials on back order and the company estimates a release date of early-August 2017.
- Sagent has leucovorin 100 mg vials on allocation. The 50 mg and 350 mg vials are on back order and the company estimates a release date of July 2017 for the 50 mg vials and August 2017 for the 350 mg vials. The 200 mg vials are on back order and the company cannot estimate a release date.
- Teva has leucovorin 100 mg and 350 mg vials on allocation.
- West-Ward has leucovorin 350 mg vials on allocation.

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

Fluconazole Injection

July 7, 2017

Reason for the Shortage

- Baxter, Claris Lifesciences, and West-Ward did not provide a reason for the fluconazole injection shortage.
- Pfizer has fluconazole injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Baxter has 200 mg/100 mL and 400 mg/200 mL in 0.9% sodium chloride premixed bags on back order and the company cannot estimate a release date.
- Claris Lifesciences has fluconazole injection 100 mg/50 mL in 0.9% sodium chloride in 6 count, 400 mg/200 mL in 0.9% sodium chloride in 6 count, 200 mg/100 mL in 5% dextrose in 6 count, and 400 mg/200 mL in 5% dextrose in 6 count on back order and the company cannot estimate a release date. Fluconazole injection 400 mg/200 mL in 5% dextrose in 10 count is available in limited supply.
- Pfizer has fluconazole injection 400 mg/200 mL in 0.9% sodium chloride premixed bags on back order and the company estimates a release date of mid-July 2017.
- West-Ward has all 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=644>

70% Dextrose Injection Large Volume Bags

July 7, 2017

Reason for the Shortage

- Baxter has 70% dextrose 2,000 mL bags on shortage due to manufacturing delays.¹
- BBraun discontinued 70% dextrose in 1,000 mL glass bottles in 2016. The 70% dextrose 2,000 mL bags are on allocation due to increased demand.²
- Pfizer had 70% dextrose 500 mL in 1000 mL partial fill bags on back order due to manufacturing delays.⁴

Estimated Resupply Dates

- Baxter has 70% dextrose 2,000 mL bags on intermittent back order with regular releases.¹
- BBraun has 70% dextrose 2,000 mL bags available to current customers.²
- Pfizer has 70% dextrose 2,000 mL bags on back order and the company estimates a release date in early-July 2017. The 500 mL in 1000 mL partial-fill bags are on back order and the company estimates a release date in early-September 2017

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1133>

Vecuronium Bromide Injection

July 10, 2017

Reason for the Shortage

- Pfizer has vecuronium on shortage due to manufacturing delays.^{1,2}
- Teva is not actively marketing vecuronium.³
- Pfizer sold vecuronium injection to Mylan Institutional in December 2013.^{4,5}
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.⁶
- Sun Pharma refuses to provide information on availability of any of their products.⁷
- Sagent is not marketing vecuronium 10 mg and 20 mg vials.⁸

Estimated Resupply Dates

- Mylan Institutional has vecuronium 10 mg vials on back order with an estimated release date of early-December 2017.⁵
- Pfizer has vecuronium 10 mg and 20 mg vials on back order and the company estimates a release date of 1st quarter 2018.²

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

Vancomycin Hydrochloride Injection

July 10, 2017

Reason for the Shortage

- Pfizer has vancomycin bulk vials on back order due to manufacturing delays. All other presentations are available.¹
- Fresenius Kabi has vancomycin injection on shortage due to increased demand.²
- Mylan Institutional has vancomycin injection available.³
- Baxter has vancomycin injection available.⁴
- Sagent has vancomycin injection on shortage due to manufacturing delays.⁵

Estimated Resupply Dates

- Fresenius Kabi has vancomycin 5 gram and 10 gram vials on intermittent back order with regular releases.²
- Pfizer has vancomycin lyophilized powder 500 mg and 5 gram vials on back order and the company estimates a release date of mid-July 2017.¹
- Sagent has vancomycin 5 gram and 10 gram vials on back order and the company estimates a release date of July 2017.⁵

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=132>

Sodium Nitroprusside Injection

July 10, 2017

Reason for the Shortage

- Valeant has Nitropress available but short-dated.
- Nexus has sodium nitroprusside 25 mg/mL 2 mL vials available.
- Sagent has sodium nitroprusside 25 mg/mL 2 mL vials available.
- Exela launched Nipride RTU 0.5 mg/mL 100 mL vials in March 2017.

Estimated Resupply Dates

- Valeant has Nitropress 25 mg/mL 2 mL vials available with an expiration date of May 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1223>

Potassium Phosphate Injection

July 10, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has potassium phosphate 3 mmol/mL 15 mL and 50 mL vials on back order and the company estimates a release date of mid-July 2017 for the 15 mL vials and late-July 2017 for the 50 mL vials.
- Pfizer has potassium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of late-July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=709>

Piperacillin Tazobactam Injection

July 10, 2017

Reason for the Shortage

- Apotex has piperacillin/tazobactam on shortage due to regulatory delays.
- AuroMedics and Sandoz could not provide a reason for the shortage.
- Fresenius Kabi has piperacillin/tazobactam on shortage due to increased demand.

- Mylan Institutional launched piperacillin/tazobactam 3.375 gram and 4.5 gram vials in early-June 2016.
- Pfizer has Zosyn single dose vials and piperacillin/tazobactam on shortage due to manufacturing delays.
- Sagent has piperacillin/tazobactam on shortage due to increased demand.
- Sandoz has piperacillin/tazobactam available for contracted customers.
- WG Critical Care states the reason for the shortage is increased demand.
- FDA in conjunction with [SteriMax](#) was allowing temporary importation of piperacillin/tazobactam 3.375 gram, 4.5 gram, and 40.5 gram vials from Canada. This was being distributed through X-Gen Pharmaceuticals. These are no longer being imported with the launch of the products from X-Gen. The product codes on these items will not be recognized by U.S. systems so institutions will need to implement alternative plans to assure the dose is being given correctly. More information can be found here on the FDA site.
- Wockhardt has piperacillin/tazobactam injection available.
- X-Gen has piperacillin/tazobactam injection available.

Estimated Resupply Dates

- Apotex has piperacillin/tazobactam 3.375 gram, 4.5 gram, and 40.5 gram vials on back order and the company estimates a release date of early-August 2017 for the 3.375 gram and 4.5 gram vials and mid-August 2017 for the 40.5 gram vials.
- AuroMedics has piperacillin/tazobactam on intermittent back order and the company is releasing product as it becomes available. Check wholesalers for inventory.
- Fresenius Kabi has piperacillin/tazobactam 40.5 gram vials on back order and the company estimates a release date of mid-July 2017.
- 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 January 2018.
- Sagent has piperacillin/tazobactam 4.5 gram vials on allocation.
- Sandoz has piperacillin/tazobactam 2.25 gram (NDC 00781-3110-85) and 4.5 gram (NDC 00781-3367-95) vials on back order and the company estimates a release date of mid-July 2017.
- WG Critical Care has piperacillin/tazobactam 3.375 gram and 4.5 gram vials on back order and the company estimates a release date of August 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1075>

Pantoprazole Injection

July 10, 2017

Reason for the Shortage

- Pfizer did not provide a reason for the back order.
- AuroMedics did not provide a reason for the back order.

Estimated Resupply Dates

- Pfizer has Protonix 40 mg vials in 10 count and 25 count packs on back order and the company estimates a release date of July 2017.
- AuroMedics has pantoprazole 40 mg vials on intermittent back order and the company and the company is releasing product as it becomes available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1153>

Isosorbide Dinitrate Extended-Release Tablets

July 10, 2017

Reason for the Shortage

- Sun Pharma is not currently manufacturing isosorbide dinitrate 40 mg extended-release tablets.

Estimated Resupply Dates

- Sun Pharma did not provide an estimated resupply date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1280>

Hydromorphone Hydrochloride Injection

July 10, 2017

Reason for the Shortage

- Pfizer did not provide a reason for the shortage.
- Purdue discontinued Dilaudid and Dilaudid HP in May 2017 for marketing reasons.
- Teva did not provide a reason for the shortage.
- West-Ward did not provide a reason for the shortage.

Estimated Resupply Dates

- Pfizer has hydromorphone 0.5 mg/0.5 mL 0.5 mL iSecure syringes, 1 mg/mL 1 mL iSecure syringes, and 2 mg/mL 1 mL vials on back order and the company estimates a release date of late-July 2017. Hydromorphone 2 mg/mL 1 mL ampules are on back order and the company estimates a release date of early-September 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=856>

Gentamicin Injection

July 10, 2017

Reason for the Shortage

- Pfizer has discontinued all premixed bags.
- Baxter did not provide a reason for the shortage.

Estimated Resupply Dates

- Pfizer has gentamicin 40 mg/mL 2 mL vials available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=728>

Famotidine Injection

July 10, 2017

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- West-Ward stated the shortage was due to manufacturing delays.
- Oral famotidine products are not affected by this shortage.
- Pfizer launched famotidine injections in March 2012.
- Mylan Institutional acquired famotidine injections from Pfizer on December 6, 2013.
- Baxter has famotidine premixed bags available.
- Fresenius Kabi has famotidine vials available.

Estimated Resupply Dates

- Mylan Institutional has famotidine 10 mg/mL 4 mL and 20 mL vials on back order and the company estimates a release date of early-August 2017 for the 4 mL vials and late-July 2017 for the 20 mL vials.
- West-Ward has famotidine 10 mg/mL 2 mL vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=810>

Etoposide Injection

July 10, 2017

Reason for the Shortage

- Bristol-Myers Squibb has Etopophos on back order due to a shortage of the active ingredient.
- Etoposide solution for injection is not affected by this shortage

Estimated Resupply Dates

- Bristol-Myers Squibb has Etopophos on back order and the company estimates a release date of September 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=652>

Etomidate Injection

July 10, 2017

Reason for the Shortage

- Zydus had etomidate on shortage due to an increase in demand.

Estimated Resupply Dates

- American Regent has etomidate 2 mg/mL 10 mL and 20 mL vials available with an expiration date of November 2017.
- Mylan Institutional has etomidate 2 mg/mL 10 mL and 20 mL vials available with an expiration date of March 2018.

- Pfizer has Amidate 2 mg/mL 20 mL LifeShield syringes on back order and the company cannot estimate a release date. The 2 mg/mL 10 mL vials are on back order and the company estimates a release date of late-July 2017. The 2 mg/mL 20 mL vials are available in limited supply.

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

Dobutamine Injection

July 10, 2017

Reason for the Shortage

- Baxter did not provide a reason for the shortage.
- Pfizer has dobutamine on shortage due to manufacturing delays.

Estimated Resupply Dates

- Baxter has all dobutamine premixed bags on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=929>

Dexamethasone Sodium Phosphate

July 10, 2017

Reason for the Shortage

- American Regent has dexamethasone sodium phosphate on shortage due to manufacturing delays.
- AuroMedics has dexamethasone sodium phosphate on intermittent back order.
- Fresenius Kabi has dexamethasone sodium phosphate presentations available.
- Mylan Institutional did not provide a reason for the shortage.
- West-Ward has dexamethasone sodium phosphate available.

Estimated Resupply Dates

- AuroMedics has dexamethasone sodium phosphate 4 mg/mL 1 mL and 30 mL vials on intermittent back order.
- Mylan has dexamethasone sodium phosphate 4 mg/mL 30 mL vials on back order and the company estimates a release date of mid-July 2017. The 4 mg/mL 1 mL vials are available with an expiration date of April 2018. The 10 mg/mL 10 mL vials are on back order and the company estimates a release date of late-July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=751>

Ceftriaxone Sodium Injection

July 10, 2017

Reason for the Shortage

- Sandoz has most ceftriaxone available.
- Wockhardt has discontinued ceftriaxone as of July 2017. The 500 mg vials will be available until inventory has been depleted.

Estimated Resupply Dates

- Apotex has ceftriaxone 250 mg, 500 mg, 1 gram, 2 gram, and 10 gram vials on back order and the company estimates a release date of mid-July 2017 for the 1 gram, 2 gram, and 10 gram vials and early-August 2017 for the 250 mg and 500 mg vials.
- Sandoz has ceftriaxone 1 gram vials on back order and the company estimates a release date of mid-July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1101>

Carboplatin Solution for Injection

July 10, 2017

Reason for the Shortage

- Pfizer has carboplatin injection on shortage due to manufacturing delays.
- Teva has carboplatin on allocation due to increased demand.

Estimated Resupply Dates

- Fresenius Kabi has carboplatin 10 mg/mL 45 mL vials available with an expiration date of <2 months.
- Sagent has all carboplatin injection on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1005>

Bumetanide Injection

July 10, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has bumetanide 0.25 mg/mL 4 mL vials on back order and the company estimates a release date of October 2017. The 10 mL vials are on back order and the company estimates a release date of 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=674>

Bleomycin Sulfate Injection

July 10, 2017

Reason for the Shortage

- Fresenius Kabi had bleomycin on back order due to shortage of active pharmaceutical ingredient.
- Pfizer has bleomycin available.
- Teva has bleomycin available.
- FDA was allowing temporary importation of bleomycin sulfate powder for injection 15,000 IU (15 units bleomycin sulfate USP). These vials were manufactured for Amneal Australia. The labeling and bar coding

for the imported product is different from the US version. The imported product should be used in the same way as the US product. FDA has the Dear Healthcare Professional letter linked on their website. The product should be available through major wholesalers while supplies last.

Estimated Resupply Dates

- All marketed presentations are available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1233>

Atropine Sulfate Injection

July 10, 2017

Reason for the Shortage

- American Regent did not provide a reason for the shortage of atropine injection.
- Pfizer states the shortage was due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has atropine 0.05 mg/mL 5 mL Ansyr syringes on allocation. The 0.1 mg/mL 10 mL LifeShield syringes are on back order and the company estimates a release date of late-September 2017. The 0.1 mg/mL 5 mL LifeShield syringes are on back order and the company estimates a release date of late-August 2017. The 0.1 mg/mL 10 mL Ansyr syringes are on back order and the company estimates a release date of mid-July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=814>

23.4% Sodium Chloride Injection

July 10, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has 23.4% sodium chloride 200 mL vials on back order and the company estimates a release date of late-July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1279>

Mepivacaine Injection

July 11, 2017

Reason for the Shortage

- Pfizer said the reason for the back order is manufacturing delays.
- Fresenius Kabi did not provide a reason for the back order.

Estimated Resupply Dates

- Pfizer has all Carbocaine presentations on back order. Carbocaine 1% in 50 mL multiple-dose vials are on back order and the company estimates a resupply date of late-September 2017. Carbocaine 1% 30 mL preservative-free vials, Carbocaine 1.5% in 30 mL preservative-free vials, and Carbocaine 2% in 20 mL preservative-free vials are all on back order with expected release dates sometime in the 4th quarter of 2017. Carbocaine 2% in 50 mL multiple-dose vials are back order and the company expects a release date in mid-July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=954>

Lidocaine Hydrochloride Oral Topical Solution (Viscous) 2%

July 11, 2017

Reason for the Shortage

- Akorn has viscous lidocaine available.
- West-Ward did not provide a reason for the viscous lidocaine shortage.

Estimated Resupply Dates

- West-Ward has viscous lidocaine 100 mL bottles on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1171>

Tobramycin Injection

July 13, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Mylan Institutional has tobramycin 40 mg/mL 2 mL vials on back order and the company estimates a release date of early-August 2017.
- Pfizer has tobramycin 40 mg/mL 2 mL vials on back order and the company estimates a release of late-July 2017.
- X-Gen has tobramycin 1.2 gram preservative-free powder 50 mL vials in 1 count and 6 count on back order and the company estimates a release date of late-July to early-August 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=701>

Rocuronium Injection

July 13, 2017

Reason for the Shortage

- Fresenius Kabi has rocuronium on shortage due to delay of raw materials.
- Pfizer has rocuronium on shortage due to manufacturing delays.
- Sagent has rocuronium on shortage due to increased demand.

- X-Gen has rocuronium on shortage due to increased demand.
- AuroMedics will be launching rocuronium with an estimated launch date of late-June 2017.

Estimated Resupply Dates

- Fresenius Kabi has rocuronium 10 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of late-August to early-September 2017 for the 5 mL vials and 3rd quarter 2017 for the 10 mL vials.
- Pfizer has rocuronium 10 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of late-September 2017 for the 5 mL vials and October 2017 for the 10 mL vials.
- Sandoz has rocuronium 10 mg/mL 5 mL and 10 mL vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=434>

Oxacillin Sodium Injection

July 13, 2017

Reason for the Shortage

- Auromedics did not provide a reason for the shortage.
- Baxter had oxacillin on shortage due to a raw material supply disruption.
- Sagent has oxacillin injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Sagent has oxacillin 10 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=1121>

Ofloxacin Ophthalmic Solution

July 13, 2017

Reason for the Shortage

- Allergan has Ocuflax ophthalmic solution available.
- Akorn did not provide a reason for the shortage.
- Rising has ofloxacin ophthalmic solution available.
- Valeant did not provide a reason for the shortage.

Estimated Resupply Dates

- Akorn has ofloxacin ophthalmic solution in 5 mL vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1235>

Methylene Blue Injection

July 13, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Akorn has methylene blue 10 mg/mL 1 mL vials on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=27>

Haloperidol lactate Injection

July 13, 2017

Reason for the Shortage

- Mylan Institutional has haloperidol lactate injection available.
- Patriot Pharmaceuticals has haloperidol lactate available.
- Sagent has haloperidol lactate on shortage due to manufacturing delays.
- Teva is not currently marketing haloperidol lactate.
- West-Ward is not actively marketing haloperidol lactate at this time.
- Janssen has Haldol injection available.

Estimated Resupply Dates

- Sagent has haloperidol lactate 5 mg/mL 10 mL vials on back order and the company cannot estimate a release date.

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

Dexrazoxane Injection

July 13, 2017

Reason for the Shortage

- Biocodex USA acquired Totect from Apricus Pharmaceuticals in April 2013.
- West-Ward is not actively marketing dexrazoxane injection at this time.
- Mylan did not provide a reason for the back order.
- Pfizer states manufacturing delay as the reason for the back order.

Estimated Resupply Dates

- Mylan has dexrazoxane 250 mg and 500 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=415>

Ampicillin Sulbactam

July 13, 2017

Reason for the Shortage

- Mylan Institutional discontinued ampicillin sulbactam 1.5 gram and 3 gram vials.
- Pfizer has discontinued generic ampicillin sulbactam.
- Sandoz cannot provide a reason for the shortage.
- Sagent has ampicillin sulbactam vials on allocation due to manufacturing delays.
- WG Critical Care states the shortage was due to increased demand.

Estimated Resupply Dates

- Sagent has ampicillin sulbactam 1.5 gram and 3 gram vials on allocation. The 15 gram vials are on back order and the company estimates a release date of July 2017.
- WG Critical Care has ampicillin sulbactam 1.5 gram vials on back order and the company estimates a release date of late-July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=805>

Sodium Chloride 0.9% Injection Bags

July 14, 2017

Reason for the Shortage

- Baxter discontinued 0.9% sodium chloride 250 mL and 500 mL AVIVA bags. The other presentations are available.
- BBraun has 0.9% sodium chloride on allocation.
- Pfizer cited increased demand as the reason for the shortage.
- Fresenius Kabi is no longer importing product.
- Baxter has received FDA approval for 0.9% sodium chloride in Viaflo containers manufactured in an FDA-approved facility in Spain.

Estimated Resupply Dates

- BBraun has 0.9% sodium chloride in 500 mL PVC/DEHP-free bags on intermittent back order with regular releases.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=993>

Rabies Vaccine

July 14, 2017

Reason for the Shortage

- GlaxoSmithKline Vaccines has RabAvert currently available.
- Sanofi Pasteur has Imovax available.

Estimated Resupply Dates

- GlaxoSmithKline Vaccines has RabAvert on back order and the company estimates a release date in May 2017. Emergency stock is available if a patient has been exposed.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=959>

Potassium Chloride Injection

July 14, 2017

Reason for the Shortage

- Baxter did not provide a reason for the current shortage.
- Pfizer has potassium chloride injection on shortage due to increase demand and manufacturing delays.

Estimated Resupply Dates

- Baxter has potassium chloride 10 mEq/1000 mL in 5% dextrose and 0.45% sodium chloride, potassium chloride 20 mEq/1000 mL in 5% dextrose and 0.2% sodium chloride, and potassium chloride 20 mEq/1000 mL in 0.45% sodium chloride available in limited quantities. Potassium chloride 20 mEq/1000 mL in 5% dextrose and 0.9% sodium chloride and potassium chloride 40 mEq/1000 mL in 5% dextrose and 0.9% sodium chloride on back order and the company cannot estimate a release date.
- Fresenius Kabi has potassium chloride 10 mEq/ 5 mL and 40 mEq/20 mL on back order and the company estimates a release date of early-August 2017 for the 10 mEq/5 mL vials and late-July 2017 for the 40 mEq/20 mL vials.
- Pfizer has potassium chloride 10 mEq/50 mL in sterile water, potassium chloride 10 mEq/100 mL in sterile water, potassium chloride 20 mEq/100 mL in sterile water, and potassium chloride 40 mEq/100 mL in sterile water on allocation. Potassium chloride 20 mEq/1000 mL in 0.9% sodium chloride and potassium chloride 40 mEq/1000 mL in 0.9% sodium chloride bags are on allocation. Potassium chloride 20 mEq/50 mL in sterile water is on back order and the company estimates resupply in late-July 2017. Potassium chloride 10 mEq/500 mL in 5% dextrose and 0.45% sodium chloride, potassium chloride 10 mEq/1000 in 5% dextrose and 0.45% sodium chloride, potassium chloride 20 mEq/1000 mL in 5% dextrose and 0.45% sodium chloride, potassium chloride 30 mEq/1000 mL in 5% dextrose and 0.45% sodium chloride, and potassium chloride 40 mEq/1000 mL in 5% dextrose and 0.45% sodium chloride bags are on allocation. Potassium chloride 20 mEq/1000 mL in 5% dextrose and 0.9% sodium chloride and potassium chloride 40 mEq/1000 mL in 5% dextrose and 0.9% sodium chloride bags are on allocation. Potassium chloride 10 mEq/500 mL in 5% dextrose and 0.225% sodium chloride premixed bags are on long-term back order. Potassium chloride 20 mEq/1000 mL in 5% dextrose and 0.225% sodium chloride bags are on allocation. Potassium chloride 20 mEq/1000 mL in 5% dextrose, potassium chloride 20 mEq/1000 mL in lactated ringers and 5% dextrose, and potassium chloride 20 mEq/1000 mL in 0.45% sodium chloride bags are on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=696>

Morphine Injection

July 14, 2017

Reason for the Shortage

- Pfizer anticipates a shortage of several prefilled syringe products, including morphine, starting in late-July 2017 due to issues at a manufacturing facility. To minimize the impact of the shortage, Pfizer is prioritizing

production of certain morphine Carpuject syringes. Pfizer expects the shortage of prefilled syringe products to recover by late-first quarter 2018.

Estimated Resupply Dates

- Pfizer has morphine 0.5 mg/mL 10 mL preservative-free vials and 1 mg/mL 10 mL preservative-free vials on back order and the company estimates a release date of early-August 2017. The 2 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of mid-July 2017. The 50 mg/mL 50 mL vials are on back order and the company estimates a release date of late-July 2017.
- West-Ward has Infumorph 10 mg/mL 20 mL and 25 mg/mL 20 mL preservative-free ampules on back order and the company estimates a release date of July or August 2017. Duramorph 0.5 mg/mL 10 mL ampules are on back order and the company estimates a release date of mid-July 2017. Morphine 4 mg/mL 1 mL vials and 8 mg/mL 1 mL vials are on a weekly allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=664>

Indigo Carmine Injection

July 14, 2017

Reason for the Shortage

- All presentations are currently available

Estimated Resupply Dates

- American Regent has indigo carmine 8 mg/mL 5 mL ampules available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=861>

Erythromycin Lactobionate Injection

July 14, 2017

Reason for the Shortage

- Pfizer has Erythrocin on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Erythrocin 500 mg ADD-Vantage vials and regular vials on back order and the company estimates a release date of first quarter 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=546>

Albendazole Tablets

July 14, 2017

Reason for the Shortage

- Impax did not provide a reason for the shortage.

Estimated Resupply Dates

- Impax has Albenza 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=1274>

Sodium Bicarbonate Injection

July 16, 2017

Reason for the Shortage

- Amphastar has sodium bicarbonate injection on shortage due to increased demand.
- Pfizer has sodium bicarbonate injection on shortage due to manufacturing delays related to obtaining glass syringe components.

Estimated Resupply Dates

- Amphastar has 8.4 % sodium bicarbonate 50 mL syringes on allocation.
- Pfizer has 8.4 % sodium bicarbonate 50 mL syringes on back order and the company estimates a release date of late-July 2017. The 8.4 % sodium bicarbonate 50 mL vials are on back order and the company cannot estimate a release date. The 8.4% sodium bicarbonate 10 mL syringes are on back order and the company estimates a release date of mid-September 2017. The 4.2% sodium bicarbonate 10 mL syringes are on back order and the company estimates a release date of mid-July 2017. The 7.5% sodium bicarbonate 50 mL syringes are on back order and the company estimates a release date of late-September 2017.
- To help alleviate the shortage, FDA is granting Athenex Pharmaceutical Division (APD) the ability to import 10 mL vials of sodium bicarbonate from Phebra, an Australian company. Supplies are limited and only available via direct orders. Orders may be placed by contacting customer service at 855-273-0154 or apddorders@dlss.com.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=788>

Selenium Injection

July 16, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- American Regent has selenium 40 mcg/mL 10 mL vials available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=784>

Papaverine Injection

July 16, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- American Regent has papaverine 30 mg/mL 2 mL vials available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=781>

Nitroglycerin Injection

July 16, 2017

Reason for the Shortage

- American Regent did not provide a reason for the shortage.
- The premixed bags are not affected by this shortage.

Estimated Resupply Dates

- American Regent has nitroglycerin 50 mg/mL 10 mL vials in limited quantities.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=786>

Mitoxantrone Hydrochloride Injection

July 16, 2017

Reason for the Shortage

- Fresenius Kabi has mitoxantrone available.
- Teva has mitoxantrone injection available except for the 10 mL vials which are temporarily discontinued.

Estimated Resupply Dates

- Teva has temporarily discontinued mitoxantrone 10 mL vials and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1212>

Metoclopramide Injection

July 16, 2017

Reason for the Shortage

- Fresenius Kabi has metoclopramide 2 mL syringes available.

Estimated Resupply Dates

- Pfizer has metoclopramide 5 mg/mL 2 mL vials on back order and the company estimates a release date of late-August 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=611>

Labetalol Injection

July 16, 2017

Reason for the Shortage

- Akorn has labetalol injection available.
- Pfizer has labetalol injection on shortage due to manufacturing delays.
- West-Ward has labetalol injection available.

Estimated Resupply Dates

- Pfizer has labetalol 5 mg/mL 20 mL and 40 mL vials on back order and the company estimates a release date of early-August 2017 for the 20 mL vials and mid-August 2017 for the 40 mL vials. The 5 mg/mL 4 mL syringes are on back order and the company estimates a release date of late-July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=397>

Ketorolac Tromethamine Injection

July 16, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has ketorolac 30 mg/mL 2 mL Carpuject syringes for intramuscular use on back order and the company estimates a release date of 2nd quarter 2018. The 30 mg/mL 2 mL vials for intramuscular injection are on back order and the company estimates a release date of late-July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=636>

Furosemide Injection

July 16, 2017

Reason for the Shortage

- American Regent is not actively marketing furosemide injection.
- Pfizer has furosemide injection on shortage due to manufacturing delays and increased demand.
- Claris has furosemide injection available.
- Fresenius Kabi has furosemide injection available.

Estimated Resupply Dates

- Pfizer has furosemide 10 mg/mL 10 mL syringes on back order and the company estimates a release date of late-July 2017. The 10 mg/mL 4 mL and 10 mL vials are on back order and the company estimates a release date of mid- to late-September 2017. The 10 mg/mL 4 mL syringes are available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=636>

Diazepam Injection

July 16, 2017

Reason for the Shortage

- Pfizer has diazepam on shortage due to manufacturing delays

Estimated Resupply Dates

- Pfizer has diazepam 5mg/mL 2 mL Carpuject syringes on back order and the company estimates a release date of mid-July 2017.

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

Ceftazidime Injection

July 16, 2017

Reason for the Shortage

- Pfizer has Tazicef on shortage due to increased demand.
- Sagent has ceftazidime injection on shortage due to manufacturing delays.
- Sandoz discontinued ceftazidime 1 gram and 2 gram vials in 2015.
- BBraun had ceftazidime on allocation due to increased demand.
- WG Critical Care has ceftazidime on shortage due to manufacturing delays.

Estimated Resupply Dates

- Sagent has ceftazidime 2 gram vials on allocation. The 1 gram vials are on back order and the company estimates a release date of July 2017.
- Teligent has Fortaz 2 gram and 6 gram vials on back order and the company cannot estimate a release date.
- WG Critical Care has ceftazidime 1 gram and 6 gram vials on back order and the company estimates a release date of October 2017 for the 1 gram vials and mid-July 2017 for the 6 gram vials.
- Pfizer has Tazicef 2 gram ADD-Vantage vials on back order and the company estimates a release date of mid-July 2017. The 6 gram vials are available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=869>

Calcium Chloride Injection

July 16, 2017

Reason for the Shortage

- American Regent has calcium chloride on shortage due to manufacturing delays.
- Amphastar has calcium chloride on shortage due to increased demand.
- Pfizer has calcium chloride on shortage due to manufacturing delays.
- Mylan Institutional has withdrawn calcium chloride syringes from the market. The company recalled the syringes in April 2015 due to incompatibility of the syringes and some needless adaptors.

Estimated Resupply Dates

- American Regent has calcium chloride 100 mg/mL 10 mL vials available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=941>

Alcohol Dehydrated Injection (Ethanol)

July 16, 2017

Reason for the Shortage

- Akron states the back order was due to manufacturing delays.

Estimated Resupply Dates

- American Regent has dehydrated alcohol 1 mL ampules on back order and the company cannot estimate a release date. The 5 mL ampules are available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=778>

Lorazepam Injection

July 17, 2017

Reason for the Shortage

- Bedford discontinued lorazepam injection in May, 2011.
- West-Ward has product on shortage due to manufacturing delays.
- Pfizer has product on shortage due to increased demand and manufacturing delays.
- Akorn has not provided a reason for the shortage.
- Amphastar has product available.

Estimated Resupply Dates

- Akron has lorazepam 2mg/mL 1 mL vials available in limited supply.
- Pfizer has lorazepam 2mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of late-July 2017. The 2 mg/mL 1 mL and 10 mL vials are on back order and the company estimates a release date of 4th quarter 2017. The 4mg/mL 1 mL vials are on back order and the company estimates release date of 3rd quarter 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1270>