PERFORMRx℠

Drug Information Update

January 2022

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Dexlansoprazole 30 mg, 60 mg capsules DR	Dexilant	Takeda	• Healing of Erosive Esophagitis • Maintenance of Healed Erosive Esophagitis and Relief of Heartburn • Treatment of Symptomatic Non-Erosive Gastroesophageal Reflux Disease
Glycopyrrolate 1 mg/5 mL (0.2 mg/mL) solution	Cuvposa	Merz	Reduction of chronic severe drooling
Lidocaine 5% kit	Lidopac	Sterling-Knight	• Anesthesia of accessible mucous membranes of the oropharynx. • It is also useful as an anesthetic lubricant for intubation and for the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites.
Combigan	Brimonidine tartrate/timolol 0.2 %-0.5 % drops	Allergan	Reduction of elevated intraocular pressure (IOP) in patients with glaucoma or ocular hypertension who require adjunctive or replacement therapy due to inadequately controlled IOP
Vasostrict	Vasopressin 20 unit/mL vial	Par	To increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines.

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Xarelto 1 mg/ml oral suspension	rivaroxaban	New oral suspension due to new pediatric indications	New Dosage Form and Strength
Dartisla 1.7 mg disintegrating tablet	glycopyrrolate	ODT form of glycopyrrolate approved for symptoms of peptic ulcer in patients undergoing treatment; 505 (b)(2) approval	New Dosage Form and Strength
Tarpeyo 4 mg capsule,delayed release	budesonide	Accelerated approval to reduce proteinuria in adults with primary IgA nephropathy in those with risk for rapid disease progression; 505(b)(2) approval	New Strength
Tezspire 210 mg/1.91 ml (110 mg/ml) subcutaneous syringe	tezepelumab-ekko	Biologic product approved as add-on treatment for severe asthma. Targets the epithelial cytokine TSLP.	New Entity
Adbry 150 mg/mL subcutaneous syringe	tralokinumab-ldrm	An IL-13 cytokine inhibitor for the treatment of moderate-to-severe atopic dermatitis in adults 18 years or older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.	New Entity
Recorlev 150 mg tablet	levoketoconazole	A cortisol synthesis inhibitor indicated for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative.	New Entity
Rinvoq 30 mg tablet,extended release	upadacitinib	New strength; new indication for moderate-severe atopic dermatitis refractory to systemic treatments	New Strength
selenium 6 mcg/mL intravenous solution	selenium	IV selenium, new strength	New Strength

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†
Xarelto	rivaroxaban 1mg/ml oral suspension	Janssen	Indicated for the treatment of: • to reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation • for treatment of deep vein thrombosis (DVT) • for treatment of pulmonary embolism (PE) • for reduction in the risk of recurrence of DVT or PE • for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery • for prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients • to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD) • to reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD • for treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years • for thromboprophylaxis in pediatric patients 2 years and older with congenital heart disease after the Fontan procedure
Rinvoq	upadacitinib extended-release tablets, 15 mg, 30 mg	AbbVie	• Adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers • Adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Lidocaine Hydrochloride, Topical Solution USP, 4% (40 mg/mL), packaged in 50 mL screw cap bottles, Rx Only, Manufactured by Teligent Pharma, Inc., Buena, NJ 08310, Distributed by: McKesson Corporation dba Sky Packaging, 4971 Southridge Blvd., Suite 101, Memphis, TN 38141, NDC 63739-997-64	Class I	Drugs	Lot #: 16345, Exp. Date 01/2024	Superpotent Drug	Teligent Pharma, Inc.
Klean Touch Hand Sanitizer (Ethyl Alcohol 70%) Ingredients Ethanol and Methanol, in 55-gallon drums, Aroma Release Technology, Inc., 7026 Discovery Drive, Chattanooga, TN 37416	Class I	Drugs	Lots: 1620-1, 1620-3, 1620-4, 1820-4, 1820-5, 1920-1, 1920-2, No Expiration Date	Marketed Without an Approved NDA/ANDA: Product labeled to contain methanol making it an unapproved new drug and contains methanol	Aroma Release Technologies Inc
Veklury (remdesivir) for injection, 100 mg/vial, Single-Dose Vial, Rx only, Manufactured for: Gilead Sciences, Inc., Foster City, CA 94404, NDC 61958-2901-2	Class I	Drugs	Lots: 2141001-1A, 2141002-1A, Exp. 01/2024	Presence of Particulate Matter: investigation into a customer complaint confirmed the presence of glass particulates.	Gilead Sciences, Inc.
kleantouch HAND SANITIZER (ethyl alcohol 70%), 8.0 FL OZ (236 ML), pump bottles, Distributed by: Valisa MFG, LLC, Farmingdale, NY, 11735, Made in USA, UPC 6 86162 99246 1	Class I	Drugs	Lot #: 1260-1, 1260-2, 1260-3, 1260-4. Exp. 04/2022	Marketed Without an Approved NDA/ANDA: Product labeled to contain methanol making it an unapproved new drug and contains methanol	Valisa MFG LLC
Clobetasol Propionate Ointment USP, 0.05%, 60g tubes, Rx only, Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel 2624761, Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532. NDC 51672-1259-3	Class I	Drugs	Lot# AC13786, exp. date DEC 2022	Microbial Contamination of Non-Sterile Products: presence of R. Pickettii bacteria	Taro Pharmaceuticals U.S.A., Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Betamethasone Dipropionate Lotion USP, 0.05% (Augmented), 30 mL bottle, (29 g), Rx Only, Teligent Pharma Inc., Buena, NJ, 08310, NDC 52565-023-29	Class II	Drugs	Lot # 16569, Exp 9/2022	Failed Stability Specifications: lot did not meet specification for the Active Pharmaceutical Ingredient (API) particle test, which was determined through routine stability testing	Teligent Pharma, Inc.
Midazolam in 0.9% Sodium Chloride Injection, 50 mg per 50 mL (1 mg per mL), Rx only, SterRx, 141 Idaho Ave. Plattsburgh, NY 12003, NDC #70324-102-01.	Class II	Drugs	Lots S21131/BSP, 10-Nov-21 S21132/BSQ, 11-Nov-21 S21139/BSX, 18-Nov-21 S21150/BTI, 24-Nov-21 S21158/BTP, 1-Dec-21 S21160/BTR, 2-Dec-21 & S21170/BUB, 9-Dec-21.	Lack of Assurance of Sterility	SterRx, LLC
Morphine Sulfate in 0.9% Sodium Chloride Injection, 100 mg per 100 mL (1 mg per mL), Rx only, SterRx, 141 Idaho Avenue, Plattsburgh, NY, 12903, NDC 70324-427-02.	Class II	Drugs	S21317/BZE	Lack of Assurance of Sterility	SterRx, LLC
dilTIAZem HCl 125 mg per 125 mL (1 mg per mL) in 0.7% Sodium Chloride Injection, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY, 12903, NDC 70324-976-01.	Class II	Drugs	Lots S21164/BTV, 3-Dec-21; S21191/BUU, 18-DEC-21; S21197/BUZ, 31-Dec-21; S21220/BVV, 13-Jan-22; S21271/BX0, 27-Jan-22; S21272/BXP, 28-Jan-22; S21299/BYP, 18-Fev-22; S21300/BYQ, 19-Feb-22	Lack of Assurance of Sterility	SterRx, LLC
NOREPINEPHRINE 4 mg per 250 mL (16 mcg per mL) in 5% Dextrose Injection, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-451-01.	Class II	Drugs	S21192/BUV 18-Apr-22 S21205/BVH 23-Apr-22 S21402/CCK 21-Aug-22	Lack of Assurance of Sterility	SterRx, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
EPINEPHrine, 2 mg per 250 mL (8 mcg per mL) in 0.9% Sodium Chloride Injection, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY, 12903, NDC 70324-027-01.	Class II	Drugs	S21257/BXC	Lack of Assurance of Sterility	SterRx, LLC
PHENYLepherine HCL in 0.9% Sodium Chloride, 20 mg per 250 mL (80 mcg per mL), Rx only, SterRx, 141 Idaho Avenue, Plattsburgh, NY 12903, NDC 70324-701-01.	Class II	Drugs	S21086/BQW 14-Dec-21 S21149/BTH 23-Jan-22 S21159/BTQ 30-Jan-22 S21265/BXI 3-Apr-22 S21305/BYU 24-Apr-22 S21311/BZA 26-Apr-22	Lack of Assurance of Sterility	SterRx, LLC
Sodium Bicarbonate in 5% Dextrose Injection, 150 mEq per 1000 mL (12.6 mg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-326-01.	Class II	Drugs	S20483/BNJ 23-Nov-21 S20484/BNK 24-Nov-21 S20485/BNL 25-Nov-21 S21008/BNV 3-Dec-21 S21010/BNX 9-Dec-21 S21025/BOM 10-Dec-21 S21026/BON 15-Dec-21 S21027/BOO 16-Dec-21 S21035/BOW 17-Dec-21 S21045/BPF 18-Dec-21 S21046/BPG 21-Dec-21 S21050/BPK 22-Dec-21 S21054/BPO 24-Dec-21 S21055/BPQ 25-Dec-21 S21061/BPW 28-Dec-21 S21062/BPX 29-Dec-21 S21063/BPY 30-Dec-21 S21064/BPZ 31-Dec-21 S21069/BQE 31-Dec-21 S21073/BQI 4-Jan-22	Lack of Assurance of Sterility	SterRx, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			S21074/BQJ 5-Jan-22 S21076/BQL 6-Jan-22 S21077/BQM 7-Jan-22 S21081/BQQ 20-Jan-22 S21083/BQS 22-Jan-22 S21084/BQT 25-Jan-22 S21110/BRU 26-Jan-22 S21111/BRV 27-Jan-22 S21112/BRW 27-Jan-22 S21113/BRX 28-Jan-22 S21114/BRY 1-Feb-22 S21115/BRZ 1-Feb-22 S21123/BSH 2-Feb-22 S21124/BSI 3-Feb-22 S21126/BSK 3-Feb-22 S21127/BSL 4-Feb-22 S21128/BSM 4-Feb-22 S21129/BSN 5-Feb-22 S21168/BTZ 10-Mar-22 S21169/BUA 11-Mar-22 S21176/BUH 15-Mar-22 S21181/BUL 17-Mar-22 S21182/BUM 17-Mar-22 S21270/BXN 26-May-22 S21274/BXR 26-May-22 S21321/BZH 1-Jun-22 S21322/BZI 2-Jun-22 S21323/BZJ 3-Jun-22 S21324/BZK 3-Jun-22 S21325/BZL 7-Jun-22		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			S21329/BZP 8-Jun-22 S21336/BZW 14-Jun-22 S21337/BZX 15-Jun-22 S21338/BZY 16-Jun-22 S21341/CAB 17-Jun-22 S21343/CAD 18-Jun-22 S21348/CAH 23-Jun-22 S21350/CAJ 24-Jun-22 S21351/CAK 28-Jun-22 S21357/CAQ 1-Jul-22 S21360/CAT 2-Jul-22 S21363/CAW 5-Jul-22 S21366/CAZ 7-Jul-22 S21374/CBH 8-Jul-22 S21376/CBJ 8-Jul-22 S21377/CBK 12-Jul-22 S21381/CBO 13-Jul-22 S21384/CBR 13-Jul-22 S21387/CBU 13-Jul-22 S21390/CBX 14-Jul-22 S21392/CBZ 14-Jul-22 S21393/CCA 15-Jul-22 S21396/CCD 15-Jul-22 S21397/CCF 19-Jul-22 S21399/CCH 19-Jul-22 S21401/CCJ 20-Jul-22 S21404/CCM 21-Jul-22		
Succinylcholine Chloride Injection, 200 mg per 10 mL (20 mg per mL), 1,000 mL, Rx	Class II	Drugs	S21367/CBA 18-Nov-21 S21403/CCL 9-Dec-21	Lack of Assurance of Sterility	SterRx, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
only, SterRx, 141 Idaho Avenue, Plattsburgh, NY 12903, NDC 70324-826-01.					
EPINEPHIrine in 0.9% Sodium Chloride Injection, 4 mg per 250 mL (16 mcg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-227-01.	Class II	Drugs	S21254/BWZ 22-Nov-21 S21263/BXG 30-Nov-21 S21333/BZT 11-Jan-22 S21398/CCG 19-Feb-22	Lack of Assurance of Sterility	SterRx, LLC
EPINEPHIrine in 0.9% Sodium Chloride Injection, 5 mg per 250 mL (20 mcg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-052-01.	Class II	Drugs	S21255/BXA 22-Jan-22 S21264/BXH 29-Jan-22 S21328/BZO 10-Mar-22	Lack of Assurance of Sterility	SterRx, LLC
EPINEPHIrine in 0.9% Sodium Chloride Injection, 8 mg per 250 mL (32 mcg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-077-01.	Class II	Drugs	S21255/BXA 22-Jan-22 S21264/BXH 29-Jan-22 S21328/BZO 10-Mar-22	Lack of Assurance of Sterility	SterRx, LLC
EPINEPHrine in 0.9% Sodium Chloride Injection, 16 mg per 250 mL (64 mcg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-627-01.	Class II	Drugs	S21335/BZV	Lack of Assurance of Sterility	SterRx, LLC
Midazolam in 0.9% Sodium Chloride Injection, 100 mg per 100 mL (1 mg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-102-02.	Class II	Drugs	S21065/BQA 12-Nov-21 S21066/BQB 19-Nov-21 S21142/BTA 19-Nov-21 S21143/BTB 20-Nov-21 S21146/BTE 21-Nov-21 S21147/BTF 25-Nov-21 S21148/BTG 25-Nov-21 S21153/BTL 26-Nov-21 S21154/BTM 27-Nov-21 S21171/BUC 10-Dec-21 S21172/BUD 11-Dec-21 S21173/BUE 15-Dec-21	Lack of Assurance of Sterility	SterRx, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			S21190/BUT 16-Dec-21 S21201/BVD 22-Dec-21 S21202/BVE 24-Dec-21 S21203/BVF 29-Dec-21 S21204/BVG 19-Jan-22 S21258/BXD 20-Jan-22 S21275/BXS 30-Jan-22 S21276/BXT 2-Feb-22 S21277/BXU 3-Feb-22 S21278/BXV 3-Feb-22 S21284/BYB 4-Feb-22 S21285/BYC 5-Feb-22 S21286/BYD 11-Feb-22 S21287/BYE 12-Feb-22 S21290/BYH 16-Feb-22 S21304/BYT 23-Feb-22 S21306/BYV 24-Feb-22 S21308/BYX 25-Feb-22 S21310/BYZ 26-Feb-22 S21379/CBM 14-Apr-22 S21382/CBP 14-Apr-22 S21385/CBS 15-Apr-22		
Morphine Sulfate in 5% Dextrose Injection, 100 mg per 100 mL (1 mg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-452-01.	Class II	Drugs	S21293/BYJ	Lack of Assurance of Sterility	SterRx, LLC
NOREPINEPHRINE in 5% Dextrose Injection, 8 mg per 250 mL (32 mg per mL) Injection, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-476-01.	Class II	Drugs	S21409/CCR	Lack of Assurance of Sterility	SterRx, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
dilTIAZem HCl in 5% Dextrose Injection, 125 mg per 125 mL, (32 mcg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-951-01.	Class II	Drugs	S21200/BVC 15-Nov-21 S21296/BYM 19-Dec-21 S21320/BZG 4-Jan-22 S21164/BTV 3-Dec-21 S21191/BUU 18-Dec-21 S21197/BUZ 31-Dec-21 S21220/BVV 13-Jan-22 S21271/BXO 27-Jan-22 S21272/BXP 28-Jan-22 S21299/BYP 18-Feb-22 S21300/BYQ 19-Feb-22	Lack of Assurance of Sterility	SterRx, LLC
Fentanyl Citrate, in 0.9% Sodium Chloride Injection, 1 mg per 100 mL, (10 mcg per mL), Rx Only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-327-01.	Class II	Drugs	S21349/CAI 23-Mar-22 S21356/CAP 1-Apr-22 S21361/CAU 2-Apr-22	Lack of Assurance of Sterility	SterRx, LLC
Fentanyl Citrate, in 0.9% Sodium Chloride Injection, 2.5 mg per 250 mL, (10 mcg per mL), Rx Only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-327-02.	Class II	Drugs	S21353/CAM 26-Mar-22 S21358/CAR 30-Mar-22 S21364/CAX 6-Apr-22	Lack of Assurance of Sterility	SterRx, LLC
MORPHINE SULFATE, in 0.9% Sodium Chloride Injection, 50 mg per 50 mL, (1 mg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-427-01.	Class II	Drugs	S21292/BYI	Lack of Assurance of Sterility	SterRx, LLC
NOREPINEPHRINE, 16 mg per 250 mL, (64 mcg per mL) in 5% Dextrose Injection, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-002-01.	Class II	Drugs	S21194/CDW	Lack of Assurance of Sterility	SterRx, LLC
NOREPINEPHRINE, 4 mg per 250 mL, (18 mcg per mL) in 0.9% Sodium Chloride	Class II	Drugs	S20415/BKY 12-Nov-21 S20418/BLB 13-Nov-21 S20452/BMI 5-Dec-21	Lack of Assurance of Sterility	SterRx, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Injection, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-651-01.			S20463/BMT 9-Dec-21 S20464/BMU 18-Dec-21 S20478/BNF 23-Dec-21 S21021/BOI 6-Jan-22 S21033/BOU 20-Jan-22 S21047/BPH 21-Jan-22 S21059/BPU 28-Jan-22 S21094/BRE 18-Feb-22 S21117/BSB 3-Mar-22 S21118/BSC 10-Mar-22 S21138/BSW 17-Mar-22 S21227/BWA 7-May-22 S21239/BWK 12-May-22 S21279/BXW 5-Jun-22 S21295/BYL 16-Jun-22 S21298/BYO 18-Jun-22 S21339/BZZ 16-Jul-22 S21346/CAF 21-Jul-22 S21355/CAO 28-Jul-22 S21370/CBD 4-Aug-22 S21372/CBF 7-Aug-22 S21438/CDS 4-Sep-22		
NOREPINEPHRINE, 8 mg per 250 mL, (32 mcg per mL) in 0.9% Sodium Chloride Injection, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-676-01.	Class II	Drugs	S21162/BTT 13-Nov-21 S21163/BTU 13-Nov-21 S21167/BTY 19-Nov-21 S21174/BUF 20-Nov-21 S21175/BUG 21-Nov-21 S21217/BVS 12-Dec-21 S21218/BVT 12-Dec-21 S21219/BVU 16-Dec-21	Lack of Assurance of Sterility	SterRx, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			S21241/BWL 24-Dec-21 S21281/BXY 20-Jan-22 S21282/BXZ 23-Jan-22 S21283/BYA 22-Jan-22 S21297/BYN 28-Jan-22 S21340/CAA 27-Feb-22 S21342/CAC 5-Mar-22 S21352/CAL 6-Mar-22 S21359/CAS 11-Mar-22 S21362/CAV 12-Mar-22 S21368/CBB 13-Mar-22 S21369/CBC 19-Mar-22 S21415/CCX 7-Apr-22 S21419/CDB 7-Apr-22 S21434/CDP 16-Apr-22		
NOREPINEPHRINE, 16 mg per 250 mL, (64 mcg per mL) in 0.9% Sodium Chloride Injection, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-926-01.	Class II	Drugs	S21082/BQV 13-Nov-21 S21102/BRM 28-Nov-21 S21135/BST 14-Dec-21 S21166/BTX 7-Jan-22 S21178/BUJ 28-Jan-22 S21226/BVZ 5-Feb-22 S21237/BWI 7-Feb-22 S21242/BWM 13-Feb-22 S21280/BXX 11-Mar-22 S21302/BYS 21-Mar-22 S21345/CAE 23-Apr-22 S21424/CDG 28-May-22	Lack of Assurance of Sterility	SterRx, LLC
PHENYLephrine HCl, 40 mg per 250 mL, (160 mcg per mL) in 0.9% Sodium Chloride	Class II	Drugs	S21087/BQX 16-Dec-21 S21151/BTJ 24-Jan-22 S21186/BUQ 14-Feb-22	Lack of Assurance of Sterility	SterRx, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Injection, Rx Only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-252-01.			S21189/BUS 16-Feb-22 S21266/BXJ 3-Apr-22 S21307/BYW 24-Apr-22 S21313/BZC 27-Apr-22		
PHENYLephrine HCl, 50 mg per 250 mL, (200 mg per mL) in 0.9% Sodium Chloride Injection, Rx Only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-901-01.	Class II	Drugs	S21088/BQY 19-Dec-21 S21152/BTK 25-Jan-22 S21161/BTS 31-Jan-22 S21289/BYG 4-Apr-22 S21309/BYY 25-Apr-22 S21314/BZD 2-May-22 S21378/CBL 12-Jun-22	Lack of Assurance of Sterility	SterRx, LLC
Sodium Bicarbonate in 5% Dextrose Injection, Rx Only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-326-03	Class II	Drugs	S20459/BMP 17-Nov-21 S20472/BMZ 18-Nov-21 S20473/BNA 18-Nov-21	Lack of Assurance of Sterility	SterRx, LLC
Lidocaine Hydrochloride, Topical Solution USP, 4% (40 mg/mL), packaged in 50 mL screw cap bottles, Rx Only, Manufactured by Teligent Pharma, Inc., Buena, NJ 08310, Distributed by: McKesson Corporation dba Sky Packaging, 4971 Southridge Blvd., Suite 101, Memphis, TN 38141, NDC 63739-997-64	Class II	Drugs	Lot #: 15594, Exp Date 05/2023	Superpotent Drug: Minimally superpotent	Teligent Pharma, Inc.
EQUALINE aller-ease fexofenadine hydrochloride tablets, 180 mg, 24 HR, packaged as a) 15 count bottle, NDC 41163-571-22, UPC 0 41163 48067 4; b) 70 tablets per bottle, NDC 41163-571-01, UPC 0 41163 49847 1; Made in the Czech Republic, Distributed by: UNFI Providence, RI 02908.	Class II	Drugs	Lot # a)0HE2530 Exp 12/31/2021, 0KE2980 EXP 02/28/2022 b)0FR0461 Exp 2/28/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
GoodSense Aller.Ease, Fexofenadine hydrochloride 12 HR, 60 mg tablets, 24 count bottle, UPC 3 0113 0425 62 7; Made in the Czech Republic, Distributed by: Perrigo Allergan MI 49010.	Class II	Drugs	Lot# 0JE2487 , 0KE2982, Exp 1/31/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
amazon, Allergy Fexofenadine Hydrochloride Tablets, 180 mg/Antihistamine, 24 HR, 30 count bottle, Made in the Czech Republic, Distributed by: Amazon.com Services LLC 410 Terry Avenue N. Seattle, WA 98109 UPC 3 70030 11466 5	Class II	Drugs	Lot # 1BR0462, Exp 10/31/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
basic+care, allergy Fexofenadine Hydrochloride Tablets, 180 mg/Antihistamine, 24 HR, 150 count bottle, Made in the Czech Republic, Distributed by: Perrigo Allergan, MI 49010, NDC 0113-7571-47 UPC 3 70030 11470 2	Class II	Drugs	Lot # 0GR0528, Exp 03/31/22; 0KR0473, Exp 04/30/22; 0LR0369, Exp 06/30/22	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
basic+care, allergy Fexofenadine Hydrochloride Tablets, 60 mg/Antihistamine, 12HR, 100 count bottle, Made in the Czech Republic, Distributed by: Perrigo Allergan, MI 49010, NDC 0113-7425-78 UPC 3 70030 14536 2	Class II	Drugs	Lot # 0CR0510, Exp 9/30/2021; 0LR0361, Exp 04/30/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
berkley jensen, ALLERGY RELIEF, Fexofenadine Hydrochloride Tablets, 180 mg Antihistamine, 24HR, 150 count bottle, Made in the Czech Republic, Distributed by: BJ's WHolesale Club 25 Research Drive Westborough, MA 01581	Class II	Drugs	Lot # 0HV1442, Exp 3/1/2022, 1CV1619, Exp 10/1/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
CAREONE Allergy Relief, Fexofenadine Hydrochloride Tablets, 180 mg Antihistamine, 24HR, packaged as a)30 count bottle, NDC 41520-229-39, UPC 3 41520 31984 6; b)45 count bottle, NDC 41520-229-95 UPC 3 41520 31983 9; Made in the Czech Republic, Distributed by: Foodhold U.S.A. LLC Landover, MD 20785. Made in Czech Republic	Class II	Drugs	Lot a) 0FR0459, Exp 2/28/2022; 0LR0362, Exp 6/30/2022; 1BR0462, Exp 10/31/2022 b) 0LR0363, Exp 6/30/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
CVS Allergy Relief, Fexofenadine Hydrochloride Tablets, 60 mg Antihistamine, 12HR, packaged as a) 12 count bottle, NDC 59779-425-53, UPC 0 50428 25414 1; b)24 count bottle, NDC 59779-425-62, UPC 0 50428 53435 9; Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895, Made in Czech Republic	Class II	Drugs	Lot # a) 0ME2516, Exp 4/30/2022 b)0ME2515, Exp 4/30/2022; 0KE2982, Exp 1/31/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
DG/health Aller.Ease, Fexofenadine Hydrochloride Tablets, 180 mg/Antihistamine, 24HR, 10 count bottle, Distributed by: Made in Czech Republic. Distributed by Dolgencorp, LLC, 100 Mission Ridge Goodlettsville, TN 37072. UPC 3 70030 65779 7	Class II	Drugs	Lot 0KE2979, 0ME2088, Exp 2/28/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
Health Mart, Fexofenadine Hydrochloride tablets, 12HR, 60mg . Antihistamine 12 count bottle, Distributed by: Mckesson 6555 State Highway 161, Irvine, TX 75039. Made in the Czech Republic, NDC 62011-0413-1, UPC 0 52569 14278 3	Class II	Drugs	Lot 0JE2491, Exp 1/31/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Health Mart, Fexofenadine Hydrochloride tablets, 24HR, 180mg . Antihistamine 70 count bottle, Distributed by: Mckesson 6555 State Highway 161, Irvine, TX 75039. Made in the Czech Republic, NDC 62011-0233-1, UPC 0 52569 13787 1	Class II	Drugs	Lot 0FR0461, Exp 2/25/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
H.E.B Allergy Relief, Fexofenadine Hydrochloride tablets, 12HR, 60mg/Antihistamine 12 count bottle, Made with Pride & Care for H.E.B. San Antonio TX 78204, Product of Czech Republic, NDC 37808-425-53, UPC 0 41220 53080 9	Class II	Drugs	Lot 0JE2491, 0LE2178, Exp 01/31/2022; 0ME2516, Exp 4/30/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
H.E.B Allergy Relief, Fexofenadine Hydrochloride tablets, 24HR, 180mg/Antihistamine packaged as a) 15 count bottle, NDC 37808-571-22, UPC 0 41220 53081 6; b) 30 count bottle, NDC 37808-571-39, UPC 0 41220 53082 3; c) 45 count bottle, NDC 37808-571-95, UPC 0 41220 53083 0; Made with Pride & Care for H.E.B. San Antonio TX 78204, Product of Czech Republic,	Class II	Drugs	Lot a) 0HE2530, Exp 12/31/2021; 0JE2407, Exp 2/28/2022: b) 1BR0462, Exp 10/31/2022 c) 0FR0460, Exp 2/28/2022: 0LR0363, Exp 6/30/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
Kroger Allergy Relief, Fexofenadine Hydrochloride tablets, 12HR, 60mg Antihistamine, 12 count bottle, Distributed by the Kroger CO. Cincinnati, Ohio 45202. Made in the Czech Republic, NDC 30142-555-53 UPC 0 41260 35588 2	Class II	Drugs	lot 0LE2178, Exp 1/31/2022; 0ME2516, Exp 4/30/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
MAJOR, Fexofenadine Hydrochloride tablets, 12HR, 60mg Antihistamine, 100 count bottle, Distributed by Major Pharmaceuticals 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152. Made in the Czech Republic, NDC 0904-6979-60 UPC 3 09046 97960 9	Class II	Drugs	Lot 0GR0445, Exp 1/31/2022; 0LR0361, Exp 4/30/2022; 1AR0558, Exp 7/31/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
Meijer allergy relief, Fexofenadine Hydrochloride tablets, 24HR, 1800mg Antihistamine, packaged as a) 15 count bottle, NDC 41250-060-22 UPC 7 60236 18716 5; b) 30 count bottle, NDC 41250-060-39, UPC 7 60236 18717 2; c) 45 count bottle, NDC 41250-060-95, UPC 7 60236 18732 5; Made in the Czech Republic, Distributed by Meijer Distribution Inc, Grand Rapids, MI 49544.	Class II	Drugs	Lot a) 0HE2530, Exp 12/31/2021; 0KE2430, Exp 2/28/2022 b) 0LR0362, Exp 6/30/2022; 1BR0462, Exp 10/31/2022 c) 0FR0460, Exp 2/28/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
allergyrelief, Fexofenadine Hydrochloride tablets, 24HR, 1800mg Antihistamine, packaged as a) 15 count bottle, NDC 56062-571-22 UPC 0 41415 38973 1; b) 45 count bottle, NDC 56062-571-95 UPC 0 41415 38773 7; Distributed by PubliX SUpermarket Inc 3300 Publix Corporate Parkway Lakeland, FL 33811, Made in the Czech Republic	Class II	Drugs	Lot a) 0JE2407, Exp 2/28/2022 b) 1BR0463, Exp 10/31/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
Perrigo Fexofenadine Hydrochloride tablets, 24HR, 180mg Antihistamine, 100 count bottle, Made in the Czech Republic, Distributed by Perrigo Allergan, MI 49010 NDC 45802-571-78 UPC 3 45802 571 78 6	Class II	Drugs	Lot 0FR0563, Exp 02/28/22; 0GR0530, Exp 03/31/22; 0KR0434, 0KR0435, 0LR0366,	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			0LR0367, 0LR0368, Exp 06/30/22.		
Perrigo Fexofenadine Hydrochloride tablets, 12HR, 60mg Antihistamine, 100 count bottle, Made in the Czech Republic, Distributed by Perrigo Allergan, MI 49010 NDC 45802-425-78 UPC 3 45802 425 78 2	Class II	Drugs	Lot# 0CR0510, Exp 09/30/21, 0GR0445, Exp 01/31/22, 0LR0361, Exp 04/30/22, 1AR0558 , Exp 07/31/22	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
Rite Aid ALLERGY RELIEF Fexofenadine Hydrochloride tablets, 12HR, 60mg Antihistamine, 24 count bottle, Made in the Czech Republic, Distributed by Rite Aid 30 Hunter Lane Camp Hill PA 17011 NDC 11822-0425-0 UPC 0 11822 85410 8	Class II	Drugs	Lot # 0JE2487, EXP 01/31/2022; 0ME2515, Exp 04/30/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
Rite Aid ALLERGY RELIEF Fexofenadine Hydrochloride tablets, 24HR, 180mg Antihistamine, packaged as a) 30 count bottle, NDC 11822-0571-2 UPC 0 11822 99908 3; b) 150 count bottle, NDC 11822-0571-5 UPC 0 11822 85411 5; Made in the Czech Republic, Distributed by Rite Aid 30 Hunter Lane Camp Hill PA 17011	Class II	Drugs	Lot # a) 1BR0462, Exp 10/31/2022 b) 0GR0528, Exp 3/31/2022; 0KR0473, Exp 4/30/2022; 0LR0369, Exp 6/30/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
TopCare Allergy Relief, Fexofenadine Hydrochloride tablets, 12HR, 60mg Antihistamine, 12 count bottle, Distributed Topco Associates LC, Elk Grove Village, IL 60007, Made in the Czech Republic, NDC 36800-954-53 UPC 0 36800 33284 3	Class II	Drugs	Lot # 0LE2178, Exp 01/31/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
TopCare Allergy Relief, Fexofenadine Hydrochloride tablets, 24HR, 180mg Antihistamine, packaged as a) 5 count	Class II	Drugs	Lot # a) 0KE2429, Exp 02/28/2022; b) 0HE2530, Exp 12/31/2021;	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
bottle, NDC 36800-319-13 UPC 0 36800 33277-5 b) 15 count bottle, NDC 36800-319-22 UPC 0 36800 33278 2; c) 45 count bottle, NDC 36800-319-95 UPC 0 36800 33280-5; d) 90 count bottle, NDC 36800-319-75 UPC 0 36800 33282 9; Distributed Topco Associates LC, Elk Grove Village, IL 60007, Made in the Czech Republic,			c)0FR0460, Exp 02/28/2022; d)0GR0531, Exp 03/31/2022 ; 0KR0465, Exp 04/302022		
up&up allergy relief, Fexofenadine Hydrochloride tablets, 24HR, 180mg/antihistamine, packaged as a) 15 count bottle, NDC 11673-571-22 UPC 3 70030 62303 7; b) 30 count bottle, NDC 11673-571-39 UPC 3 70030 62301 3; Distributed by Target Corp., Mpls., MN 55403, Made in the Czech Republic,	Class II	Drugs	Lot a) 1AE2334, Exp 02/28/2022; b) 1BR0462, Exp 10/31/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
Wal-Fex Fexofenadine Hydrochloride tablets, 180mg/antihistamine, 24HR, packaged as a) 5 count bottle, NDC 0363-0600-13,UPC 3 11917 12267 0, b)30 count bottle, NDC 0363-0600-39 UPC 3 11917 16172 3 c) 90 count bottle, NDC 0363-0600-75 UPC 3 11917 12271 7 ; Distributed by Walgreen Co. 200 Wilmot Rd Deerfield IL 60015, Made in the Czech Republic,	Class II	Drugs	Lot # a)0JE2406, Exp 02/28/2022 b) 0FR0459, Exp 02/28/2022. c) 0KR0465, Exp 04/30/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
Wal-Fex Fexofenadine Hydrochloride tablets, 60mg/antihistamine, 12HR, 24 count bottle, Distributed by Walgreen Co. 200 Wilmot Rd Deerfield IL 60015, Made in	Class II	Drugs	Lot # 0KE2447, 0KE2982, Exp 01/31/2022; 0ME2515, Exp 04/30/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
the Czech Republic, NDC 0363-0903-62 UPC 3 11917 18625 2					
amazon basic+care, Allergy Fexofenadine Hydrochloride Tablets, 60 mg/Antihistamine, 12HR, 100 count bottle, Made in the Czech Republic, Distributed by: Amazon.com services LLC 410 Terry Avenue N., Seattle WA 98109, NDC 72288-425-78 UPC 3 70030 14536 2	Class II	Drugs	Lot # 1AR0558, Exp 7/31/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
KIRKLAND ALLER-FEX, Fexofenadine Hydrochloride Tablets, 180 mg/Antihistamine, 24HR, 180 count bottle, Made in the Czech Republic, Packaged by Perrigo 515 Eastern Ave., Allegan, MI 49010, For Costco Wholesale Corporation. P.O. Box 34535 Seattle, WA 98124-1535, NDC 63981-571-48, UPC 0 96619 98776 4	Class II	Drugs	Lot # 0HV1246, exp 1/1/2022; 0GV1974, 0GV1459, exp 2/1/2022, 0HV1438, exp 3/1/2022, 0KV2116, 0KV2117, exp 5/1/2022; 0KV2119, 0LV2196, 0MV2203, 0MV2204, 0MV2205, exp 6/1/2022;	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
CVS Allergy Relief, Fexofenadine Hydrochloride Tablets, 180 mg Antihistamine, 24HR, 30 count bottle, NDC 69842-698-39, UPC 0 50428 62564 4	Class II	Drugs	Lot # 1DV1855, exp 4/1/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
GoodSense Aller.Ease, Fexofenadine hydrochloride 24 HR, 180 mg tablets, 30 count bottle, Made in the Czech Republic, Distributed by Perrigo Allergan MI., 49010, UPC 3 0113 0571 39 3; NDC 0113-0571-30,	Class II	Drugs	Lot # 0MV2158, exp 6/1/2022	Out of specification impurity A result obtained during stability testing.	Perrigo Company PLC
Pregabalin Capsules, 50 mg, 100 count bottle, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ	Class II	Drugs	Lot number: DNC0432A, expiration 01/2023	Failed Tablet/Capsule Specifications: Out of Specification results for particle Size	SUN PHARMACEUTICAL

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
08512, Manufactured by: Sun Pharmaceutical Industries Ltd., Survey No. 259/15 Dadra-396 191, (U.T. of D & NH), India, NDC 47335-687-88.				Distribution and Bulk Density of the Active Pharmaceutical Ingredient.	INDUSTRIES INC
PAIN AID ESF- (Acetaminopehn USP 250mg, Asprin USP 250mg Caffeine 65mg) coated, bulk OTC tablets packaged in corrugated boxes lined with 2 polyethylene bags 100 lb, ULTRAtab Laboratories, Inc. NDC# 62959-560-00, Product Code M560L	Class II	Drugs	Bulk Lots: 18K070, exp. date Nov-21; 19A046, exp. date Jan-22; 19C073, exp. date Mar-22; 19E014, exp. date May-22; 19G039, exp. date Jul-22; 19K002, exp. date Nov-22; 20A013, exp. date Jan-23; 20B050, exp. date Feb-23; 20C011, exp. date Mar-23; 20C049, exp. date Mar-23; 20F071, exp. date Jun-23; 20F072, exp. date Jun-23; 20G033, exp. date Jul-23; 20G041, exp. date Jul-23.	CGMP Deviations: failed stability results, inadequate laboratory investigations,	ULTRAtab Laboratories, Inc.
Cefixime Capsules, 400 mg, 50-count bottles, Rx only, Manufactured by: Alkem Laboratories Ltd., Mumbai, India, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ, NDC 67877-584-50	Class II	Drugs	Lot #: 20140293, Exp Dec 2021; 20141525, 20141526, 20141527, Exp Mar 2022; 20143019, 20143020, 20143021, 20143022, Exp July 2022; 20144759, 20144760, 20144761, Exp Nov 22	Failed impurities/degradation specifications	Ascend Laboratories, LLC
Cefixime 400 mg capsule, packaged in a) 2-count bottle (NDC 70518-2749-02), b) 2-count blister pack (NDC 70518-2749-03), Rx	Class II	Drugs	Lot #: a) B1429436-110821, Exp 07/2022; B1429434-110821, Exp	Failed Impurities/Degradation Specifications	RemedyRepack Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
only, MFG: Ascend Labs, LLC, Montvale, NJ 07645			11/2022; B1429435-110821, Exp 11/2022; B1279449-072021, Exp 07/2022; B1279457-072021, Exp 07/2022; B1279442-072021,Exp 07/2022; B1057718-012621, Exp 01/2022; B1057727-012621, Exp 01/2022; b) B1358139-092121, Exp 03/2022; B1424654-110421, B1437578-111421, Exp 05/2022		
Carbamazepine Tablets, USP 200 mg 100 Tablets Rx only NDC 13668-268-01 Manufactured by: Torrent Pharmaceuticals Ltd. Bharuch-392130, India Manufactured for: Torrent Pharma Inc., Basking Ridge, NJ 07920.	Class II	Drugs	Batch: 4J11G002 Exp. 08/2024	Failed Dissolution Specifications	Torrent Pharma Inc.
The Natural Dentist Healthy Balance Peppermint Sage, Menthol 0.12%, 16.9 FL OZ (500 mL) bottles, Manufactured for Revive Personal Products Company, Madison, NJ 07940, UPC 7 14132 00071 4	Class II	Drugs	Lot 2091A, exp 7/2023	Labeling; Label mix-up and Wrong Bar Code; back label incorrectly states active ingredient as Menthol with UPC 7 14132 00071 4 instead of Peppermint Oil and Sage Oil with UPC 7 14132 00073 8	Revive Personal Products Company
Nitroglycerin Lingual Spray, 400 mcg per spray, 200 metered sprays, 12 g bottles, Rx only, Manufactured by Perrigo, Yeruham,	Class II	Drugs	Lot, expiry: Lot 150892, exp Oct 2022; Lot 153199,	Defective Delivery System	Padagis US LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Israel; Distributed by Perrigo, Allegan, MI 49010, NDC 45802-210-02			exp Feb 2023; Lot 156041, exp Apr 2023		
Metoprolol Tartrate Tablets, USP 25 mg, 1000 - count bottle, Rx Only, Distributed by: TruPharma, LLC. Tampa, FL 33609; Manufactured by: Rubicon Research Prvate Limited Ambernath, Dist. Thane, 421506 India. NDC 52817-360-00	Class II	Drugs	Batch # 210211H1, Exp. date FEB 2024	Complaint received of foreign matter (metal) embedded in tablet.	Rubicon Research Private Limited
MethylPREDNISolone Acetate Injectable Suspension USP 400 mg/10mL (40mg/mL), 10 mL Multiple-Dose Vial, Rx Only, Manufactured for: Northstar Rx LLC, Memphis, TN 38141, Manufactured By: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054, NDC 16714-090-01, packaged in cartons.	Class II	Drugs	Lot # 100022393, exp 09/2022	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Norepinephrine Bitartrate Injection USP 4 mg/4 mL (1 mg/mL), 4 mL Single-Dose Vials, 10 vials per carton, Rx Only, Manufactured By: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054, NDC 0703-1153-03.	Class II	Drugs	Lot # 100020800, exp 07/2022	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Metformin 750 mg Extended Release NDC # 70518-2920-00	Class II	Drugs	Lot # J0511265-021121, exp. date 02/28/2022 J0499451-122220, exp. date 01/31/2022 J0496563-120820, exp. date 12/31/2021 J0495111-120120, exp. date 12/31/2021	CGMP Deviations: Detection of N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit.	RemedyRepack Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
8.4% Sodium Bicarbonate Injection, USP 50 mEq/50 mL (1 mEq/mL), 50 mL vials, Rx Only, Manufactured and Distributed by: Exela Pharma Sciences, LLC., Lenoir, NC 28645, NDC 51754-5001-1	Class II	Drugs	Lot #: C0001088/P0001317, Exp. Date 08/2023	Lack of Assurance of Sterility	Exela Pharma Sciences LLC
Gatifloxacin Ophthalmic Solution, 0.5%, 2.5 mL bottle, Rx only, Manufactured by: Lupin Limited, Pithampur (M.P.) 454 775, INDIA, NDC 68180-435-01.	Class III	Drugs	Lot #: H003037, exp. date May 2022; H100132, exp. date June 2022; H100847, exp. date October 2022	Failed Stability Specifications: Out-of-specification results observed in a water loss test that might affect the assay content and alter drug concentration.	Lupin Pharmaceuticals Inc.
Oxycodone Hydrochloride Tablets, USP C-II, 5 mg, 100 count bottles, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202. Manufactured by: Novel Laboratories, Inc. Somerset, NJ 08873. NDC 43386-432-01	Class III	Drugs	Lot # S000268, Exp. date January 2022	Out-of-specification impurity test result observed at 18-month long term stability time point.	Lupin Pharmaceuticals Inc.
Morphine Sulfate Oral Solution 100 mg per 5 mL (20 mg/mL) 30 mL bottles, Rx only, Hi-Tech Pharmacal Co., Inc., Amityville, NY 11701 -- NDC 50383-965-30	Class III	Drugs	Lot: 375153 Exp. 10/31/2022	Labeling: Missing Label	Akorn, Inc.
Oxycodone Hydrochloride Oral Solution, USP 5 mg per 5 mL (1 mg/mL), 500 mL bottle, Rx only, Manufactured by: Hi-Tech Pharmacal Co., Inc., Amityville, NY 11701 --- NDC 50383-961-34	Class III	Drugs	Lots: 377186 Exp. 2/28/2023; 377188 Exp. 3/31/2023	Labeling: Missing Label	Akorn, Inc.

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

FDA DRUG SAFETY COMMUNICATIONS

[1/12/2022] FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain: Benefits for use outweigh these risks and oral care can help
What safety concern is FDA announcing?

The U.S. Food and Drug Administration (FDA) is warning that dental problems have been reported with medicines containing buprenorphine that are dissolved in the mouth. The dental problems, including tooth decay, cavities, oral infections, and loss of teeth, can be serious and have been reported even in patients with no history of dental issues. Despite these risks, buprenorphine is an important treatment option for opioid use disorder (OUD) and pain, and the benefits of these medicines clearly outweigh the risks.
Regular adherence to buprenorphine to treat OUD reduces withdrawal symptoms and the desire to use opioids, without causing the cycle of highs and lows associated with opioid misuse. The comprehensive approach of buprenorphine combined with counseling and other behavioral therapies is often one of the most effective ways to treat OUD. This approach, called medication-assisted treatment (MAT), is tailored to meet each patient's needs and can help sustain recovery and prevent or reduce opioid overdose. According to the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), MAT has been shown to be effective in improving patient survival, decreasing opioid use, and allowing patients to live a self-directed life, including the ability to gain and maintain employment.

What is FDA doing?

We are requiring a new warning about the risk of dental problems be added to the prescribing information and the patient Medication Guide for all buprenorphine-containing medicines dissolved in the mouth. The prescribing and patient information will also include strategies to maintain or improve oral health while undergoing treatment with these medicines. These strategies will include recommending that prescribers refer patients to dental care services and encourage them to have regular checkups while taking these products. Patients should tell the dentist about all medicines they take, including buprenorphine.

What is buprenorphine and how can it help me?

Buprenorphine was approved in 2002 as a tablet to be administered under the tongue to treat OUD. In 2015, buprenorphine was approved as a film to be placed inside the cheek to treat pain. There are also buprenorphine products for pain and OUD delivered by other routes such as a skin patch and injection, but FDA has not identified a concern for dental health related to these other forms. Buprenorphine works by changing the way the brain and nervous system respond to pain. At proper doses, buprenorphine also decreases the pleasurable effects of other opioids, making misuse of them less appealing. The benefits of buprenorphine medicines clearly outweigh the risks, particularly in the treatment of OUD.
The buprenorphine medicines that are associated with dental problems are tablets and films dissolved under the tongue or placed against the inside of the cheek. They are available as single-ingredient products and also in combination with naloxone. Buprenorphine medicines are marketed under the

brand names Belbuca, Bunavail, Cassipa, Suboxone, Subutex, and Zubsolv. They are also available as generics.

What should patients and caregivers do?

Continue taking your buprenorphine medicine as prescribed; do not suddenly stop taking it without first talking to your health care professional as it could lead to serious consequences. Suddenly stopping these medicines could cause you to become sick with withdrawal symptoms because your body has become used to the buprenorphine medicine, or to relapse to opioid misuse that could result in overdose and death. For those suffering from addiction to opioids, the benefits of using buprenorphine medicines clearly outweigh the risks and should be considered in conjunction with counseling and other behavioral therapies. This comprehensive MAT approach is often one of the most effective ways to treat OUD, and can help sustain recovery and prevent or reduce opioid overdose.

Patients using buprenorphine medicines dissolved in the mouth should take extra steps to help lessen the risk of serious dental problems. After the medicine is completely dissolved, take a large sip of water, swish it gently around your teeth and gums, and swallow. You should wait at least 1 hour before brushing your teeth to avoid damage to your teeth and give your mouth a chance to return to its natural state.

Inform your health care professional if you have a history of tooth problems, including cavities. Schedule a dentist visit soon after starting this medicine and inform your dentist that you are taking buprenorphine, and schedule regular dental checkups while taking this medicine. Your dentist can customize a tooth decay prevention plan for you. Notify both your health care professional and your dentist immediately if you experience any problems with your teeth or gums.

What should health care professionals do?

Health care professionals should be aware the benefits of buprenorphine medicines clearly outweigh the risks and are an important tool to treat OUD. When combined with counseling and other behavioral therapies, this comprehensive MAT approach is often the most effective way for treating OUD, and can help sustain recovery and prevent or reduce opioid overdose.

Ask patients about their oral health history prior to prescribing treatment with a transmucosal buprenorphine medicine. These serious dental problems have been reported even in patients with no history of dental issues, so refer them to a dentist as soon as possible after starting transmucosal buprenorphine. Counsel patients about the potential for dental problems and the importance of taking extra steps after the medicine has completely dissolved, including to gently rinse their teeth and gums with water and then swallow. Patients should be advised to wait at least 1 hour before brushing their teeth. Dentists treating someone taking a transmucosal buprenorphine product should perform a baseline dental evaluation and caries risk assessment, establish a dental caries preventive plan, and encourage regular dental checkups.

What did the FDA find?

Since buprenorphine was approved, we identified 305 cases of dental problems (131 cases classified as serious) with buprenorphine medicines dissolved in the mouth. These only include cases reported to FDA* or published in the medical literature,[1,2] so there may be additional cases about which we are unaware. The average age of the patients was 42 years, but those as young as 18 years were also

affected. Most cases were in patients using the medicines for OUD; however, 28 cases of dental problems occurred in patients using it to treat pain. In 26 cases, patients had no prior history of dental problems. Some cases reported dental problems occurring as soon as 2 weeks after treatment began, with the median time to diagnosis being approximately 2 years after starting treatment. Many cases were reported by health care professionals and provided documentation of extensive dental adverse events. Of the 305 cases, 113 mentioned two or more teeth were affected. The most common treatment for these dental problems was tooth extraction/removal, which was reported in 71 cases. Other cases reported requiring root canals, dental surgery, and other procedures such as crowns and implants.
*The cases were reported to the FDA Adverse Event Reporting System (FAERS) database.

What is my risk?

All medicines have side effects even when used correctly as prescribed, but in general the benefits of taking a medicine outweigh the risks. It is important to know that people respond differently to all medicines depending on their health, other medicines they are taking, the diseases they have, genetic factors, and many other reasons. As a result, we cannot determine how likely it is that someone will experience these side effects when taking buprenorphine medicines that dissolve in the mouth. However, the benefits of buprenorphine medicines for OUD and pain management clearly outweigh the risks. In particular, the comprehensive MAT approach of buprenorphine combined with counseling and other behavioral therapies is often one of the most effective ways to treat OUD, and can help sustain recovery and prevent or reduce opioid overdose.

How do I report side effects from buprenorphine?

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving buprenorphine 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 medicine 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 buprenorphine

- Buprenorphine-containing medicines that are dissolved in the mouth are approved to treat opioid use disorder (OUD), and one product is approved to treat pain. These medicines are available as tablets and films to be placed under the tongue or on the inside of the check and kept there until completely dissolved.
- These medicines are available as single-ingredient products and in combination with naloxone. Buprenorphine medicines are marketed under the brand names Belbuca, Bunavail, Cassipa, Suboxone, Subutex, and Zubsolv. They are also available as generics.
- Buprenorphine is an opioid and works by changing the way the brain and nervous system respond to pain.

- In patients taking buprenorphine for OUD, it reduces opioid withdrawal symptoms and the desire to use opioids, without causing the cycle of highs and lows associated with opioid misuse or abuse. At proper doses, buprenorphine also decreases the pleasurable effects of other opioids, making continued opioid use less appealing. When combined with counseling and other behavioral therapies, this comprehensive medication-assisted treatment (MAT) approach is often the most effective way for treating OUD. It can help sustain recovery and prevent or reduce opioid overdose.
- Common side effects of buprenorphine include headache, nausea, vomiting, constipation, pain, increased sweating, and insomnia.
- The use of buprenorphine-containing medicines that are dissolved in the mouth has been growing. The estimated number of prescriptions dispensed from U.S. outpatient retail and mail-order pharmacies increased from 11 million in 2014 to 16 million in 2020.[3]

Additional Information for Patients and Caregivers

- FDA is warning that dental problems such as tooth decay, cavities, oral infections, and loss of teeth have been reported with buprenorphine medicine that are dissolved in the mouth to treat opioid use disorder (OUD) or pain. These problems, some of which have been serious, have been reported even in patients with no history of dental issues. Despite this, the benefits of buprenorphine medicines clearly outweigh the risks.
- Buprenorphine medicines are an important tool to treat OUD. When combined with counseling and other behavioral therapies, this comprehensive approach is often the most effective way for treating OUD. It can help sustain recovery and prevent or reduce opioid overdose. For help finding opioid treatment centers nearest to you, visit the U.S. Department of Health and Human Services Treatment for Opioid Use Disorder and Addiction webpage or FindTreatment.gov.
- Additional information about MAT can be found on the following web pages: FDA: Information about Medication-Assisted Treatment (MAT) and SAMHSA: Medication-Assisted Treatment (MAT).
- Schedule an appointment with your dentist soon after starting this medicine and inform your dentist that you are taking it. Your dentist can customize a tooth decay prevention plan for you. Visit the dentist for regular checkups while taking this medicine.
- Notify your health care professionals immediately and seek dental treatment if you experience any problems with your teeth or gums while taking buprenorphine medicines that are dissolved in the mouth. If you are starting this medicine, tell your health care professional if you have any tooth problems, including a history of cavities.
- When taking your buprenorphine medicine and after it is completely dissolved, take a large sip of water, swish it gently around your teeth and gums, and swallow. Wait at least 1 hour before brushing your teeth.
- Do not suddenly stop taking your buprenorphine medicine without first talking to your health care professional as it could lead to serious consequences, including relapse to opioid misuse or abuse that could result in overdose and death. You could also become sick with withdrawal symptoms because your body has become used to the buprenorphine medicine.
- Read the patient Medication Guide every time you receive a prescription for buprenorphine. The Medication Guide will be updated with this new or other important information. It explains the important things that you need to know. These include the side effects, what the medicine is

used for, how to take and store it properly, and other things to watch out for when you are taking the medicine.
- Talk to your health care professional if you have any questions or concerns.
- To help FDA track safety issues with medicines, report side effects from buprenorphine 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 cases of dental adverse events, some severe, have been reported following the use of transmucosal buprenorphine-containing medicines. Reported events include cavities/tooth decay, including rampant caries; dental abscesses/infection; tooth erosion; fillings falling out; and, in some cases, total tooth loss. Multiple cases were reported in patients with no prior history of dental problems. The most common treatment for the dental adverse events was tooth extraction/removal.
- The benefits of buprenorphine medicines clearly outweigh the risks.
- Buprenorphine medicines are an important tool to treat opioid use disorder (OUD). When combined with counseling and other behavioral therapies, this comprehensive approach is often one of the most effective ways of treating OUD. It can help sustain recovery and prevent or reduce opioid overdose. Refer patients to find opioid treatment centers by visiting the U.S. Department of Health and Human Services Treatment for Opioid Use Disorder and Addiction webpage or FindTreatment.gov.
- Additional information about MAT can be found on the following web pages: FDA: Information about Medication-Assisted Treatment (MAT) and SAMHSA: Medication-Assisted Treatment (MAT).
- Counsel OUD patients they should use their buprenorphine only as prescribed and should not stop it because they can experience serious consequences, including relapse, misuse or abuse of other opioids, overdose, and death.
- Screen patients for oral disease and ask about their oral health history prior to beginning therapy with a transmucosal buprenorphine medicine.
- Counsel patients that severe and extensive tooth decay, tooth loss, and tooth fracture have been reported with the use of this medicine and it is important to visit their dentist to closely monitor their teeth.
- Refer patients to a dentist as soon as possible after starting transmucosal buprenorphine for a baseline dental evaluation, dental caries risk assessment and preventive plan, and encourage them to have regular dental checkups while taking the medicine.
- Educate patients on strategies to maintain or improve oral health while being treated with transmucosal buprenorphine medicines. Counsel them that after the medicine has completely dissolved in the oral mucosa, to gently rinse their teeth and gums with water and then swallow. Patients should wait at least 1 hour before brushing their teeth after using the medicine, which will allow the mouth to gradually return to oral homeostasis and avoid any mechanical damage that may occur due to brushing.
- Encourage patients to read the Medication Guide they receive with each prescription, which explains the safety risks and provides other important information.

- To help FDA track safety issues with medicines, report adverse events involving alcohol-based hand sanitizers 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

A search of the FDA Adverse Event Reporting System (FAERS) database and the medical literature[1,2] through December 31, 2018, identified 305 cases of dental adverse events reported with transmucosal buprenorphine use. Patients with opioid use disorder (OUD) may have a higher incidence of poor dental health;[4] however, many cases described severe dental issues in patients with no reported prior history of dental problems (n=26). In addition, although most of the cases were in patients using transmucosal buprenorphine products for OUD, there was a subset of patients (n=28) who experienced severe dental adverse events while receiving pain-only indicated products (e.g., Belbuca) or stated the indication was for pain.

The average age of the patients in this case series was 41.8 years (range 18-71), and the median time to diagnosis was 24.25 months (range 0.5-182). Many cases reported a combination of dental decay, tooth loss, and tooth fractures in numerous teeth. Many cases were reported by health care professionals and provided documentation of extensive dental adverse events including “all upper,” “all lower,” “all,” “majority,” “most,” “multiple teeth,” and “rampant decay.” The cases often noted the number of teeth involved, with 113 cases mentioning two or more teeth. Some cases specifically mentioned involvement of 11 to 12 or more teeth, as well as all teeth in 11 cases. Of the 305 cases, 151 reported the treatment for the adverse event, with tooth extraction/removal as the most common, which was reported in 71 cases. Other treatments included root canal, dental surgery, and other restorative procedures such as crowns and implants.

References

1. Suzuki J, Park EM. Buprenorphine/naloxone and dental caries: a case report. Am J Addict 2012;21:494-5.
2. Suzuki J, Mittal L, Woo SB. Sublingual buprenorphine and dental problems: a case series. Prim Care Companion CNS Disord 2013;15:PCC.13l01533.
3. Symphony Health Metys™. Data 2010-2020. Data extracted May 2021.
4. Yazdanian M, Armoon B, Noroozi A, Mohammadi R, Bayat AH, Ahounbar E, et al. Dental caries and periodontal disease among people who use drugs: a systematic review and meta-analysis. BMC Oral Health 2020;20:44.

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
Amphetamine Oral Suspension, Extended Release
Atropine Sulfate Injection
Azacitidine for Injection
Bacteriostatic 0.9% Sodium Chloride Injection
Bacteriostatic Water for Injection
Belatacept (Nulojix) Lyophilized Powder for Injection
Bumetanide Injection
Bupivacaine Hydrochloride and Epinephrine Injection
Bupivacaine Hydrochloride Injection
Calcium Disodium Versenate Injection
Calcium Gluconate Injection
Cefazolin Injection
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Ceftazidime and Avibactam (AVYCAZÂ®) for Injection, 2 grams/0.5 grams
Ceftolozane and Tazobactam (Zerbaxa) Injection
Chlordiazepoxide Hydrochloride Capsules
Chloroprocaine Hydrochloride Injection
Continuous Renal Replacement Therapy (CRRT) Solutions
Cortisone Acetate Tablets
Cyclopentolate Ophthalmic Solution
Cysteamine Hydrochloride Ophthalmic Solution
Cytarabine Injection
Dacarbazine Injection
Desmopressin Acetate Nasal Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Injection
Dextrose 50% Injection
Digoxin Injection
Diltiazem Hydrochloride Injection
Disopyramide Phosphate (Norpace) Capsules
Dobutamine Hydrochloride Injection

Dopamine Hydrochloride Injection
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution
Enalaprilat Injection
Epinephrine Injection, 0.1 mg/mL
Epinephrine Injection, Auto-Injector
Fentanyl Citrate (Sublimaze) Injection
Floxuridine for Injection
Fluvoxamine ER Capsules
Furosemide Injection
Gemifloxacin Mesylate (Factive) Tablets
Gentamicin Sulfate Injection
Guanfacine Hydrochloride Tablets
Heparin Sodium and Sodium Chloride 0.9% Injection
Hydrocortisone Tablets
Hydromorphone Hydrochloride Injection
Hydroxocobalamin Injection
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert
Imipenem and Cilastatin for Injection
Isoniazid Injection
Ketamine Injection
Ketoprofen Capsules
Ketorolac Tromethamine 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
Lipid Injection
Lithium Oral Solution
Lorazepam Injection
Loxapine Capsules
Mannitol Injection
Mepivacaine Hydrochloride Injection
Methyldopa Tablets
Methylprednisolone Acetate Injection
Metronidazole Injection
Midazolam Injection
Misoprostol Tablets
Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric)
Nefazodone Hydrochloride Tablets
Nizatidine Capsules
Ondansetron Hydrochloride Injection
Paclitaxel Injection (protein-bound particles)
Pantoprazole Sodium for Injection
Parathyroid Hormone (Natpara) Injection

Physostigmine Salicylate Injection
Potassium Acetate Injection
Potassium Chloride Concentrate Injection
Promethazine (Phenergan) Injection
Propofol Injectable Emulsion
Protamine Sulfate Injection
Rifampin Capsules
Rifampin Injection
Rifapentine Tablets
Ropivacaine Hydrochloride Injection
Sclerosol Intrapleural Aerosol
Sincalide (Kinevac) Lyophilized Powder for Injection
Sodium Acetate Injection
Sodium Bicarbonate Injection
Sodium Chloride 0.9% Injection Bags
Sodium Chloride 23.4% Injection
Sodium Chloride Injection USP, 0.9% Vials and Syringes
Sodium Phosphates Injection
Sterile Water for Injection
Sulfasalazine Tablets
Tacrolimus Capsules
Technetium Tc 99m Sulfur Colloid Injection
Technetium Tc99m Succimer Injection (DMSA)
Teprotumumab-trbw
Thiothixene Capsules
Tocilizumab Injection
Triamcinolone Acetonide Injectable Suspension
Triamcinolone Hexacetonide Injectable suspension
Trimethobenzamide Hydrochloride Capsules
Valproate Sodium Injection
Varenicline Tartrate (Chantix) Tablets
Vecuronium Bromide for Injection
Vitamin A Palmitate (Aquasol A) Injection