PERFORMRx℠

Drug Information Update

August 2024

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NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description
Taltz Subcutaneous Solution Prefilled Syringe 20 MG/0.25ML, 40 MG/0.5ML	Ixekizumab	New dosage form and strength. Product was approved February 2024 and just now launching. Interleukin-17A antagonist indicated for treatment of patients 6 and older with moderate to severe plaque psoriasis, adults with active psoriatic arthritis, adults with active ankylosing spondylitis, and adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
Otezla Oral Tablet 20 MG, Otezla Oral Tablet Therapy Pack 4 x 10 & 51 x20 MG	Apremilast	New strength. PDE4 inhibitor indicated for adults with active psoriatic arthritis, plaque psoriasis, oral ulcers associated with Behcet's disease, and pediatric patients 6 years and older (weighing at least 20kg) with moderate to severe plaque psoriasis. Also available in a 10mg & 20mg &30mg therapy pack.
Livmarli Oral Solution 19 MG/ML	Maralixibat	New strength. Livmarli was previously only approved in a 9.5 mg/mL strength. IBAT inhibitor indicated for treatment of cholestatic pruritus in patients 3 months of age and older with Alagille syndrome (ALGS), and treatment of cholestatic pruritus in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC).
Zepbound Subcutaneous Solution 2.5 MG/0.5ML , 5 MG/0.5ML	Tirzepatide	New dosage form. Already available in auto-injector pens. Indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in obese or overweight adults with specific comorbidities.
Retevmo Oral Tablet 40 MG, 80 MG, 120 MG, 160 MG,	Selpercatinib	New dosage form and strength. Kinase inhibitor indicated for treatment for people with RET-positive advanced non-small cell lung cancer (NSCLC), thyroid cancers, and certain other cancers. Previously only 40mg and 80mg capsules.
Vigafyde Oral Solution 100 MG/ML	Vigabatrin	First and only ready-to-use vigabatrin oral solution. Indicated as monotherapy for the treatment of infantile spasms in pediatric patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.
MydCombi Ophthalmic Solution Cartridge 1-2.5 %	Tropicamide-Phenylephrine	First and only approved combination ophthalmic spray indicated for inducing mydriasis. Used for diagnostic procedures and in conditions where short term pupil dilation is desired. Approved in February 2023.
Tecelra Intravenous Suspension 10000000000 CELLS	Afamitresgene Autoleucel	New entity. Gene therapy for solid tumors. Melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy indicated for the

Drug Name	Generic Name	Description
		treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices. Approved under accelerated approval.
Nemluvio Subcutaneous Auto-injector 30 MG	nemolizumab	Interleukin-31 receptor antagonist for the treatment of adult patients with prurigo nodularis. Pre-filled pen for subcutaneous injection given every 4 weeks. Also being studied for the treatment of moderate-to-severe atopic dermatitis, with a decision anticipated later in 2024.
Crexont Oral Capsule Extended Release 35-140 MG, 52.5-210 MG, 70-280 MG, 87.5-350 MG	carbidopa and levodopa	Extended-release capsules for the treatment of Parkinson's disease. 505b2 approval.
Voranigo Oral Tablet 10 MG, 40 MG	vorasidenib	Isocitrate dehydrogenase-1 (IDH1) and isocitrate dehydrogenase-2 (IDH2) inhibitor, indicated for the treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery including biopsy, sub-total resection, or gross total resection. First targeted therapy for Grade 2 IDH-mutant glioma.
Livdelzi Oral Capsule 10 MG	seladelpar	For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. Will compete with Iqirvo (elafibranor) which was approved June 2024.
Neffy Nasal Solution 2 MG/0.1ML	epinephrine	Epinephrine nasal spray for the treatment of Type I Allergic Reactions, including anaphylaxis, in adults and children who weigh ≥30 kg. First needle free treatment for type 1 allergic reactions. ARS Pharma plans to file a supplemental NDA application with the FDA for Neffy for children who weigh 15 to <30 kg by the end of the third quarter of 2024.

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†

Jemperli	dostarlimab-gxly 500mg/10ml solution	GSK	• Endometrial Cancer:
			  ○ in combination with carboplatin and paclitaxel, followed by Jemperli as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) ~~that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H)~~
			  ○ as a single agent for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced EC, as determined by an FDAapproved test, that has progressed on or following prior treatment with a platinum-containing regimen in any setting and are not candidates for curative surgery or radiation
			• Mismatch Repair Deficient Recurrent or Advanced Solid Tumors:
			  ○ as a single agent for the treatment of adult patients with dMMR recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options.[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 a confirmatory trial(s)

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Fabhalta	Iptacopan 200mg capsule	Novartis	• For the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH) • **For the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g**
Furoscix	furosemide injection kit 80mg/10ml	scPharmaceuticals Inc.	• For the treatment of congestion due to fluid overload in adults with ~~NYHA Class II/III~~ chronic heart failure.
NexoBrid	anacaulase-bcdb 8.8% topical gel	Vericel Corporation	• For eschar removal in adults **and pediatric** patients with deep partial thickness and/or full thickness thermal burns.
Imfinzi	Durvalumab 500 mg/10 mL, 120 mg/2.4 mL	AstraZeneca	• **In combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by IMFINZI continued as a single agent as adjuvant treatment after surgery, for the treatment of adult patients with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.** *Note: Imfinzi has many other approved indications not mentioned here; see full prescribing information for details.*
Rybrevant	amivantamab-vmjw 350 mg/7 mL vial	Johnson & Johnson	• **In combination with lazertinib for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test.**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• In combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test. • As a single agent for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.
ACAM2000	Smallpox (vaccinia) vaccine, live	Emergent	• For active immunization for the prevention of smallpox **and mpox disease** in individuals determined to be at high risk for smallpox **or mpox infection.**
Voquezna	Vonoprazan 10mg oral tablet	Phathom Pharmaceuticals, Inc	• For healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults. • To maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults. • **For the relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults.** • In combination with amoxicillin and clarithromycin for the treatment of Helicobacter pylori (H. pylori) infection in adults. • In combination with amoxicillin for the treatment of H. pylori infection in adults.
Darzalex Faspro	daratumumab and hyaluronidase-fihj 1800 mg/15 mL solution	Janssen Biotech	• **Multiple myeloma in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			Note: Darzalex Faspro has many other approved indications not mentioned here; see full prescribing information for details.
Fibryga	Fibrinogen concentrate (human) 1 gm powder for reconstitution	Octapharma	• **Fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency** • Treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia Limitation of Use: Fibryga is not indicated for dysfibrinogenemia

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Potassium Chloride Extended-Release Capsules, USP, (750 mg) 10 mEq K, a).100-count bottle (NDC 68001-396-00), b) 500-count bottle (NDC 68001-396-03), Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd., Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Distributed by: Dhar, Madhya Pradesh 454 775, India. Distributed for: BluePoint Laboratories.	Class I	Drugs	[100 count bottles]: Lot 17221738, Exp 07/31/2024; Lot 17222494, Exp 10/31/2024; Lot 17230533, Exp 01/31/2025; Lot 17232208, Exp 09/30/2025; [500 count bottles]: Lot 17221823, Lot 17221830, Exp 07/31/2024; Lot 17221831, Exp 08/31/2024; Lot 17230248, Lot 17230253, Lot 17230271, Exp 12/31/2024; Lot 17230796, Lot 17230820, Exp 02/28/2025; Lot 17230825, Lot 17230833, Lot 17230840, Exp 03/31/2025; Lot 17231537, Lot	Failed Dissolution Specifications	Amerisource Health Services LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			17231540, Lot 17231719, Lot 17231737, Exp 06/30/2025; Lot 17232111, Lot 17232164, Exp 09/30/2025		
Acetaminophen Extra Strength Tablets, 500 mg each, 100 count bottles, Packaged By: A-S Medication Solutions, Libertyville, IL 60048. NDC: 50090-5313-2	Class I	Drugs	Lot: 4138197; Exp 10/31/2025	Labeling: Label Mix-Up: Some bottles of Acetaminophen Extra Strength 500 mg tablets were incorrectly labeled with the drug facts label for Aspirin 81 mg tablets.	A-S Medication Solutions LLC
Healthy Living Acetaminophen, Aspirin (NSAID) and Caffeine, tablets USP, 250 mg/250 mg/65 mg, 100-count bottles, Distributed by: Aurohealth LLC, 279 Princeton-Hightstown Road, East Windsor, NJ , Made in India, NDC 58602-882-21.	Class I	Drugs	Lot#: AC2523005A, Exp 6/30/2025	Labeling: Missing Label - some bottles are missing the the manufacturers label that includes the drug facts information.	Aurobindo Pharma USA Inc
0.9% Sodium Chloride Injection USP, E8000, 1000mL container, Rx only, B. Braun Medical Inc., Irvine, CA, NDC 0264-7800-09.	Class I	Drugs	Lot #: J2L763, J2L764, Exp: 31 March 2025	Presence of Particulate Matter	B. Braun Medical Inc
Clonazepam Orally Disintegrating Tablets, USP (C-IV) 0.125mg, 60 tablets per carton (10 blister cards containing 6 tablets each), Rx Only, Distributed by: Par Pharmaceutical, Chestnut Ridge, NY 10977, NDC# 49884-306-02.	Class I	Drugs	Lot 550147301, Exp. 08/31/2026	Labeling: Label Error on Declared Strength; Some cartons were incorrectly labeled as 0.125 mg instead of 0.25 mg. The blister strips inside the product carton reflect	Endo Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				the correct strength of 0.25 mg.	
Acetaminophen Injection, 1,000 mg per 100 mL (10 mg/mL), 100 mL Single Dose bags, For Intravenous Use Only, Rx Only, Manufactured by: Hikma Farmaceutica (Portugal), SA, distributed by Hikma Pharmaceuticals USA Inc Berkeley Heights, NJ NDC 0143-9386-01	Class I	Drugs	Lot #24070381; Exp. 09/30/2025	Labeling: Label Mix-up: a bag of Dexmedetomidine HCl in 0.9% Sodium Chloride Injection was found inside an overwrap labeled Acetaminophen Injection 1,000 mg per 100 mL (10 mg/mL)	Hikma Pharmaceuticals USA Inc.
Umary Acido Hialuronico, Suplemento Alimenticio, 850 mg caplets, packaged in 30-count bottles.	Class I	Drugs	All lots within expiry	Marketed without Approved NDA/ANDA. FDA analysis found product to be tainted with undeclared Diclofenac and Omeprazole.	MAIN PRODUCTS INC
Umary Acido Hialuronico, Suplemento Alimenticio, 850 mg caplets, packaged in 30-count bottles.	Class I	Drugs	All lots within Expiry	Marketed without an Approved NDA/ANDA: FDA analysis found product to be tainted with undeclared Diclofenac and Omeprazole.	SoloVital
Empower Pharmacy, Estradiol Cypionate Injection, 10mg/mL, 5mL Sterile Multiple Dose Vial, For IM or SQ use only, RX only, Compounded by: Empower Pharmacy 7601 N Sam Houston Pkwy W Ste 100, Houston, TX 77064	Class II	Drugs	Lot #: 179338, Beyond use date: 08/14/2024	Lack of Assurance of Sterility	EMPOWER CLINIC SERVICES LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Progesterone Injection, USP, 500 mg per 10 mL (50mg/mL), 10 mL Multiple-Dose Vial, Rx Only, Mfd. in India for: Eugia US LLC, E Windsor, NJ 08520, NDC 55150-306-10.	Class II	Drugs	Lot #: CPR230029A	Presence of Particulate Matter: Complaint received of a glass particle in the vial.	Eugia US LLC
Ciprofloxacin ophthalmic solution USP, 0.3% as base, package in bottles: a) 10 mL (NDC 69315-308-10), b) 2.5 mL (NDC 69315-308-02), Rx Only, Distributed by: Leading Pharma LLC, Fairfield, NJ. Manufactured by: FDC Limited, Maharashtra, India.	Class II	Drugs	Lot#: a) 084C040, Exp 02/28/2026; b) 084A024, Exp12/31/2025.	Defective container: unable to get the solution out of the bottle as the spike of the cap was lodged in the nozzle of the product bottle.	FDC Limited
Timolol Maleate Ophthalmic Solution USP, 0.5%, Sterile, 5mL bottles, Rx only, Manufactured by: FDC Limited, Waluj, Aurangabad, Maharashtra, India, Distributed by: Rising Pharmaceuticals Inc, New Jersey, [NDC 64980-514-05].	Class II	Drugs	Lot Number: 083J022, Expiration Date: September- 25; 083L046, Expiration date: November- 25; 083H009, Expiration date: July- 25	Defective container; yellow colored spike from cap lodged in the nozzle	FDC Limited
Timolol Maleate Ophthalmic Solution USP, 0.5%, packaged in: a) 5mL bottle (NDC 64980-514-05), and b) 10mL bottle (NDC 64980-514-01), Rx only, Manufactured by: FDC Limited, Waluj, Aurangabad, India, Distributed by: Rising Pharmaceuticals Inc, New Jersey	Class II	Drugs	Lot #: a) 083K063, Exp 10/31/2025; b) 083I091, Exp 08/31/2025.	Defective Container: patients are unable to get the solution out of the bottle as the spike of the cap was lodged in the nozzle of the product bottle.	FDC Limited
Glenmark, Azelaic Acid Gel, 15 %, 50 grams, Rx only, Manufactured by: Glenmark Pharmaceuticals Limited, Colvale-Bardez, Goa, 403513, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430, NDC 68462-626-52.	Class II	Drugs	Lot# 19241453; Exp MARCH 2026	CGMP Deviations	Glenmark Pharmaceuticals Inc., USA

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Gabapentin Tablets, USP, 600 mg, 500-count bottles, Rx only, Manufactured by: Granules India Limited Hyderabad-500 081, India, Manufactured for: Granules Pharmaceuticals Inc., Chantilly, VA NDC 70010-227-05	Class II	Drugs	Lot 1380040A, Exp. date July 31, 2025	Presence of Foreign Tablets; 3 fused tablets of Metformin ER 500 mg were found in bottle of Gabapentin Tablets	Granules Pharmaceuticals Inc.
Testosterone Gel, 1.62%, (Alcohol 80% v/v), 30 unit-dose packets, Rx Only, Teva Pharmaceuticals, USA, Inc. North Wales, PA 19454, NDC 0591-2925-30. Packet NDC # 0591-2925-32 Carton NDC # 0591-2925-30	Class II	Drugs	Lot #: 100042386, Exp. Date 06/2025	Superpotent Drug	Teva Pharmaceuticals USA, Inc
Rubbing Alcohol (70% Isopropyl Alcohol), First-Aid Antiseptic, packaged in a) 3.78L (1-gallon jug); and b) 208.19L (55-gallon drum), Sold by: ZEE Company- A Member of the Vincit Group, 3401 Cummings Road, Chattanooga, TN 37419, Made in USA.	Class II	Drugs	Lot #: a) BC05977, Exp. Date 08/05/2024; B06664, Exp. Date 08/17/2024, B06664, Exp. Date 08/17/2024; b) B06664, Exp. Date 08/17/2024; BC06867, Exp. Date 10/03/2024; BC06867, Exp. Date 10/03/2024; BCT08309, Exp. Date 10/11/2024; BK06696, Exp. Date 08/17/2024; CCT01774, Exp. Date 02/24/2025; CCT03579, Exp. Date 05/01/2025; CKM06510, Exp. Date 08/02/2025; DCT04332, Exp. Date 05/17/2026	CGMP Deviations: sterile water not used for production	Zeco LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
HAND-I-SAN, No-Rinse Hand Sanitizer (75% Isopropyl Alcohol), packaged in a) 3.78L (1-gallon jug packaged in a case of 4x1 gallon jugs), b) 18.92L (5-gallon pail), c) 208.19L (55-gallon drum), and d) 1040.98L (275-gallon tote), ZEE Company 3401 Cummings Road, Chattanooga, TN, 37419, NDC 86161-210	Class II	Drugs	Lot #: a) 41320, Exp. Date 7/27/2024; 41020, Exp. Date 8/9/2024; BC06614, Exp. Date 8/15/2024; BCT07768, Exp. Date 9/23/2024; BCT09410, Exp. Date 11/17/2024; CCT02139, Exp. Date 3/10/2025; CCT01561, Exp. Date 3/15/2025; CCT02953, Exp. Date 4/10/2025; CCT02346, Exp. Date 4/21/2025; CCT03654, Exp. Date 5/11/2025; CCT04010, Exp. Date 5/17/2025; CCT07274, Exp. Date 8/24/2025; CCT09516, Exp. Date 11/1/2025; CCT10500, Exp. Date 12/5/2025; DCT01157, Exp. Date 2/1/2026; DCT01586, Exp. Date 2/14/2026; DCT03947, Exp. Date 4/30/2026; DCT04406, Exp. Date 5/24/2026; CCT01651, Exp. Date 2/21/2025 b) CCT03654, Exp. Date	CGMP Deviations: sterile water not used for production	Zeco LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			5/11/2025 c) BCT07768, Exp. Date 9/23/2024; BCT07975, Exp. Date 9/29/2024; BCT09410, Exp. Date 11/17/2024; BCT10246, Exp. Date 12/20/2024; CCT00705, Exp. Date 1/23/2025; CCT01952, Exp. Date 3/3/2025; CCT02139, Exp. Date 3/10/2025; CCT02689, Exp. Date 3/30/2025; CCT02346, Exp. Date 4/21/2025; CCT03654, Exp. Date 5/11/2025; CCT04010, Exp. Date 5/17/2025; CCT04630, Exp. Date 6/6/2025; CCT05946, Exp. Date 7/17/2025; CCT06785, Exp. Date 8/10/2025; CCT07274, Exp. Date 8/24/2025; CCT08515, Exp. Date 10/2/2025; CCT08936, Exp. Date 10/13/2025; CCT09516, Exp. Date 11/1/2025; CCT10888, Exp. Date 12/18/2025; DCT01157,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp. Date 2/1/2026; DCT01586, Exp. Date 2/14/2026; DCT02902, Exp. Date 3/27/2026; DCT03947, Exp. Date 4/30/2026; CCT01952, Exp. Date 3/3/2025; d) BC06614, Exp. Date 8/15/2024; CCT00705, Exp. Date 1/23/2025; CCT06785, Exp. Date 8/10/2025; CCT10500, Exp. Date 12/5/2025; DCT01586, Exp. Date 2/14/2026		
Methotrexate Tablets, USP, 2.5mg, 100-count Bottle, RX Only, Distributed By: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807, NDC# 69238-1423-1	Class III	Drugs	Lot # BB29124, Exp. 02/28/2026	Presence of Foreign Tablets: Potential presence of Fludrocortisone Acetate Tablet USP 0.1 mg within the Methotrexate 2.5 mg 100-count Bottle.	Amneal Pharmaceuticals, LLC
Sevelamer Carbonate for Oral Suspension 0.8g packets, packaged in 90 packets per container, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, Made in India NDC 43598-478-90	Class III	Drugs	Lot #: T2305999, Exp. Date 11/2025	Labeling: Incorrect or Missing Lot and/or Exp Date. Missing lot number and expiration dates on packets	Dr. Reddy's Laboratories, Inc.
Acetaminophen, USP 500mg, Pain Reliever/Fever Reducer, Extra Strength, Rapid Release Gelcaps, packaged in a 225-count HDPE	Class III	Drugs	Lot #: 31670346AA, Exp 12/31/2026	Label mix-up: Carton incorrectly labeled.	Granules Consumer Health Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
bottle, further packaged in a carton, Distributed by Walgreen Co., 200 Wilmot Rd, Deerfield, IL 60015, Made in India					
PEG-3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate, and Ascorbic Acid for Oral Solution 100g/7.5 g /2.691 g/1.015 g/ 5.9 g / 4.7 g, 3 pouches/carton, Rx only, Distributed by: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC# 0093-3560-26.	Class III	Drugs	Lot #S300542, exp. date June 30, 2025	Defective container: potential for non-sealed pouches which can lead to product leakage.	Novel Laboratories, Inc. d.b.a Lupin Somerset
Hydrocortisone 1% & Acetic Acid 2% Otic Solution, 10 mL bottle, Rx only, Mfg by: Taro Pharmaceuticals, Inc., Brampton, Ontario, Canada L6T 1C1, Distributed by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532, NDC 51672-3007-01	Class III	Drugs	Lot # AD12890, Exp 09/30/2024	Failed Impurities/Degradation Specifications: Out-of-specification results obtained for related impurities and slightly lower than the established level of the Hydrocortisone Assay obtained during stability testing.	Taro Pharmaceuticals U.S.A., Inc.

*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

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

Bumetanide Injection

Bupivacaine Hydrochloride Injection

Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection

Carboplatin Injection

Cefotaxime Sodium Injection

Cefotetan Disodium Injection

Chloroprocaine Hydrochloride Injection

Clindamycin Phosphate Injection

Clonazepam Tablet

Conivaptan Hydrochloride Injection

Cromolyn Sodium Concentrate

Cyclopentolate Hydrochloride Ophthalmic Solution

Dacarbazine Injection

Desmopressin Acetate Spray

Dexamethasone Sodium Phosphate Injection

Dexmedetomidine Hydrochloride Injection

Dextrose Monohydrate Injection

Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection

Dobutamine Hydrochloride Injection

Dopamine Hydrochloride Injection

Dulaglutide Injection

Echothiophate Iodide Ophthalmic Solution

Epinephrine Bitartrate, Lidocaine Hydrochloride Injection

Epinephrine Injection, Syringes

Etomidate Injection

Fentanyl Citrate Injection

Flurazepam Hydrochloride Capsule

Furosemide Injection

Heparin Sodium Injection

Hydrocortisone Sodium Succinate Injection

Hydromorphone Hydrochloride Injection

Hydroxocobalamin Injection

Hydroxypropyl Cellulose (1600000 Wamw) Insert

Indocyanine Green Injection

Isoniazid Tablet

Ketamine Hydrochloride Injection

Ketorolac Tromethamine Injection

Leucovorin Calcium Injection

Lidocaine Hydrochloride Injection

Lidocaine Hydrochloride Solution

Liraglutide Injection

Lisdexamfetamine Dimesylate Capsule

Lisdexamfetamine Dimesylate Tablet, Chewable

Lorazepam Injection

Mefloquine Hydrochloride Tablet

Methamphetamine Hydrochloride Tablet

Methotrexate Sodium Injection

Methylphenidate Hydrochloride Tablet, Extended Release

Methylprednisolone Acetate Injection

Metronidazole Injection

Midazolam Hydrochloride Injection

Morphine Sulfate Injection

Naltrexone Hydrochloride Tablet

Nitroglycerin Injection

Parathyroid Hormone Injection

Penicillin G Benzathine Injection

Potassium Acetate Injection

Promethazine Hydrochloride Injection

Propranolol Hydrochloride Injection

Quinapril Hydrochloride Tablet

Quinapril/Hydrochlorothiazide Tablet

Remifentanil Hydrochloride Injection

Rifampin Capsule

Rifampin Injection

Rifapentine Tablet, Film Coated

Riluzole Oral Suspension

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

Somatropin Injection

Sterile Water Injection

Sterile Water Irrigant

Streptozocin Powder, For Solution

Sufentanil Citrate Injection

Technetium TC-99M Pyrophosphate Kit Injection

Tirzepatide Injection

Triamcinolone Acetonide Injection

Triamcinolone Hexacetonide Injection

Valproate Sodium Injection

Vecuronium Bromide Injection

Vinblastine Sulfate Injection

Vitamin A Palmitate Injection