PERFORMRx℠

Drug Information Update

April 2021

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
tazarotene 0.1% foam	Fabior	Mayne	A retinoid indicated for the topical treatment of acne vulgaris in patients 12 years of age or older
gadoterate meglumine 10 mmol/20 mL (0.5 mmol/mL = 376.9 mg/mL) syringe	Dotarem	Guerbet	A gadolinium-based contrast agent indicated for intravenous use with magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adult and pediatric patients (including term neonates) to detect and visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity
pregabalin 82.5 mg, 165 mg, 330 mg ER tablets	Lyrica CR	Pfizer	For the management of: • Neuropathic pain associated with diabetic peripheral neuropathy (DPN) • Postherpetic neuralgia

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Elepsia XR 1,000 mg, 1500 mg tablet, extended release	levetiracetam	Higher strength of extended release levetiracetam. Keppra XR is only available in 500 mg and 750 mg strengths.	New Strength
Fotivda 0.89 mg, 1.34 mg capsule	tivozanib hcl	A kinase inhibitor indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.	New Entity
Abilify MyCite Starter Kit 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg oral tablet with sensor, strip, pod	aripiprazole	Appears to be new tablets + patch + pod where patch and pod are two separate components (previously they were combined into one). This makes the pod reusable.	New Dosage Form
Abilify MyCite Maintenance Kit 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg tablet with sensor and strip	aripiprazole	Appears to be a new tablets + patch + pod where patch and pod are 2 separate components (previously they were combined into one). This makes the pod reusable.	New Dosage Form
Ponvory 20 mg tablet, 14-Day Starter Pack 2-3-4-5-6-7-8-9-10 mg tablets	ponesimod	A sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Similar to Gilenya (now generic) which requires 1st dose monitoring for bradycardia, Mayzent which requires genetic testing, and Zeposia.	New Entity
Barhemsys 10 mg/4 mL (2.5 mg/mL) intravenous solution	amisulpride	New vial size	New Strength

Drug Name	Generic Name	Description	Comments
Abecma 300x10exp6 to 460x10exp6 cell intravenous suspension	idecabtagene vicleucel	A B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody	New Entity
Roszet 10 mg-40 mg , 10 mg-20 mg, 10 mg-10 mg, 10 mg-5 mg tablet	ezetimibe/ rosuvastatin calcium	Combination Zetia and Crestor, 505(b)2	New Combination
PreGen DHA 28 mg-1,000 mcg-35 mg-200 mg capsule	pnv174/iron/fa/o3/dha/epa/fish	Prenatal vitamin Q class supplement	New Formulation
Zegalogue 0.6 mg/0.6 mL subcutaneous syringe, 0.6 mg/0.6 mL subcutaneous auto-injector	dasiglucagon HCl	Ready to use glucaon like Gvoke	New Entity

NEW INDICATIONS (EXISTING DRUGS)

†**Bolded** items reflect newly approved indication; ~~strikethrough~~ of removed indication/age limit/etc.

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Exparel	bupivacaine liposome injectable suspension, 266 mg/20 mL, 133 mg/10 mL in single-dose vials	Pacira	• **In patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia** • In adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia
Keytruda	pembrolizumab injection, 100 mg/4 mL solution in a single-dose vial	Merck	Esophageal Cancer For the treatment of patients with ~~recurrent~~ locally advanced or metastatic **esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation either:** ○ **in combination with platinum- and fluoropyrimidine-based chemotherapy, or** ○ as a single agent after one or more prior lines of systemic therapy for patients with tumors of squamous cell histology that express PD-L1 (CPS ≥10) as determined by an FDA-approved test *Note: Keytruda has many other indications not presented here because there were no changes.*
Praluent	alirocumab injection, 75 mg/mL or 150 mg/mL in a single-dose pre-filled pen	Regeneron	• To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• As adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C. • **As an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C**
Sarclisa	isatuximab-irfc injection 100 mg/5 mL, 500 mg/25 mL solution in single dose vials	Sanofi Aventis	• in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor. • **in combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy.**
Tyvaso	treprostinil sterile solution for oral inhalation, 2.9 mL ampule containing 1.74 mg treprostinil	United Therapeutics	• Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%). • **Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF),**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).
Vyxeos	daunorubicin and cytarabine liposome for injection, 44 mg daunorubicin and 100 mg cytarabine encapsulated in lyposomes as a lyophilized cake in a single dose vial	Celator	a liposomal combination of daunorubicin, an anthracycline topoisomerase inhibitor, and cytarabine, a nucleoside metabolic inhibitor, that is indicated for the treatment of ~~adults with~~ newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) **in adults and pediatric patients 1 year and older**
Myrbetriq	mirabegron 25 mg, 50 mg tablet	Astellas Pharma	Myrbetriq is a beta-3 adrenergic agonist indicated for the treatment of: • Overactive bladder (OAB) in adult patients with symptoms of urge urinary incontinence, urgency, and urinary frequency, either alone or in combination with the muscarinic antagonist solifenacin succinate. • **Neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older and weighing 35 kg or more.**
Trodelvy	sacituzumab govitecan-hziy for injection, 180 mg lyophilized powder in single-dose vials	Immunomedics	Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with: • **Unresectable locally advanced or** metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease. • **Locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PDL1) inhibitor.**

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Adam's Secret Extra Strength 1500, 800 mg, 10 count blister packs, Distributed by KP Inc., Made in USA, UPC 6 09728 43462 5	Class I	Drugs	All lots within expiry.	Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and sildenafil.	Adams.Secret.co
Adam's Secret Extra Strength 3000, 840 mg, 10 count blister packs, Distributed by AS Inc., Made in USA, UPC 6 09728 43452 6.	Class I	Drugs	All lots within expiry.	Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and sildenafil.	Adams.Secret.co
Acyclovir Sodium Injection 1000mg/20mL (50mg/mL) vial NDC 68382-049-01, For Intravenous Infusion Only MUST BE DILUTED PRIOR TO USE, packaged in 10 x 20mL Single-Dose Vials per pack NDC 68382-049-10, Rx only, Manufactured by: Cadila Healthcare Ltd., Vadodara, India. Distributed by:	Class I	Drugs	Lot#: L000155, Exp 12/2021; L000156, Exp 1/2022	Crystallization: customer complaints for crystallization in finished product.	Zydus Pharmaceuticals (USA) Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534.					
Acyclovir Sodium Injection 500mg/10mL (50mg/mL) vial NDC 68382-048-01, For Intravenous Infusion Only MUST BE DILUTED PRIOR TO USE, packaged in 10 x 10mL Single-Dose Vials per pack NDC 68382-048-10, Rx only, Manufactured by: Cadila Healthcare Ltd., Vadodara, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534.	Class I	Drugs	Lot#: L000126, L000127, Exp 12/31/2021	Crystallization: customer complaints for crystallization in finished product.	Zydus Pharmaceuticals (USA) Inc
Telmisartan Tablets, USP 20 mg, 30-count bottles, Rx only, Manufactured by: Alembic Pharmaceuticals Limited (Formulation Division) Panelav 38935, Gujarat, India Manufactured for: Alembic Pharmaceuticals, Inc. 750 Route 202, Bridgewater, NJ 08807, NDC 62332-087-30	Class I	Drugs	Lot #: 1905005661, Exp March 2022	Labeling: Label-mixup	Alembic Pharmaceuticals Limited

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
0.9% SODIUM CHLORIDE Irrigation, USP 1000 mL Semi-Rigid Bottle, Rx only, Manufactured for ICU Medical, Inc., Lake Forest, Illinois, 60045 USA. NDC 0990-7138-09	Class II	Drugs	Lots: 16-808-4B, 16-803-4B, 16-809-4B, Exp. April 01, 2023	Presence of particulate matter.one confirmed customer report of particulate matter within two semi-rigid bottles identified prior to use	ICU Medical Inc
Omeprazole Delayed Release Capsules, USP, 20 mg, 1000-count bottles, Rx only, Packaged by GSMS Incorporated, Camarillo, CA 93012-8601 USA, NDC 51407-129-10	Class II	Drugs	Lot #: GS029673, Exp. Date 5/2021	Failed Impurities/Degradation Specifications: Out of Specification results obtained for unknown impurities during stability testing by manufacturer	Golden State Medical Supply Inc.
ZOMA-Jet 5 Demonstration Kit, Needle-free delivery device for use with ZOMACTON (somatropin) for injection 5mg vial, Rx only, ZOMA-Jet 5 Demonstration Kit contains - ZOMA-Jet 5 device - 5 Needle-Free Head A's - 2 Vial Adaptors -	Class II	Drugs	201601320031 201702320207 201731220039 201817120044 201912720086 201912320044	Defective Delivery System: customer complaints concerning the injector pen breaking apart and disintegrating into pieces.	Ferring Pharmaceuticals Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
1 Carrying Case - 1 User Manual; Manufactured for: Ferring Pharmaceuticals Inc. Parsippany, NJ 07054; UPC 3 55566 18031 5.					
ZOMA-Jet 10 Demonstration Kit, Needle-free delivery device for use with ZOMACTON (somatropin) for injection 10 mg vial, ZOMA-Jet 10 Demonstration Kit contains - ZOMA-Jet 10 device - 7 Needle-Free Head A's - 1 Carrying Case - 1 User Manual; Manufactured for: Ferring Pharmaceuticals Inc. Parsippany, NJ 07054; UPC 3 55566 19031 4.	Class II	Drugs	201827020015 201826020065 201835320058 201835320009 201834920003 201835220007 201901820009 201901420200 201902120010 201901120019 201901420005 201901020180 201901520015 201900720001 201900920004 201904620003 201902120011 201904420007 201904520015 201904920002 201905020111 201904620004	Defective Delivery System: customer complaints concerning the injector pen breaking apart and disintegrating into pieces.	Ferring Pharmaceuticals Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			201905720011 201907320003 201907320030 201907820007 201907420017 201910820009 201915620014 201910920016 201910620017 201910820020 201911320048 201911320095 201913720148 201912920021		
Scott¿ Moisturizing Foam Hand Sanitizer, 1.2 Liters (40.5 fl oz), Distributed in the U.S. by Kimberly-Clark Global Sales, LLC, Roswell, GA 30076-2199 Distributed in Canada by Kimberly-Clark Inc., Mississauga, Ontario L5B 3Y5 UPC 0 36000 91592 1	Class II	Drugs	Product Code 91590 Lot #WV0280SLA EXP: 2022/09/29	Labeling; Label Mix-up; some bottles containing Foam Skin Cleanser soap are incorrectly labeled as Moisturizing Foam Hand Sanitizer	Kimberly-Clark Corporation
Neomycin Sulfate Tablets, USP 500mg, Rx Only, 10x10 Unit dose 100 Tablets,	Class II	Drugs	Lot # CFMBX, EXP 9/2022	Failed Stability Specifications: Out of Specification	X-Gen Pharmaceuticals Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Manufactured for: X-GEN Phamaceuticals, Inc. Big Flats, NY 14814. NDC 39822-0310-5				(OOS) result reported for microbiological assay and Neomycin C for the 3-month 25¿C/65% RH stability timepoint for the representative 2020 annual stability Lot CFPXF that utilized the same API Lot (CM8254) and was manufactured in the same campaign as Lot CFMBX. The OOS for microbiological assay was reported as 87.0%, outside the stability specifications of 90.0 to 120.0%. Lot CFMBX had a reported microbiological assay value of 93.4% at time of release and,	

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
				although within specifications, is on the lower end of the specification and is not expected to meet its expiry dating of 24 months.	
Ganirelix Acetate Injection, 250 mcg/0.5 mL, Sterile Prefilled Syringe, Rx only, Distributor: Ferring Pharmaceuticals, Inc., Parsippany, NJ 07054 USA, Manufactured by: Sun Pharmaceutical Industries Ltd, Halol, Gujarat, India Made in India, NDC 55566-1000-1.	Class II	Drugs	Lots JKU1212A, JKU1503A, JKU1504A, JKU1505A, JKU1506A, Exp 03/2021; JKU3313A & JKU3314A, Exp 08/2021.	Failed Impurities/Degradation Specifications	SUN PHARMACEUTICAL INDUSTRIES INC
Mometasone Furoate Topical Solution, USP, 0.1%, (Lotion), a) 30 mL (NDC 0713-0701-85) and b) 60 mL (NDC 0713-0701-53), Rx Only, Distributed by: Cosette Pharmaceuticals, Inc., South Plainfield, NJ 07080	Class II	Drugs	a) 30 mL: 1014611 and 1014612, exp 12/2022 b) 60 mL:1014593, 1014594 and 1014595, exp 10/2022	CGMP Deviaitons	Cosette Pharmaceuticals, Inc.
Guanfacine Extended-Release Tablets 2 mg,100-count bottles, Rx Only, Manufactured by:	Class II	Drugs	Lot #: RX1662, RX1663, RX1664 Exp. 11/2022	Cross Contamination with Other Product: Product is being	Apotex Corp.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Apotex Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for: Apotex Corp. Weston, Florida 33326, NDC 60505-3928-1, UPC 3 60505 39281 0				recalled due to Trace Amounts of Quetiapine Fumarate	
Cefprozil for Oral Suspension USP, 250mg/5mL, packaged as a) 50 mL (when mixed) bottles (NDC 68180-402-01); b) 75 mL (when mixed) bottles (NDC 68180-402-02); and c) 100 mL (when mixed) bottles (NDC 68180-402-03); Rx only, Manufactured for: Lupin Pharmaceutical, Inc., Baltimore, MD 21202; Manufactured by: Lupin Limited, Mandideep 462 046, India.	Class II	Drugs	Lot Numbers: a) F801122, exp. date June 2021; b) F801123, exp. date June 2021; c) F801124, exp. date June 2021	Superpotent Drug	Lupin Pharmaceuticals Inc.
Riomet (metformin hydrochloride oral solution) 500 mg/5 mL Cherry Flavor, 16 fl. oz., 473 mL bottles Rx Only, Manufactured by: Mikart, LLC, Atlanta, GA 30318, Distributed by: Sun Pharmaceutical	Class II	Drugs	Lot #: J190386A, X190354A, Exp. 3/2021, J190393A, Exp. 5/2021, A200035A, Exp. 6/2021, B200064A, Exp. 8/2021; H200236A, Exp. 1/2022	Microbial Contamination of Non-Sterile Product	SUN PHARMACEUTICAL INDUSTRIES INC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Industries Inc., Cranbury, NJ 08512, NDC 10631-206-02.					
Itraconazole Capsules, 100 mg, 30-count bottles, Rx only, Manufactured by: Jubilant Generics Ltd., Roorkee - 247661, India; Marketed by: Jubilant Cadista Pharmaceuticals, Inc., Salisbury, MD 21801, NDC 59746-282-30.	Class II	Drugs	Lot #s: IT119008B, Exp 05/2021; IT120001A, IT120002A, Exp 12/2021	Failed Dissolution Specifications	Jubilant Cadista Pharmaceuticals, Inc.
Tremfya (guselkumab) Injection, 100 mg/mL, one single-dose prefilled syringe per carton, Rx only, Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044; NDC 57894-640-01.	Class III	Drugs	KESOY.AI Exp. 04/2022	Temperature Abuse	Cardinal Health Inc.
Macula Pellets Homeopathic Medicine, 1 Oz bottles, Rx only, Manufactured for: Natural Ophthalmics Inc. PO Box 1510 Dillon, CO 80435, NDC 58770-190-42	Class III	Drugs	Lot # 27479, exp. date 11/2022	An error occurred where the product was manufactured with Potassium Chloride instead of Potassium Phosphate.	Washington Homeopathic Products, Inc.
Sp-4, 100 mL solution bottles, Rx only, Washington Homeopathic Products, Inc.260 J R	Class III	Drugs	Lot # 24844, 25500, 26310	An error occurred where the product was manufactured	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Hawvermale Way Berkeley Springs West Virginia 25411				with Potassium Chloride instead of Potassium Phosphate.	
LCL-2-0191, 5 gallon carboys, Rx only, Manufactured for: LaCore Labs, LLC, by: Washington Homeopathic Products, Inc.260 J R Hawvermale Way Berkeley Springs West Virginia 25411	Class III	Drugs	Lot # 28506	An error occurred where the product was manufactured with Potassium Chloride instead of Potassium Phosphate.	Washington Homeopathic Products, Inc.
Metformin HCl Extended-Release Tablets, USP, 500 mg, Rx Only, 500-count bottle, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512; Manufactured by: Sun Pharmaceutical Industries Ltd., Halol-Baroda HIghway, Halol-389 350 Gujarat, India, NDC 62756-142-02.	Class III	Drugs	Lot #JKU4639A, Exp 10/2022	Failed Moisture Limits: Out of specification for water content	SUN PHARMACEUTICAL INDUSTRIES INC
Distributed by: DocRx, Methylprednisolone Tablets, USP 4 mg, Rx, 21 Count Blister, NDC: 69306-004-21, Relabeled	Class III	Drugs	Lot #: 20K0043P, Exp. 8/31/2022; 20L0026P, Exp. 9/30/2022	Labeling: Illegible label: Manufacturer received complaint of mis-alignment	Asclemed USA Inc. dba Enovachem Pharmaceuticals

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
by: Enovachem Pharmaceuticals 379 Van Ness Ave. Suite 1403-1406, Torrance, CA 90501, Manufactured by: Jubilant Cadista Pharmaceuticals Inc. Source NDC: 59746-001-03, DocRx, Mobile, AL 36608				print of the printed dosing instructions on the blister card.	
Candesartan Cilexetil Tablets, USP, 4 mg, 30-count bottles, Rx only, Manufactured for: Macleods Pharma USA, Inc., Plainsboro, NJ 08536, Manufactured by: Macleods Pharmaceuticals Ltd., Daman (U.T.), India, NDC 33342-114-10	Class III	Drugs	Lots # : ECD5908C, Exp 7/2021; ECD5909A, ECD5910A, ECD5911A, ECD5912A, Exp. 09/2021.	Failed Impurities/Degradation Specifications	Macleods Pharma Usa Inc
Lidocaine Ointment USP, 5%, NET WT 35.44 g (1 1/4 Oz) tube, Rx Only, Teligent Pharma Inc., Buena, New Jersey, 08310, NDC 52565-008-14.	Class III	Drugs	Lot 13269, Exp March 2021	Failed Stability Specifications: product did not meet viscosity results.	Teligent Pharma, Inc.

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

FDA DRUG SAFETY COMMUNICATIONS

FDA warns that abuse and misuse of the nasal decongestant propylhexedrine causes serious harm [posted 3/25/2021]

What safety concern is FDA announcing?
The U.S. Food and Drug Administration (FDA) is warning that the abuse and misuse of the over-the-counter (OTC) nasal decongestant propylhexedrine can lead to serious harm such as heart and mental health problems. Some of these complications, which include fast or abnormal heart rhythm, high blood pressure, and paranoia, can lead to hospitalization, disability, or death. Reports of individuals abusing and misusing propylhexedrine have increased in recent years. Propylhexedrine is safe and effective when used as directed.

What is FDA doing?
We are requesting that all manufacturers of OTC propylhexedrine nasal decongestant inhalers consider product design changes that support its safe use. For example, modifying the product to create a physical barrier that would make tampering with the device and abusing the propylhexedrine inside more difficult. In addition, decreasing the amount of medicine the device contains could also reduce the risk of serious side effects if abused or misused. We continue to evaluate this safety issue and will determine if additional FDA actions are needed.

What is propylhexedrine and how can it help me?
Propylhexedrine is a nasal decongestant that is available OTC in an inhaler. It is used short term to temporarily relieve nasal congestion due to colds, hay fever, or other upper respiratory allergies. It works by reducing swelling and inflammation of the mucous membrane lining of the nose. The recommended dose for adults and children older than 6 years is two inhalations in each nostril not more often than every 2 hours. Do not use it for more than 3 days at a time. Prolonged use may cause nasal congestion to recur or worsen. Currently, propylhexedrine is only marketed under the brand name Benzedrex.

What should consumers do?
Consumers should only use propylhexedrine according to the directions on the Drug Facts label. Do not use it in ways other than by inhalation because doing so can cause serious harm, such as heart and mental health problems. Some of these problems can lead to death. Seek medical attention immediately by calling 911 or poison control at 1-800-222-1222 for anyone using propylhexedrine who experiences the following:
• Severe anxiety or agitation, confusion, hallucinations, or paranoia
• Rapid heartbeat or abnormal heart rhythm
• Chest pain or tightness
Ask a pharmacist or your health care professional if you have any questions about propylhexedrine, how to use it, or whether a medicine you are taking may interact with it. Always tell your health care professionals about all medicines you are taking, including OTC medicines.

What should health care professionals do?
Health care professionals should be aware that some individuals are abusing or misusing propylhexedrine, particularly using it by routes other than nasal inhalation, which can result in serious

cardiac and psychiatric adverse events or death. In the event of a suspected overdose, attempt to determine whether a patient used propylhexedrine alone or with other substances. There is no specific reversal agent in cases of acute intoxication, so symptomatic and supportive care should be provided. (See Additional Information for Health Care Professionals for more information).

What did FDA find?
We reviewed cases from U.S. poison control center calls, case reports submitted to FDA, the medical literature, and emergency department visits. In the 20 years between January 1, 2000, and December 31, 2019, U.S. poison control centers documented 460 cases of propylhexedrine abuse (415 cases) or misuse (45 cases). Annual cases increased from 11 cases in 2011 to 74 cases in 2019, with abuse cases making up the majority of this increase. Most of the cases involved abuse or misuse of propylhexedrine alone without other substances. The most commonly reported side effects included rapid heart rate, agitation, high blood pressure, chest pain, tremor, hallucinations, delusions, confusion, nausea, and vomiting. Among the 460 cases, 21 had severe outcomes (adverse effects that were life-threatening), with 13 resulting in intensive care admissions.

Fifty-three cases of propylhexedrine abuse and misuse were voluntarily reported to FDA in the several decades from January 1969 through January 31, 2020.† An additional seven cases of serious adverse events related to propylhexedrine abuse were found from emergency department visits* in the 3 years between January 1, 2016, and December 31, 2018. There are likely additional cases that we have not identified. Some harms occurred several hours after abuse. Of these 60 cases, 23 experienced life-threatening adverse events or hospitalization, and nine died. Most of the deaths resulted from propylhexedrine abuse in combination with other substances.

We also reviewed 49 case reports and an observational study published in the medical literature. These publications showed similar findings compared to the cases identified from poison control calls and emergency department visits and the cases reported to FDA.

*National Electronic Injury Surveillance System-Cooperative Adverse Event Surveillance Project (NEISS-CADES).
†The cases were reported to the FDA Adverse Event Reporting System (FAERS) database.

How do I report side effects from propylhexedrine?
To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving propylhexedrine or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

How can I get new safety information on medicines I’m prescribing or taking?
You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Facts about propylhexedrine

- Propylhexedrine is an over-the-counter (OTC) inhaled nasal decongestant that is used to temporarily relieve nasal congestion due to colds, hay fever, or other upper respiratory allergies.
- Propylhexedrine works by reducing swelling and inflammation of the mucous membrane lining of the nose.

- The recommended dosage of propylhexedrine for adults and children older than 6 years is two inhalations in each nostril not more than every 2 hours. For children younger than 6, consult a health care professional before using. Do not exceed the recommended dosage.
- Do not use propylhexedrine for more than 3 days. Prolonged use may cause nasal congestion to recur or worsen.
- Use propylhexedrine only as directed.
- Propylhexedrine is marketed under the brand name Benzedrex.
- Common side effects of propylhexedrine may include temporary discomfort such as burning, stinging, sneezing, or increasing nasal discharge.

Additional Information for Consumers

- FDA is warning that abuse or misuse of propylhexedrine, an over-the-counter (OTC) nasal decongestant, can lead to serious heart and mental health problems. These include fast or abnormal heart rhythms, high blood pressure, heart attack, heart failure, agitation, delusions, paranoia, hallucinations, and death even after a few hours of abuse or misuse.
- Seek medical attention immediately by calling 911 or poison control at 1-800-222-1222 for anyone using propylhexedrine who experiences the following:
    - Severe anxiety or agitation, confusion, hallucinations, or paranoia
    - Rapid heartbeat or abnormal heart rhythm
    - Chest pain or tightness
- Only use propylhexedrine according to the directions listed on the Drug Facts label.
- Do not exceed recommended dosage or use for more than 3 days. Prolonged use may cause nasal congestion to recur or worsen.
- Do not share inhalers, as use of the product by more than one person may spread infection.
- Ask a pharmacist or your health care professional if you have any questions about propylhexedrine, how to use it, or whether another medicine you are taking may interact with it.
- Always tell your health care professionals about all the medicines you are taking, including OTC medicines such as propylhexedrine, vitamins, and other supplements. It is helpful to keep a list of all your current medicines in your wallet or another location where it is easily retrieved. You can fill out and print a copy of My Medicine Record.
- To help FDA track safety issues with medicines, report side effects from propylhexedrine or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Additional Information for Health Care Professionals

- FDA is warning that some individuals are abusing or misusing the over-the-counter (OTC) nasal decongestant propylhexedrine, including by ingesting or injecting it which can result in serious cardiac and psychiatric adverse events and possibly death.
- In the event of a suspected overdose, attempt to determine whether a patient used propylhexedrine alone or with other substances.
- There is no specific reversal agent in cases of acute propylhexedrine intoxication, so management is symptomatic and supportive.

- Major issues that may have to be managed in the context of intoxication include severe agitation, tachycardia, hypertension, myocardial infarction, hyperthermia, stroke, bowel obstruction, pulmonary hypertension, and seizures. Long-term use can also lead to lung damage, arrhythmias, and cardiac damage.
- Counsel consumers not to use more than the recommended dose of propylhexedrine listed on the Drug Facts label or to use it in ways other than intended, as doing so can result in serious adverse events.
- To help FDA track safety issues with medicines, report adverse events involving propylhexedrine or other medicines to the FDA MedWatch program, using the information in the "Contact Us" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Data Summary

In response to increasing reports of abuse and misuse of propylhexedrine, we reviewed several sources of data. These included calls to U.S. poison control centers, case reports submitted to FDA and published in the medical literature, cases presenting to U.S. emergency departments participating in NEISS-CADES, and an observational study.

Using data from the American Association of Poison Control Centers-National Poison Data System (AAPCC-NPDS), we identified 460 cases involving propylhexedrine abuse or misuse between January 1, 2000, and December 31, 2019. Poison control centers define misuse as the intentional, improper use for a reason other than self-harm or for achieving a psychotropic effect. Annual case numbers increased after 2011, with a sharp rise starting in 2015. They involved individuals 12 to 68 years, and most were males. Most cases (n=345, 75 percent) involved abuse or misuse of propylhexedrine alone. Ingestion was the most common route of exposure, followed by inhalation and injection. When more than one substance was involved (n=115, 25 percent), frequent co-exposures included cold and cough medicines, alcohol, antidepressants, opioids, sedatives/hypnotics/antipsychotics, and a variety of stimulants and street drugs. The most frequent clinical effects were tachycardia, agitation, hypertension, mydriasis, nausea, chest pain, tremor, hallucinations/delusions, diaphoresis, confusion, and vomiting. Frequently recommended and/or performed therapies for single-substance propylhexedrine abuse or misuse included benzodiazepines, intravenous fluids, sedation, charcoal, and oxygen. Among the 460 calls, 21 had adverse effects that were life-threatening, 13 of which resulted in intensive care unit admissions.

A search of the FDA Adverse Event Reporting System (FAERS) database from January 1969 through January 31, 2020, and the National Electronic Injury Surveillance System-Cooperative Adverse Event Surveillance Project (NEISS-CADES) from January 1, 2016, through December 31, 2018, identified 60 U.S. cases, of serious adverse events related to propylhexedrine abuse, misuse, dependence, or withdrawal, 53 from FAERS and 7 from NEISS-CADES. Among the 60 cases, there were 57 cases of abuse, 18 cases of dependence, three cases of withdrawal, and one case of misuse. The majority of these 60 cases involved males (n=55, 92 percent) and adults 18 to 65 years (n=40, 66 percent). Among the 53 FAERS cases, oral ingestion (n=19, 36 percent) and intravenous (IV) injection (n=13, 25 percent) were the most common routes of exposure, and other routes included intranasal inhalation (n=3, 6 percent) and smoking (n=1, 2 percent). The amount abused ranged from part of one inhaler to the content of 10 inhalers per day, and the duration of abuse ranged from 3 days to 18 years. Each inhaler contains 250 mg of propylhexedrine and each inhalation contains 0.4-0.5 mg. 23 of the 60 patients experienced life-threatening adverse

events or hospitalization, and nine patients died. Among the nine deaths, propylhexedrine abuse in combination with other substances contributed to the cause of death in six cases, and propylhexedrine abuse alone was the cause of one death. For one of the two remaining deaths, the cause of death was not reported. The other reported the cause of death was multiple injuries sustained in a motor vehicle accident; however, the individual had a postmortem propylhexedrine blood concentration in the toxic range. The routes of exposure were reported in only four of the death cases and were IV (n=3) and oral (n=1). The amount and duration of abuse was not reported for the majority of death cases. A blood propylhexedrine level was reported for seven of the nine death cases, with only one explicitly stating the level was within the lethal range.

We also reviewed 49 case reports and an observational study published in the medical literature. Most of these described young men abusing propylhexedrine and there were 18 deaths. The most common adverse events experienced in older literature reports included ischemic limb injury, cranial nerve dysfunction, psychosis, cardiomyopathy, adrenergic overstimulation, and anxiety or agitation. This is consistent with the frequently reported parenteral route of use. More recent literature was primarily associated with psychosis, adrenergic stimulation, and agitation. This is consistent with the frequently reported oral route of use. Also, consistent with FDA's analysis of poison control center call data, a retrospective study described single-substance propylhexedrine abuse cases documented by U.S. Poison Control Centers from 2007-2016. The study identified 283 calls, which increased annually from 2007 (n=16) to 2016 (n=58). Most (66 percent) of calls involved males. The majority of adverse effects were sympathomimetic and no deaths were noted, although deaths are expected to be under-ascertained in poison control center data.

Studies show increased risk of heart rhythm problems with seizure and mental health medicine lamotrigine (Lamictal) in patients with heart disease [posted 3/31/2021]
A U.S. Food and Drug Administration (FDA) review of study findings showed a potential increased risk of heart rhythm problems, called arrhythmias, in patients with heart disease who are taking the seizure and mental health medicine lamotrigine (Lamictal). We want to evaluate whether other medicines in the same drug class have similar effects on the heart and are requiring safety studies on those also. We will update the public when additional information from these studies becomes available.

FDA required these studies, called in vitro studies, to further investigate Lamictal's effects on the heart after we received reports of abnormal electrocardiographic (ECG) findings and some other serious problems. In some cases, problems including chest pain, loss of consciousness, and cardiac arrest occurred. In vitro studies are studies done in test tubes or petri dishes and not in people or animals. We first added information about this risk to the lamotrigine prescribing information and Medication Guides in October 2020, which we have updated.

Lamotrigine is used alone or with other medicines to treat seizures in patients 2 years and older. It may also be used as maintenance treatment in patients with the mental health condition bipolar disorder to help delay the occurrence of mood episodes such as depression, mania, or hypomania. Lamotrigine has been approved and on the market for more than 25 years and is available under the brand name Lamictal and as generics.

Patients should not stop taking your medicine without first talking to your prescriber because stopping lamotrigine can lead to uncontrolled seizures, or new or worsening mental health problems. Contact

your health care professional right away or go to an emergency room if you experience an abnormal heart rate or irregular rhythm, or symptoms such as a racing heartbeat, skipped or slow heartbeat, shortness of breath, dizziness, or fainting.

Health care professionals should assess whether the potential benefits of lamotrigine outweigh the potential risk of arrhythmias for each patient. Laboratory testing performed at therapeutically relevant concentrations has shown that lamotrigine can increase the risk of serious arrhythmias, which can be life-threatening, in patients with clinically important structural or functional heart disorders. Clinically important structural and functional heart disorders include heart failure, valvular heart disease, congenital heart disease, conduction system disease, ventricular arrhythmias, cardiac channelopathies such as Brugada syndrome, clinically important ischemic heart disease, or multiple risk factors for coronary artery disease. The risk of arrhythmias may increase further if used in combination with other medicines that block sodium channels in the heart. Other sodium channel blockers approved for epilepsy, bipolar disorder, and other indications should not be considered safer alternatives to lamotrigine in the absence of additional information (see List of Sodium Channel Blockers Required to Conduct Postmarket Studies).

We previously communicated safety information associated with lamotrigine in April 2018 (serious immune system reaction), August 2010 (aseptic meningitis warning), and September 2006 (possible association between Lamictal exposure during pregnancy and oral clefts in newborns). Lamotrigine was also covered as part of a May 2009 safety alert concerning suicidal thoughts and behavior with the entire class of anti-seizure medicines.

All medicines have side effects even when used correctly as prescribed. It is important to know that people respond differently to all medicines depending on their health, the diseases they have, genetic factors, other medicines they are taking, and many other factors. As a result, we cannot determine how likely it is that someone will experience these side effects when taking lamotrigine. Your health care professionals know you best, so talk to them if you have questions or concerns.

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving lamotrigine or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of this page.

CURRENT DRUG SHORTAGES

Below is the list of drugs listed by the FDA as currently in shortage. Please refer to the FDA website for more information at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

Generic Name or Active Ingredient

Acetazolamide Injection
Amifostine Injection
Amino Acids
Amoxapine Tablets
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine sulfate Tablets
Anagrelide Hydrochloride Capsules
Asparaginase Erwinia Chrysanthemi (Erwinaze)
Atropine Sulfate Injection
Atropine Sulfate Ophthalmic Ointment
Azacitidine for Injection
Belatacept (Nulojix) Lyophilized Powder for Injection
Bumetanide Injection, USP
Bupivacaine Hydrochloride and Epinephrine Injection, USP
Bupivacaine Hydrochloride Injection, USP
Calcitriol Injection USP 1MCG /ML
Calcium Disodium Versenate Injection
Calcium Gluconate Injection
Capreomycin Injection, USP
Cefazolin Injection
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Cefoxitin for Injection, USP
Ceftazidime and Avibactam (AVYCAZ®) for Injection, 2 grams/0.5 grams
Ceftolozane and Tazobactam (Zerbaxa) Injection
Chlordiazepoxide Hydrochloride USP, Capsules
Cisatracurium Besylate Injection
Continuous Renal Replacement Therapy (CRRT) Solutions
Cortisone Acetate Tablets
Cyclopentolate Ophthalmic Solution
Cysteamine Hydrochloride Ophthalmic Solution
Desmopressin Acetate (Stimate) Nasal Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Injection
Diltiazem Hydrochloride Injection
Dimercaprol (Bal in Oil) Injection USP
Disopyramide Phosphate (Norpace) Capsules
Dobutamine Hydrochloride Injection
Dopamine Hydrochloride Injection

Dorzolamide Hydrochloride and Timolol Maleate (Cosopt) Ophthalmic Solution
Dorzolamide Hydrochloride Ophthalmic Solution
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution
Enalaprilat Injection, USP
Epinephrine Injection, 0.1 mg/mL
Epinephrine Injection, Auto-Injector
Erythromycin Ophthalmic Ointment
Famotidine Injection
Famotidine Tablets
Fentanyl Citrate (Sublimaze) Injection
Floxuridine for Injection, USP
Fluorescein Strips
Fluvoxamine ER Capsules
Furosemide Injection, USP
Gemifloxacin Mesylate (Factive) Tablets
Guanfacine Hydrochloride Tablets
Heparin Sodium and Sodium Chloride 0.9% Injection
Histreline Acetate Implant
Hydralazine Hydrochloride Injection, USP
Hydrocortisone Tablets, USP
Hydromorphone Hydrochloride Injection, USP
Hydroxocobalamin Injection
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert
Imipenem and Cilastatin for Injection, USP
Isoniazid Injection USP
Ketamine Injection
Ketoprofen Capsules
Ketorolac Tromethamine Injection
Letermovir (Prevymis) Injection
Leucovorin Calcium Lyophilized Powder for Injection
Leuprolide Acetate Injection
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags
Lidocaine Hydrochloride (Xylocaine) Injection
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine
Lithium Oral Solution
Lorazepam Injection, USP
Loxapine Capsules
Methadone Hydrochloride Injection
Methyldopa Tablets
Midazolam Injection, USP
Misoprostol Tablets
Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric)
Nalbuphine Hydrochloride Injection
Nefazodone Hydrochloride Tablets
Nizatidine Capsules

Ondansetron Hydrochloride Injection
Oxytocin Injection, USP Synthetic
Pantoprazole Sodium for Injection
Parathyroid Hormone (Natpara) Injection
Physostigmine Salicylate Injection, USP
Pindolol Tablets
Potassium Acetate Injection, USP
Promethazine (Phenergan) Injection
Propofol Injectable Emulsion
Protamine Sulfate Injection, USP
Rifampin Injection
Rifapentine Tablets
Ropivacaine Hydrochloride Injection
Sclerosol Intrapleural Aerosol
Sincalide (Kinevac) Lyophilized Powder for Injection
Sodium Acetate Injection, USP
Sodium Bicarbonate Injection, USP
Sodium Chloride 23.4% Injection
Sodium Chloride Injection USP, 0.9% Vials and Syringes
Succimer (Chemet) Capsules
Sulfasalazine Tablets
Tacrolimus Capsules
Technetium Tc99m Succimer Injection (DMSA)
Teprotumumab-trbw
Thiothixene Capsules
Timolol Maleate Ophthalmic Gel Forming Solution
Trimethobenzamide Hydrochloride Capsules
Valproate Sodium Injection, USP
Vecuronium Bromide for Injection
Zinc Acetate Capsules