PERFORMRx℠

Drug Information Update

December 2023

www.performrx.com

TABLE OF CONTENTS

NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
teriparatide 600 mcg/2.4 ml subcutaneous auto-injector	Forteo	Apotex, Prasco Laboratories	• Treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy • Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy • Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy
methylene blue 50 mg/10 ml intravenous vial	ProvayBlue	Zydus Pharmaceuticals	• Treatment of pediatric and adult patients with acquired methemoglobinemia This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials.
cyanocobalamin 500 mcg/0.1 ml nasal spray	Nascobal	Lupin Pharmaceuticals, Padagis	• Vitamin B12 maintenance therapy in adult patients with pernicious anemia who are in remission following intramuscular vitamin B12 therapy and who have no nervous system involvement • Treatment of adult patients with dietary, drug-induced, or malabsorption-related vitamin B12 deficiency not due to pernicious anemia • Prevention of vitamin B12 deficiency in adult patients with vitamin B12 requirements in excess of normal
podofilox 0.5% topical gel	Condylox	Padagis	• Topical treatment of anogenital warts (external genital warts and perianal warts)
risperidone extended release 12.5 mg intramuscular vial	Risperdal Consta	Teva Pharmaceuticals	• Treatment of schizophrenia • To be used as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder
risperidone extended release 25 mg, 37.5 mg, 50 mg intramuscular vials	Rykindo	Teva Pharmaceuticals	• Treatment of schizophrenia • To be used as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description
Adalimumab-aacf subcutaneous auto-injector kit 40 mg/0.8ml	Adalimumab-aacf	Humira biosimilar. Unbranded version of Idacio. Only available in low concentration strength.
Augtyro oral capsule 40 mg	Repotrectinib	New entity. Next-generation tyrosine kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic ROS1-positive non–small cell lung cancer (NSCLC). Will compete with existing ROS1 inhibitors, including Rozlytrek (entrectinib) and Xalkori (crizotinib).
Zemaira intravenous solution reconstituted 4000 mg, 5000 mg	Alpha1-Proteinase Inhibitor (Human)	New stength. Previously only available as 1000 mg vial.
Xalkori oral capsule sprinkle 20 mg, 50 mg, 150 mg	Crizotinib	New strength and dosage form. New oral pellets for pediatric patients. Previously only available as oral capsules.
Cabtreo external gel 0.15-3.1-1.2 %	Clindamycin Phosphate/Adapalene/Benzoyl peroxide	New strength. First triple-combination topical treatment for acne.
Truqap oral tablet 160 mg, 200 mg	Capivasertib	New entity. Indicated to be used in combination with Faslodex (fulvestrant) for the treatment of adult patients with hormone receptor (HR)–positive, human epidermal growth factor receptor 2 (HER2)–negative locally advanced or metastatic breast cancer with one or more gene biomarker alterations (PIK3CA, AKT1, or PTEN) as detected by an FDA-approved test, and have progressed on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy. Will compete with other available targeted therapies in second-line HER2-negative breast cancer, most notably Piqray (alpelisib), which specifically targets activated PIK3CA mutations.

Drug Name	Generic Name	Description
Amjevita subcutaneous solution prefilled syringe 20 mg/0.2ml, 40 mg/0.4ml Amjevita subcutaneous solution auto-injector 40 mg/0.4ml, 80 mg/0.8ml	Adalimumab-atto	New strength. Humira biosimilar. New high concentration formulation of Amjevita.
Adzynma intravenous kit 500 unit, 1500 unit	ADAMTS13, recombinant-krhn	New entity. Enzyme replacement therapy (ERT) for the prophylactic and on-demand treatment of adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP). cTTP is an ultra-rare blood clotting disorder associated with potentially fatal acute and subacute crises, and serious long-term issues, including seizures, hemiplegia, and anemia. In the U.S., cTTP affects less than 1000 people. Adzynma replaces the deficient ADAMTS13 enzyme in patients with cTTP.
Loqtorzi intravenous solution 240 mg/6ml	Toripalimab-tpzi	New entity. Programmed death receptor-1 (PD-1)–blocking monoclonal antibody indicated to be used in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced nasopharyngeal carcinoma (NPC), and as monotherapy for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy. First and only FDA-approved treatment for NPC.
Yuflyma subcutaneous auto-injector kit 80 mg/0.8ml Yuflyma-CD/UC/HS starter subcutaneous auto-injector kit 80 mg/0.8ml	Adalimumab-aqvh	New strength. Humira biosimilar. Only available in high concentration strength.
Jylamvo oral solution 2 mg/ml	Methotrexate	New strength. Methotrexate oral solution. Approved under 505(b)(2) approval pathway.

Drug Name	Generic Name	Description
Ogsiveo oral tablet 50 mg	Nirogacestat	New entity. First FDA-approved treatment for adult patients with progressing desmoid tumors (DTs) who require systemic treatment. DTs are a rare type of noncancerous soft-tissue tumor. Approximately 900 to 1500 new cases of DT are diagnosed in the U.S. per year.
Bijuva oral capsule 0.5-100 mg	Estradiol/Progesterone	New strength.
Coxanto oral capsule 300 mg	Oxaprozin	New strength and dosage form. 505(b)(2) approval. Shares same indications as generic Daypro, which is available as 600 mg tablets.
Fabhalta oral capsule 200 mg	Iptacopan	New entity. Complement factor B inhibitor indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). First FDA-approved oral monotherapy for the treatment of PNH.
Rezipres intravenous solution 47 mg/10ml	Ephedrine Hydrochloride	New dosage form & strength.
Casgevy intravenous suspension	Exagamglogene autotemcel	New entity. Gene therapy that uses CRISPR/Cas9-editing technology for genetic modification. Indicated for the treatment of sickle cell disease (SCD) in patients 12 years of age and older with recurrent vaso-occlusive crises (VOCs).
Lyfgenia intravenous suspension	Lovotibeglogene autotemcel	New entity. Gene therapy that uses a lentiviral vector for genetic modification. Indicated for the treatment of patients 12 years of age and older with sickle cell disease (SCD) and a history of vaso-occlusive crises (VOC) events.
Vevye ophthalmic solution 0.1 %	Cyclosporine	New strength. 505(b)(2) approval. Waterless solution for treating dry eye disease and contains no preservatives.

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†
Jaypirca	pirtobrutinib 50 mg, 100 mg oral tablets	Eli Lilly and Company	• Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. • **Treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor** **This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.**
Wilate	von Willebrand Factor/Coagulation Factor VIII complex (Human) 500-500 unit, 1000-1000 unit intravenous kit	Octapharma USA	• Indicated in children and adults with von Willebrand disease for: o On-demand treatment and control of bleeding episodes o Perioperative management of bleeding o **Routine prophylaxis to reduce the frequency of bleeding episodes in patients 6 years of age and older** • Indicated in adolescents and adults with hemophilia A for: o Routine prophylaxis to reduce the frequency of bleeding episodes o On-demand treatment and control of bleeding episodes
Cresemba	isavuconazonium sulfate 372 mg intravenous vial	Astellas Pharma US	• Treatment of invasive aspergillosis in adults **and pediatric patients 1 year of age and older**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• Treatment of invasive mucormycosis in adults **and pediatric patients 1 year of age and older**
Cresemba	isavuconazonium sulfate 74.5 mg, 186 mg oral capsules	Astellas Pharma US	• Treatment of invasive aspergillosis in adults **and pediatric patients 6 years of age and older who weigh 16 kg and greater** • Treatment of invasive mucormycosis in adults **and pediatric patients 6 years of age and older who weigh 16 kg and greater**
Bivigam	immune globulin (human) 5 g/50 ml, 10 g/100 ml intravenous vials	ADMA Biologics	• Treatment of adults and pediatric patients **2** ~~12~~ years of age and older with primary humoral immunodeficiency (PI)
Adbry	tralokinumab-ldrm 150 mg/ml subcutaneous syringe	LEO Pharma	• Treatment of moderate-to-severe atopic dermatitis in ~~adult~~ patients **aged 12 years and older** whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
Welireg	belzutifan 40 mg oral tablets	Merck Sharp & Dohme	• Treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery • **Treatment of adult patients with advanced RCC following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)**
Padcev	enfortumab vedotin-ejfv 20 mg, 30 mg intravenous vials	Astellas Pharma US	• To be used as a single agent for the treatment of adult patients with locally advanced or metastatic urothelial cancer who: o Have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy, or

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			○ Are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy • In combination with pembrolizumab for the treatment of adult patients with locally advanced or metastatic urothelial cancer ~~who are not eligible for cisplatin-containing chemotherapy~~[1] ~~[1]This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.~~

FDA DRUG SAFETY COMMUNICATIONS

[11/28/2023] FDA warns of rare but serious drug reaction to the antiseizure medicines levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan)

The U.S. Food and Drug Administration (FDA) is warning that the antiseizure medicines levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan), can cause a rare but serious reaction that can be life-threatening if not diagnosed and treated quickly. This reaction is called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). It may start as a rash but can quickly progress, resulting in injury to internal organs, the need for hospitalization, and even death. As a result, we are requiring warnings about this risk to be added to the prescribing information and patient Medication Guides for these medicines.

This hypersensitivity reaction to these medicines is serious but rare. DRESS can include fever, rash, swollen lymph nodes, or injury to organs including the liver, kidneys, lungs, heart, or pancreas.

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
8.4% Sodium Bicarbonate Injection, USP, 50 mEq/50 mL (1mEq/mL), a) 20x50 mL Single Dose Vials (Vial NDC 51754-5001-1; Carton NDC 51754-5001-5) and b) 25x50 mL Single Dose Vials (Vial NDC 51754-5001-1; Carton NDC 51754-5001-4), For Intravenous Use Only, RX Only, Manufactured and Distributed by: Exela Pharma Sciences, LLC, Lenoir, NC 28645; ALSO LABELED 8.4% Sodium Bicarbonate Injection, USP, 50 mEq/50 mL (1mEq/mL), c) 20x50 mL Single Dose Vials, (Vial NDC 72572-740-01; Carton NDC 72572-740-20), Rx Only, Mfd for: Civica, Inc., Lehi, Utah, 84043, Mfd by: Exela Pharma Sciences, LLC, Lenoir, NC 28645.	Class I	Drugs	a) P0001429, EXP 11/30/2023 b) P0001900, P0001902, EXP 08/31/2024; P0001903, P0001909, P0001945, EXP 09/30/2024; P0002002, EXP 11/30/2024; P0002052, EXP 12/31/2024 c) P0001912, EXP 08/31/2024	Presence of Particulate Matter: Silicone	Exela Pharma Sciences LLC
Midazolam in 0.8% Sodium Chloride Injection 100 mg/100 mL (1mg/mL), 100 mL Single-Dose Vial, 25 count carton, Ready to Use For Intravenous Infusion Only Preservative Free, Rx Only, Manufactured and Distributed by Exela Pharma Sciences, LLC, Lenoir, NC 28645, (Vial NDC 51754-2131-1; Carton NDC 51754-2131-4).	Class I	Drugs	Lot # 10001088 exp 07/31/2024	Presence of Particulate Matter: Silicone	Exela Pharma Sciences LLC
ELCYS (cysteine hydrochloride injection), USP, 500 mg/10mL (50 mg/mL), 10x10 mL Single Dose Sterile Vials, For Intravenous Infusion Only, Rx Only, Manufactured and Distributed by Exela Pharma Sciences, LLC, Lenoir, NC 28645, (Vial: NDC 51754-1007-1; Carton: 51754-1007-3).	Class I	Drugs	Lot # 10000798, Expiration Date 03/31/2025	Presence of Particulate Matter: Silicone	Exela Pharma Sciences LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Polyvinyl Alcohol 1.4% Lubricating Eye Drops, packaged in 0.5 FL OZ (15mL) bottles, Dist. by: RUGBY LABORATORIES, Livonia, MI 48152, NDC 0536-1325-94.	Class I	Drugs	All lots	Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
Lubricating Tears Eye Drops (Dextran/Hypromellose), 0.1%/0.3%, packaged in 0.5 FL OZ (15mL) bottles, Distributed by: RUGBY LABORATORIES, Livonia, MI 48152, NDC 0536-1282-94	Class I	Drugs	All lots	Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
LEADER brand Eye Irritation Relief (Polyvinyl alcohol 0.5%, Povidone 0.6%, Tetrahydrozoline Hydrochloride 0.05%), 0.5 FL OZ (15 mL) dropper bottles, Sterile, Distributed By Cardinal Health, Dublin, Ohio 43017, Made in India NDC: 70000-0087-1	Class I	Drugs	ALL LOTS	Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.	Cardinal Health Inc.
LEADER brand Dry Eye Relief (Carboxymethylcellulose Sodium, 1%); 0.5 FL OZ (15 mL) dropper bottle, Sterile, Distributed By Cardinal Health, Dublin, Ohio. 43017, Made in India NDC: 70000-0089-1	Class I	Drugs	ALL LOTS	Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.	Cardinal Health Inc.
LEADER brand Lubricant Eye Drops (Carboxymethylcellulose Sodium, 0.5%); 0.5 FL	Class I	Drugs	ALL LOTS	Non-Sterility: FDA found insanitary conditions and	Cardinal Health Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
OZ (15 mL) dropper bottles, Sterile, Distributed By Cardinal Health, Dublin, Ohio 43017. Made in India NDC: 70000-0090-1				positive bacterial test results from environmental sampling at the manufacturing facility.	
LEADER brand Lubricant Eye Drops (Carboxymethylcellulose Sodium, 0.5%); 2 bottles, 0.5 FL OZ (15 mL) dropper bottles, Sterile, Distributed By Cardinal Health, Dublin, Ohio 43017, Made in India NDC:70000-0090-2 (Carton); 70000-0090-1 (Bottle)	Class I	Drugs	ALL LOTS	Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.	Cardinal Health Inc.
LEADER brand Dry Eye Relief (Polyethylene Glycol 400, 0.4% Propylene Glycol, 0.3%); 0.33 FL OZ (10 mL) dropper bottle, Sterile, Distributed By Cardinal Health, Dublin, Ohio 43017, Made in India NDC: 70000-0088-1	Class I	Drugs	ALL LOTS	Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.	Cardinal Health Inc.
LEADER brand Lubricant Eye Drops (Propylene Glycol, 0.6%); 0.33 FL OZ (10 mL) dropper bottles, Sterile, Distributed By Cardinal Health, Dublin, Ohio 43017. Made in India NDC: 70000-0587-1	Class I	Drugs	ALL LOTS	Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.	Cardinal Health Inc.
VITRAKVI (larotractenib) oral solution, 20mg/mL, 100 mL bottle, Rx only, Manufactured for Bayer HealthCare	Class I	Drugs	Lot# 2114228, EXP. 02/29/2024	Microbial Contamination of Non-Sterile Products: microbial contamination identified as Penicillium	Bayer Healthcare Pharmaceuticals Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pharmaceuticals Inc., Whippany, NJ 07981. NDC 50419-392-01				brevicompactum observed during routine ongoing stability testing	
Dr. Ergin's SugarMD, ADVANCED GLUCOSE SUPPORT Capsules, Dietary Supplement, helps support healthy glucose levels a) 60 count (UPC 1 95893 92767 8), b) 120 count (UPC 1 95893 54697 8), c) 180 count (UPC 1 95893 99957 6) bottles, Manufactured for SUGARMDS LLC, Port St. Lucie, FL 34952.	Class I	Drugs	LOT# 22165-003, EXP 09/30/2024	MARKETED WITHOUT AN APPROVED NDA/ANDA: Product found to be tainted with metformin and glyburide	SUGARMDS LLC
SANDIMMUNE Oral Solution (cyclosporine oral solution, USP) 100 mg/mL, 50 mL bottle, Rx Only, Manufactured by: DELPHARM Huningue S.A.S., Huningue, France, Distributed by: Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936. NDC 0078-0110-22	Class I	Drugs	Lot #: FX001500, FX001582, Exp. 09/30/2024	Crystallization: bottles of Sandimmune Oral Solution were determined to contain crystals	Novartis Pharmaceuticals Corporation
Integrity Biochem HSC 70-LM, Alcohol Antiseptic 70%, Hand Sanitizer, Lemon Scented Topical Gel, 208.19 L (55 gallons) drum, Integrity Biochem, 1100 North Cresson Hwy, Cresson, TX 76035. Made in the USA NDC: 77512-044-03	Class II	Drugs	Lot #: 2133607, Manufacturing Date 11/23/2021 No Exp date on label.	CGMP Deviation: Third party test results showing a presence of acetal and acetaldehyde at levels above USP specified amounts.	Integrity Bio-Chemicals LLC
Integrity Biochem HSC70-LV, Alcohol Antiseptic 70%, Hand Sanitizer, Lavender Scented Topical Gel 208.19L (55 gallons) drum, Integrity Biochem, 1100 North Cresson Hwy, Cresson, TX 76035. Made in the USA, NDC: 77512-047-03	Class II	Drugs	Lot #: 2133608, No exp Date. Manufacturing Date: 11/23/21	CGMP Deviation: Third party test results showing a presence of acetal and acetaldehyde at levels above USP specified amounts.	Integrity Bio-Chemicals LLC
Integrity Biochem HSC 70-VA, Alcohol Antiseptic 70%, Hand Sanitizer, Vanilla Scented Topical Gel	Class II	Drugs	Lot #: 2134106, No Exp date,	CGMP Deviation: Third party test results	Integrity Bio-Chemicals LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
208.19L (55 gallons)- drum. Integrity Biochem, 1100 North Cresson Hwy, Cresson, TX 76035. Made in the USA, NDC: 77512-052-03			Manufacturing Date: 11/23/21	showing a presence of acetal and acetaldehyde at levels above USP specified amounts.	
Tiglutik (riluzole) Oral Suspension 50 mg/10 mL (5 mg/mL), 600 mL (two bottles/300 mL each), RX only, Manufactured for ITF Pharma, Inc., Berwyn, PA 19312 USA NDC:70726-0303-1 (carton) and 70726-0303-2 (bottle)	Class II	Drugs	LOT# 2231901, Exp. 11/30/2025; 2307901, Exp. 03/31/2026	Failed Viscosity Specifications: Out-of-specification test results for viscosity	ITF PHARMA INC
Paroxetine Hydrochloride Tablets USP, RX only, 10 mg a) 30-count bottle, NDC#: 60505-0097-1; b) 100-count bottle, NDC#: 60505-0097-2; c) 1000-count bottle, NDC#: 60505-0097-4, Manufactured by: Apotex Inc., Toronto, Ontario, Canada M9L 1T9, Manufactured for: Apotex Corp., Weston, Florida 33326.	Class II	Drugs	Lot numbers: a)100 count bottle: RV2376, RV2377; b) 1000 count bottle: RV2379, RV2380; c) 30 count bottle: RV2375; Exp. 08/2024	Failed Impurities/Degradation Specifications-Out of specification (OOS) results for the excipient Amadori Glucose adduct of Paroxetine	Apotex Corp.
Paroxetine Hydrochloride Tablets USP, RX only, 20 mg, a) 100-count bottle, NDC#:60505-0083-2; b) 1000-count bottle, NDC#: 60505-0083-4 Manufactured by: Apotex Inc., Toronto, Ontario, Canada M9L 1T9, Manufactured for: Apotex Corp., Weston, Florida 33326.	Class II	Drugs	Lot numbers: a)100 count bottle: RV2384, RV2385; b) 1000 count bottle: RV2396, RV2397; Exp. 08/2024	Failed Impurities/Degradation Specifications-Out of specification (OOS) results for the excipient Amadori Glucose adduct of Paroxetine	Apotex Corp.
Paroxetine Hydrochloride Tablets USP, RX only, 30 mg, a)30-count bottle, NDC#: 60505-0084-1, b)100-count bottle, NDC#:60505-0084-2, c)1000-count bottle, NDC#: 60505-0084-4, Manufactured by: Apotex Inc., Toronto, Ontario, Canada M9L 1T9, Manufactured for: Apotex Corp., Weston, Florida 33326.	Class II	Drugs	Lot numbers: a)100 count bottle: RV8686; b) 1000 count bottle: RX0119; c) 30 count bottle: RV2254; Exp. 08/2024	Failed Impurities/Degradation Specifications-Out of specification (OOS) results for the excipient Amadori Glucose adduct of Paroxetine	Apotex Corp.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Paroxetine Hydrochloride Tablets USP, RX only, 40 mg, 1000-count bottle, NDC#:60505-0101-4 Manufactured by: Apotex Inc., Toronto, Ontario, Canada M9L 1T9, Manufactured for: Apotex Corp., Weston, Florida 33326.	Class II	Drugs	Lot numbers: RV0131, RV2387, RV2389, RW3296, RV2388; Exp. 08/2024	Failed Impurities/Degradation Specifications-Out of specification (OOS) results for the excipient Amadori Glucose adduct of Paroxetine	Apotex Corp.
Indomethacin 25mg Capsules, USP, 100-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd. Colvale-Bardez, Goa 403513, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, NDC 68462-406-01	Class II	Drugs	Lot# 19231903; Exp 4/2025 Lot# 19231858; Exp 4/2025 Lot# 19231881; Exp 4/2025 Lot# 19233484; Exp 8/2025 Lot# 19233490; Exp 8/2025	Labeling: Label Mix-Up-Indomethacin bottles may be labeled as Naproxen	Glenmark Pharmaceuticals Inc., USA
Naproxen Tablets, USP 250mg, 100-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd. Colvale-Bardez, Goa 403513, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, NDC 68462-188-01.	Class II	Drugs	Lot# 19231903; Exp 4/2025 Lot# 19231858; Exp 4/2025 Lot# 19231881; Exp 4/2025 Lot# 19233484: Exp 8/2025 Lot# 19233490; Exp 8/2025	Labeling: Label Mix-Up-Indomethacin bottles may be labeled as Naproxen	Glenmark Pharmaceuticals Inc., USA
PAROXETINE tablets, USP, 10 mg, Packaged as a) 30-count bottle, NDC 60429-734-30; b) 90-count bottle NDC 60429-734-90; c)1000-count	Class II	Drugs	Lot # a) Lot GS041383, GS042141, Exp.	Failed Impurities/Degradation Specifications-	Golden State Medical Supply Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
bottle, NDC 60429-734-10; Rx Only, Manufactured by Apotex, Inc., Toronto, Ontario, Canada, M9L 1T9, Packaged by GSMS, Incorporated, Camarillo, CA 93012.			08/31/2024; b) Lot GS040841, Lot GS041384, Lot GS042039, Exp. 08/31/2024; c) Lot GS040910, Lot GS041621, Lot GS042237, Exp. 08/31/2024;	Manufacturer Apotex Inc. recalling lots due to Out of specification results for the excipient Amadori Glucose adduct of Paroxetine	
PAROXETINE tablets, USP, 20 mg, Packaged as a) 90-count bottle NDC 60429-735-90; b)1000-count bottle, NDC 60429-735-10; Rx Only, Manufactured by Apotex, Inc., Toronto, Ontario, Canada, M9L 1T9, Packaged by GSMS, Incorporated, Camarillo, CA 93012.	Class II	Drugs	Lot # a) GS036696, GS037068, GS037934, GS038564, Exp. 08/31/2024 b) GS036381, GS036712, GS037116, GS037692, GS038388, Exp. 08/31/2024;	Failed Impurities/Degradation Specifications-Manufacturer Apotex Inc. recalling lots due to Out of specification results for the excipient Amadori Glucose adduct of Paroxetine	Golden State Medical Supply Inc.
PAROXETINE tablets, USP, 40 mg, Packaged as a) 30-count bottle, NDC 60429-737-30; b) 90-count bottle NDC 60429-737-90; c)1000-count bottle, NDC 60429-737-10; Rx Only, Manufactured by Apotex, Inc., Toronto, Ontario, Canada, M9L 1T9, Packaged by GSMS, Incorporated, Camarillo, CA 93012.	Class II	Drugs	Lot # a) GS036488, GS037091, GS037701, Exp. 08/31/2024; b) GS037090, GS037702, Exp. 08/31/2024; c) GS036677, GS037117,	Failed Impurities/Degradation Specifications-Manufacturer Apotex Inc. recalling lots due to Out of specification results for the excipient Amadori Glucose adduct of Paroxetine	Golden State Medical Supply Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			GS037699, Exp. 08/31/2024		
Trospium Chloride Extended-Release Capsules, 60 mg, 30 Capsules per bottle, Rx Only, Manufactured By: Sidmak Laboratories (India) Pvt. Ltd. Plot No. 20, Pharmacity, Selaqui Industrial Area, Dehradun-248 197 Uttarakhand, India Distributed By: Padagis, Allegan, MI 49010. NDC: 0574-0118-30	Class II	Drugs	Lot: 231104, 231105, 231106, exp 7/31/2025	Failed Tablets/Capsules specifications; missing/broken/extra tablets within the capsules	Padagis US LLC
Ondansetron Injection, USP, 4 mg/2 mL (2 mg/mL), 2 mL per vial, Rx only, Manufactured for: Baxter Healthcare Corporation, Deerfield, IL 60015 USA. Manufactured by: Baxter Pharmaceuticals India Private Ltd, Ahmedabad 382213, India. NDC 36000-012-25	Class II	Drugs	Lot # A0E0959A, A0E0961A, A0E1015A, A0E1020A, Exp. Date 30-Nov-23; A0F0016A, Exp. Date 31-Dec-23; A0F0260A, A0F0261A, A0F0262A, Exp. Date 29-Feb-24; A0F0414A, A0F0415A, A0F0416A, A0F0417A, A0F0418A, Exp. Date 30-Apr-24; A0F0503A, Exp. Date 31-May-24, A0F0533A, A0F0534A,	Failed pH Specifications	Baxter Healthcare Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			A0F0535A, A0F0536A, A0F0537A, A0F0540A, A0F0541A, Exp. Date 30-Jun-24; A0F0573A, A0F0574A, A0F0575A, A0F0592A, Exp. Date 31-Jul-24; A0F0596A, A0F0599A, Exp. Date 31-Aug-24 ; A0F0676A, 31-Oct-24.		
KinderMed KIDS' PAIN & FEVER Acetaminophen, 160 mg per 5 mL bottles, Oral Suspension, Organic Cherry Flavor, 4 FL OZ (118 mL), Distributed By: KinderFarms, Redondo Beach, CA 90277, NDC 82673-097-04, UPC 850001805728.	Class II	Drugs	Lot: CJ70900, CJ76796, Exp: 8/2024; CJ77051, Exp: 09/2024; WK02998, WK02997, WK04390, WK02999, Exp: 10/2024; WK03716, Exp:12/2024; WK05150, WK05151, WK07174, Exp:02/2025; WK05539, WK06534, Exp: 03/2025; WK10259, WK23040, Exp: 04/2025;	Failed Impurities/Degradation Specifications	KINDER FARMS LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			WK27455, Exp: 08/2025.		
KinderMed INFANTS' PAIN & FEVER Acetaminophen, 160 mg per 5 mL bottles, Oral Suspension, Organic Cherry Flavor, 2 FL OZ (59 mL), Distributed By: KinderFarms, Redondo Beach, CA 90277, NDC 82673-096-02, UPC 850001805698.	Class II	Drugs	Lot #: CJ70902, Exp: 07/2024; CJ76275, WJ81412, Exp: 08/2024; WK02194, WK02196, WK04141, WK02873, WK05542, Exp: 10/2024; WK02874, WK04794, Exp: 01/2025; WK04793, WK06535, Exp: 03/2025.	Failed Impurities/Degradation Specifications	KINDER FARMS LLC
ceFAZolin sodium in Sterile Water for injection, Injectable Solution, 1g/10mL (0.1 g per mL), Syringe, Rx only, Wells Pharma, NDC 73702-131-10	Class II	Drugs	Lot # 11092313110#01, Exp 01/12/24	Lack of assurance of sterility.	Wells Pharma of Houston LLC
ROPivacaine HCl 0.2% PF in Sodium Chloride 1,000 mg/500 mL (2 mg per mL) Injection, 500 mL bags, Rx only, STAQ Pharma Inc. 14135 E 42nd Ave, Unit 50, Denver, Colorado 80239, NDC 73177-0109-26,	Class II	Drugs	Lot#: 23109472A, Exp. date 03/10/2024; 23109473A, Exp. date 03/11/2024; 23109474A, Exp. date 03/13/2024; 23109491A, Exp. date 03/16/2024; 23109492A, Exp. date 03/19/2024; 23109501A, Exp. date 03/25/2024;	STAQ Pharma Inc. received consumer complaints related to leaking bags and other potential bag concerns. Upon investigation, they determine the source of the issue was with the bag manufacturer who released bags Lot # 134142-001A which had failed internal QC tests for leaks.	STAQ Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			23109520A, Exp. date 04/10/2024; 23109521A, Exp. date 04/13/2024; 23109522A, Exp. date 04/03/2024.		
Penicillamine Tablets USP 250 mg, 100-count bottle, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202 Manufactured by: Lupin Limited, Nagpur-441 108, India, NDC# 70748-153-01	Class II	Drugs	Lot # M200498, Exp. June 2024	Failed Dissolution Specifications	Lupin Pharmaceuticals Inc.
Liothyronine Sodium Tablets, USP 5 mcg, 100-count bottle, Rx Only, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512 Manufactured by: Sun Pharmaceutical Industries Ltd. Survey No. 259/15, Dadra-396 191, (U.T. of D & NH), India. NDC 62756-589-88	Class II	Drugs	Lot DND0059A Expires 12/2023 Lot DND0060A Expires 12/2023 Lot DND0061A Expires 12/2023 Lot DND0062A Expires 01/2024 Lot DND0063A Expires 01/2024 Lot DND0064A Expires 01/2024 Lot DND0065A Expires 01/2024 Lot DND0180A Expires 01/2024 Lot DND0181A Expires 01/2024 Lot DND0182A Expires	Failed Impurities/Degradation Specifications	SUN PHARMACEUTICAL INDUSTRIES INC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			01/2024 Lot DND0183A Expires 01/2024 Lot DND0184A Expires 01/2024 Lot DND0597A Expires 02/2024		
Esomeprazole Magnesium Delayed-Release Capsules, USP 20mg, Packaged as (a) 30-count bottle, NDC 68462-390-30; (b) 1000-count Bottle, NDC 68462-390-10: RX Only, Manufactured for: Glenmark, Pharmaceuticals Inc., USA, Mahwah, NJ 07430, Product of India,	Class III	Drugs	Lot # 17220002, Exp Date 11/30/2023	Failed Impurities/Degradation Specifications:Out of Specification result reported for the test of organic impurities for the drug product,at the 18 month time point in long term stability study (25¿C/60% RH).	Glenmark Pharmaceuticals Inc., USA
Buspirone Hydrochloride Tabs USP 10 mg, packaged in a) 15-count blister card (NDC 0615-7718-05) b) 30-count blister card (NDC 0615-7718-39), Rx only, Mfd By Pliva HRVATSKA for Teva USA, PKG by Vangard Glasgow, KY 42141.	Class III	Drugs	Lot#: a) 7718-3008, Exp 08/31/2024; b) 7718-3008, Exp 08/31/2024	Presence of Foreign Tablets: Potential of stray tablet(s) of Amlodipine Besylate 10 mg Tablet within the recalled lots	NCS Healthcare of Kentucky Inc
Lisinopril Tablets USP 20 mg, packaged in a) 15-count blister card (NDC 0615-7718-05), b) 30-count blister card (NDC 0615-8255-39), Rx only, Mfd By Lupin, PKG by Vangard Glasgow, KY 42141.	Class III	Drugs	Lot#: a) 8255-3012, Exp 08/31/2024; b) 8255-3012, Exp 08/31/2024	Presence of Foreign Tablets: Potential of stray tablet(s) of Amlodipine Besylate 10 mg Tablet within the recalled lots	NCS Healthcare of Kentucky Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Aminocaproic Acid Oral Solution, 0.25 grams/mL, Rx only, packaged in 8 Fl. Oz. (236.5 mL) HDPE bottles, Manufactured for: VistaPharm, Inc., Largo, FL 33771, UAS, NDC 66689-330-08	Class III	Drugs	Lot #: 22ZKY1, Exp. 11/27/23; 22ZMC1, Exp. 12/21/23; 22ZTP1, Exp. 03/29/24; 23ZAD1, Exp. 07/07/24.	Failed Excipient Specifications: high content of ethylene glycol (EG)	VistaPharm LLC
Testosterone Gel, 1.62% CIII (Alcohol 80% v/v), packaged in 30 unit-dose packets per carton, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0591-2926-30	Class III	Drugs	Lot #: 100029472, Exp. 2/29/2024	OOS for viscosity	Teva Pharmaceuticals USA, Inc
Tropicamide 1% (10mg/mL), Cyclopentolate 1% (10mg/mL), Phenylephrine 2.5% (25mg/mL), Ketorolac 0.5% (5mg/mL), 5 mL bottles, For Topical Ophthalmic Use Only, Not for IV Use, This is a Compounded Drug, Hospital & Office Use Only, Fagron Sterile Services, 8710 E 34th St N Wichita, KS 67226. NDC 71266-8240-01	Class III	Drugs	Lot #: C274-000033372, Exp. Date 01-17-2024; C274-000033764, Exp. Date 02-06-2024	Labeling: Label Mix-Up: The label of a dropper bottle mistakenly states the container is a 0.5mL single-use syringe instead of a 5 mL dropper	Fagron Compounding Services
LET Gel (Lidocaine HCL/Epinephrine Bitartrate/Tetracaine HCL 4%/0.18%/0.5% Topical Gel), Single-use Topical Syringe, 3mL syringe, 10/pack, Rx only, Carie Boyd Pharmaceuticals, 8400 Esters Blvd, Ste# 190, Irving, TX 75063, NDC73271-1003-1	Class III	Drugs	Lot#: 09202023@7, Exp 03/18/2024	Product Mix-up: Incorrect Product Formulation	Right Value Drug Stores, LLC dba Carie Boyd's Prescription Shop
buPROPion Hydrochloride Extended-Release Tablets, USP (SR) 200 mg, 60 Tablets bottle, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited, Halol-Baroda Highway, Halol-389 350, Gujarat, India NDC 47335-738-86	Class III	Drugs	Lot HAD0630A, exp 1/2024	Failed Dissolution Specifications	SUN PHARMACEUTICAL INDUSTRIES INC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Votrient (pazopanib) 200 mg tablets, 120-count bottle, Rx Only, Manufactured by: Siegried Barbera, S.L., Barbera del Valles, Spain, Distributed by: Novartis Pharmaceuticals Corp., East Hanover, N.J. 07936, NDC 0078-1077-66	Class III	Drugs	Lot# ME2713; Exp. 02/2025 Lot # MF8286, ML1860; Exp. 04/2025	Failed Dissolution Specifications	Siegfried Barbera, SL

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

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

Albuterol Sulfate Solution
Alprostadil Suppository
Amifostine Injection
Amino Acid Injection
Amoxapine Tablet
Amoxicillin Powder, For Suspension
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet
Atropa Belladonna, Opium Suppository
Atropine Sulfate Injection
Azacitidine Injection
Bazedoxifene Acetate, Estrogens, Conjugated Tablet, Film Coated
Bumetanide Injection
Bupivacaine Hydrochloride Injection
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection, Solution
Capecitabine Tablet
Carboplatin Injection
Cefixime Capsule
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Chloramphenicol Sodium Succinate Injection
Chloroprocaine Hydrochloride Injection
Cisplatin Injection
Clindaymycin Phosphate Injection
Clonazepam Tablet
Collagenase Clostridium Histolyticum Ointment
Conivaptan Hydrochloride Injection
Cromolyn Sodium Concentrate
Cyclopentolate Hydrochloride Ophthalmic Solution
Cyclopentolate Hydrochloride, Phenylephrine Hydrochloride Ophthalmic Solution
Cytarabine Injection, Solution
Dacarbazine Injection
Desmopressin Acetate Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Hydrochloride Injection
Dextrose Monohydrate Injection
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection
Diazepam Gel

Difluprednate Emulsion
Digoxin Injection
Diltiazem Hydrochloride Injection
Disopyramide Phosphate Capsule
Dobutamine Hydrochloride Injection
Dopamine Hydrochloride Injection
Dulaglutide Injection
Echothiophate Iodide Ophthalmic Solution
Enalaprilat Injection
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection
Epinephrine Injection
Erythromycin Ointment
Etomidate Injection
Fentanyl Citrate Injection
Fluconazole Injection
Fludarabine Phosphate Injection
Flurazepam Hydrochloride Capsule
Furosemide Injection
Gentamicin Sulfate Injection
Heparin Sodium Injection
Hydrocortisone Sodium Succinate Injection
Hydromorphone Hydrochloride Injection
Hydroxypropyl Cellulose (1600000 Wamw) Insert
I.V. Fat Emulsion
Indigotindisulfonate Sodium Injection
Isoniazid Tablet
Ketamine Hydrochloride Injection
Ketorolac Tromethamine Injection
Ketorolac Tromethamine Tablet, Film Coated
Leucovorin Calcium Injection
Lidocaine Hydrochloride Injection
Lidocaine Hydrochloride Solution
Liraglutide Injection
Lisdexamfetamine Dimesylate Capsule
Lisdexamfetamine Dimesylate Tablet, Chewable
Lorazepam Injection
Mannitol Injection
Mepivacaine Hydrochloride Injection
Methamphetamine Hydrochloride Tablet
Methotrexate Sodium Injection
Methotrexate Sodium Tablet
Methyldopa Tablet, Film Coated
Methylphenidate Hydrochloride Tablet, Extended Release
Methylprednisolone Acetate Injection
Metronidazole Injection
Midazolam Hydrochloride Injection

Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric) Injection
Neomycin Sulfate Tablet
Nitroglycerin Injection
Nizatidine Capsule
Oxybutynin Chloride Syrup
Parathyroid Hormone Injection
Penicillin G Benzathine Injection
Potassium Acetate Injection
Potassium Chloride Injection
Promethazine Hydrochloride Injection
Propranolol Hydrochloride Injection
Quinapril Hydrochloride Tablet
Quinapril/Hydrochlorothiazide Tablet
Remifentanil Hydrochloride Injection
Rifampin Capsule
Rifampin Injection
Rifapentine Tablet, Film Coated
Rocuronium Bromide Injection
Ropivacaine Hydrochloride Injection
Semaglutide Injection
Sodium Acetate Injection
Sodium Bicarbonate Injection
Sodium Chloride 0.9% Injection
Sodium Chloride 0.9% Irrigation
Sodium Chloride 14.6% Injection
Sodium Chloride 23.4% Injection
Sodium Phosphate, Dibasic, Anhydrous, Sodium Phosphate, Monobasic, Monohydrate Injection, Solution
Somatropin Injection
Sterile Water Injection
Sterile Water Irrigant
Streptozocin Powder, For Solution
Sucralfate Tablet
Sufentanil Citrate Injection
Sulfasalazine Tablet
Tirzepatide Injection
Triamcinolone Acetonide Injection
Triamcinolone Hexacetonide Injection
Trimethobenzamide Hydrochloride Capsule
Valproate Sodium Injection
Vecuronium Bromide Injection
Vinblastine Sulfate Injection