PERFORMRx℠

Drug Information Update

February 2025

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Newly Available Generics

Brand Name	Generic Name/ Dosage Form	Manufacturer	Indication
Kristalose	lactulose oral packet 20 gm	Foxland Pharmaceuticals	For the treatment of constipation.
Ridaura	auranofin oral capsule 3 mg	Trifluent Pharma	For the the management of adults with active classical or definite rheumatoid arthritis (ARA criteria) who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of full doses of one or more nonsteroidal anti-inflammatory drugs. Auranofin Capsules should be added to a comprehensive baseline program, including non-drug therapies.

New Drug Entities/Strengths/Combinations

Drug Name	Generic Name	Description
Esperoct Intravenous Solution Reconstituted 4000 UNIT	antihemoph fact rcmb gPEG-exei	New strength of hemophilia product. Already available in 500, 1000, 1500, 2000, 3000 units. Dose is body weight dependent and differs between prophylaxis vs control of bleeding.
Simlandi (2 Syringe) Subcutaneous Prefilled Syringe Kit 20 MG/0.2ML, (1 Syringe) Subcutaneous Prefilled Syringe Kit 80 MG/0.8ML	adalimumab-ryvk	New dosage form of Humira biosimilar. Already available in prefilled syringe kit 40mg/0.4ml. Interchangeable with Humira.
Fulvicin P/G 165 Oral Tablet 165 MG	griseofulvin	New strength and brand relaunch of previously discontinued antifungal product.
Steqeyma Intravenous Solution 130 MG/26ML	ustekinumab-stba	New strength of Stelara biosimilar. Will compete with the other Stelara biosimilars (Selarsdi, Pyzchiva, Otulfi, Imuldosa, and Wezlana).
Yesintek Subcutaneous Solution Prefilled Syringe and vial 45 MG/0.5ML, Prefilled Syringe 90 MG/ML,	ustekinumab-kfce	Stelara biosimilar. Approved in December, just now launching. Will compete with the other Stelara biosimilars (Selarsdi, Pyzchiva, Otulfi, Imuldosa, and Wezlana). Wezlana and Steqeyma have launched, others expected to launch within the next few months.
Yesintek Intravenous Solution 130 MG/26ML vial	ustekinumab-kfce	Stelara biosimilar. Approved in December, just now launching. Will compete with the other Stelara biosimilars (Selarsdi, Pyzchiva, Otulfi, Imuldosa, and Wezlana). Wezlana and Steqeyma have launched, others expected to launch within the next few months.
Niktimvo Intravenous Solution 9 MG/0.18ML, 22 MG/0.44ML	axatilimab-csfr	New entity approved in August 2024, just now launching. Colony stimulating factor-1 receptor (CSF-1R)-blocking antibody indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg.
Frindovyx Intravenous Solution 1 GM/2ML, 500 MG/ML, 2 GM/4ML	cyclophosphamide	New brand name of alkylating drug indicated for treatment of adults and pediatric patients with malignant diseases.
Griseofulvin Ultramicrosize Oral Tablet 165 MG	griseofulvin	New strength of antifungal.
Halcinonide External Solution 0.1 %	halcinonide	New dosage form of generic high potency steroid for relief of inflammatory and pruritic manifestations.

Drug Name	Generic Name	Description
Ustekinumab-ttwe Subcutaneous Solution Prefilled Syringe 45 MG/0.5ML, 90 MG/ML	ustekinumab-ttwe	Unbranded Pyzchiva (Stelara biosimilar). Will compete with other Stelara biosimilars. Wezlana, Yesintek, and Steqeyma have launched, others expected to launch within the next few months.
Ustekinumab-ttwe Intravenous Solution 130 MG/26ML	ustekinumab-ttwe	Unbranded Pyzchiva (Stelara biosimilar). Will compete with other Stelara biosimilars. Wezlana, Yesintek, and Steqeyma have launched, others expected to launch within the next few months.
Journavx Oral Tablet 50 MG	suzetrigine	First-in-class sodium channel blocker, non-opioid analgesic, to treat moderate to severe acute pain in adults. $434 for 14 days of treatment (use has not been studied beyond 14 days).
Feirza 1.5/30 Oral Tablet 1.5-30 MG-MCG	ethinyl estradiol and norethindrone	Competes with Loestrin, Microgestin, Larin, Junel, etc.
Valtya 1/50 Oral Tablet 1-50 MG-MCG	ethynodiol diacetate and ethinyl estradiol	Competes with Kelnor 1/50.
Rybelsus Oral Tablet 1.4 MG, 4 MG, 9 MG	semaglutide	New strength. Second rybelsus formuation (R2) which enhances drug absorption, allowing for lower doses to achieve the same effects as the first formulation (R1). R1 consists of 3mg, 7mg, and 14mg tablets. (Explanation found here: https://pharmagiant.com/rybelsus-dosing/).
Palforzia Initial Dose 1-3yrs Oral Capsule Sprinkle Therapy Pack 0.5 & 1 & 1.5 & 3 MG	peanut allergen powder	New therapy pack for peanut allergy immunotherapy.
Palforzia Initial Dose 4-17yrs Oral Capsule Sprinkle Therapy Pack 0.5 & 1 & 1.5 & 3 & 6 MG	peanut allergen powder	New therapy pack for peanut allergy immunotherapy.
Palforzia (1 MG Daily Dose) Oral Capsule Sprinkle Therapy Pack 1 x 1 MG	peanut allergen powder	New therapy pack for peanut allergy immunotherapy.
Evrysdi Oral Tablet 5 MG	risdiplam	New strength and dosage form. First and only tablet for spinal muscular atrophy.
Selarsdi Subcutaneous Solution Prefilled Syringe 45 MG/0.5ML, 90 MG/ML	ustekinumab-aekn	Stelara biosimilar. Approved in April 2024, just now launching. Will compete with the other Stelara biosimilars (Yesintek, Pyzchiva, Otulfi, Imuldosa, and Wezlana).
Grafapex Intravenous Solution Reconstituted 1 GM, 5 GM	treosulfan	Indicated for use with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (alloHSCT) in adult and pediatric patients one year of age and older with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS).

Drug Name	Generic Name	Description
Gomekli Oral Capsule 1 MG, 2 MG	mirdametinib	Indicated for treatment of adult and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection. Will compete with Koselugo.
Gomekli Oral Tablet Soluble 1 MG	mirdametinib	Indicated for treatment of adult and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection. Will compete with Koselugo.

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†
Susvimo	ranibizumab injection 100mg/ml	Genentech	• Neovascular (wet) Age-related Macular Degeneration (AMD) who have previously responded to at least two intravitreal injections of a VEGF inhibitor. • **Diabetic Macular Edema (DME) who have previously responded to at least two intravitreal injections of a VEGF inhibitor.**
Adcetris	brentuximab vedotin 50mg intravaneous solution	Seagen Inc.	• **Adult patients with relapsed or refractory large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) NOS, DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy who are not eligible for auto-HSCT or CAR T-cell therapy, in combination with lenalidomide and a rituximab product.** *Note: Adcetris has many approved indications. See PI for full indications and usage.*
Sublocade	buprenorphine ER prefilled syringe 100 mg/0.5 mL and 300 mg/1.5 mL	Indivior Inc.	• For the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a ~~buprenorphine containing product, followed by dose adjustment for a minimum of 7 days~~ **single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.** Sublocade should be used as part of a complete treatment program that includes counseling and psychosocial support.

Recalls

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Astagraf XL (tacrolimus extended-release capsules) 0.5 mg, 30-count bottles, RX Only, Product of Japan, Distributed by: Astellas Pharma US Inc., Northbrook, IL 60062, NDC 0469-0647-73.	Class I	Drugs	Lot# 0R3092A, EXP 03/31/2026	Failed Tablet/Capsule Specifications: Bottles shipped to the USA may contain empty capsules	Astellas Pharma US Inc.
Prograf (tacrolimus) capsules, USP, 0.5 mg, 100-count bottle, Rx Only, Product of Japan, Distributed by: Astellas Pharma US, Inc., Northbrook, IL 60062, NDC 0469-0607-73.	Class I	Drugs	Lot# 0E3353D, Exp 03/31/2026	Failed Tablet/Capsule Specifications: Bottles shipped to the USA may contain empty capsules	Astellas Pharma US Inc.
Adrenalin Chloride Solution (Epinephrine Nasal Solution, USP), 30mg/30mL (1mg/mL), packaged in 30 mL vials, Distributed by: Par Pharmaceutical, Chestnut Ridge, NY 10977, NDC 42023-103-01	Class I	Drugs	All lots within expiry	Labeling: Not Elsewhere Classified: misleading label similar in appearance to the FDA-approved drug product Adrenalin¿ (epinephrine injection, USP)	ENDO USA, Inc.
Phenylephrine HCl Injection, USP 100 mg/10 mL (10 mg/mL) vials, Rx only, Pharmacy Bulk Package (supplied as a single unit), Dist. by: Provepharm, Inc., Collegeville, PA 19426	Class I	Drugs	Lot# 24020027, Exp Date: 12/31/2025	Presence of Particulate Matter.	Provepharm Inc.
Fentanyl Transdermal System CII, 25mcg/h, packaged in a pouch, further packaged in 5-count carton, Rx only, Distributed by: Alvogen, Inc., Pine Brook, NJ 07058, Manufactured by: Kindeva Drug Delivery L/P, Northridge, CA 91324, NDC 47781-424-47.	Class I	Drugs	Lot #: 108319, Exp: 04/30/2027	Defective delivery system - patches could be multi-stacked, adhered one on top of the other, in a single product pouch.	Alvogen, Inc
Duloxetine Delayed-Release Capsules USP, 20 mg, packaged in a) 30 Unit Doses (3x10 blister packs) NDC 0904-7043-04 and b)	Class II	Drugs	Lot #: a) N01530, Exp. Date 01/2025; b) N01540, Exp. Date. 01/2025	Failed Impurities/Degradation Specifications: Due to presence of Nitrosamine Drug Substances	The Harvard Drug Group LLC dba Major

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
100 Unit Doses (10x10 blister packs) NDC 0904-7043-61, Rx only, Packaged and Distributed by: Major Pharmaceuticals, Indianapolis, IN 46268 USA.				Related Impurity (NDSRI), N-Nitroso-Duloxetine above the interim acceptable intake limit of 5 ppm.	Pharmaceuticals and Rugby Laboratories
Inflectra (infliximab-dyyb), For injection, 100mg per vial, packaged in 10 mL single-dose vial, Rx only, Mfd by: CELLTRION, INC, Dist. by: Pfizer Labs, Division of Pfizer Inc., New York, NY 10001, NDC 0069-0809-01	Class II	Drugs	Lot# 04647349, Exp Date 5/31/2029	cGMP Deviations: Product intended for quarantine was inadvertently distributed.	McKesson
Granix (tbo-filgrastim) Injection 300 mcg/0.5 mL, Single Dose prefilled syringe, packaged as a) 1 syringe in 1 CARTON, NDC 63459-910-11, Blister NDC 63459-910-12; (b)10 syringes in 1 CARTON, NDC 63459-910-15, Blister NDC 63459-910-12; (c) 1 syringe in 1 CARTON, NDC 63459-910-17 without safety guard and blister, Rx Only, Manufactured by: UAB Teva Baltics, Vilnius, Lithuania. Distributed by Teva Pharmaceuticals USA, Inc. North Wales PA 19454. Product of Israel.	Class II	Drugs	Lot # (a) 135738, (b) 137149, (c) 137148, Exp. date 09/30/2025	Failed Stability Specifications - 12-month stability test result for one of the known peptides is below the specification limit	Teva Pharmaceuticals USA, Inc
HydrALAZINE Hydrochloride, 25 mg, 100 Unit Dose Tablets (10x10), USP, Rx only, Manufactured by Strides Pharma Science Ltd, Bengaluru, India, Distributed by McKesson by: McKesson Corporation dba SKY Packaging, TN 38141. NDC 63739-327-10	Class II	Drugs	Lot #: 0000127312, Exp. Date 31-Mar-2025; 0000127576, 0000127577, Exp. Date 31-Jul-2025; 0000128204, Exp. Date 31-Dec-2025; 0000128358, Exp. Date 31-Jan-2026	Failed Impurities/Degradation Specifications	SKY PACKAGING
HydrALAZINE Hydrochloride, 100 Tablets (10x10), USP, 50mg, Rx only, Manufactured by Strides Pharma Science Ltd, Bengaluru, India, Distributed by	Class II	Drugs	Lot #: 0000127410, 63739-328-10, Exp. Date 30-Apr-2025; 0000127579, Exp. Date 31-Aug-2025; 0000128245,	Failed Impurities/Degradation Specifications	SKY PACKAGING

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
McKesson by: McKesson Corporation dba SKY Packaging, TN 38141. NDC 63739-328-10			Exp. Date 31-Dec-2025; 0000128486, Exp. Date 28-Feb-2026.		
Carvediol Tablets, USP, 25 mg, Rx only, a)500 Tablets, NDC 68462-165-05; b) 100 Tablets, NDC 68462-165-01, Manufactured for Glenmark Pharmaceuticals, NJ.	Class II	Drugs	Lot numbers: a) 17230500, 17230509,17230526,17230546,17230551,17230603,17230628, 17230642,17230645,17230681, Exp.:02/2025; 17230829,17230832,17230854, 17230864,17230874,17230876,17230889,17230894, Exp.: 03/2025; 17230960, 17230964,17230976,17230981,17230985,17231161,17231171, Exp.: 04/2025 17231315,17231318,17231332,17231333,17231365, Exp.: 05/2025; 17231539, 17231563, Exp.: 06/2025; 17231653,17231662,17231663,17231680,17231691, 17231781,17231782,17231789, Exp.: 07/2025;17231838,17231880, Exp.: 08/2025; 17232144,17232147,17232151, Exp.: 09/2025; 17232369,17232370,17232408,17232409, 17232416,17232504,17232522,17232531,17232538,17232	CGMP Deviations:N-Nitroso Carvedilol I impurity (NNCI-I) were found to be failing per current FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			543, Exp.: 11/2025; 17240377,17240385,17240415,17240422,17240430,17240510, Exp.: 02/2026. b) 17230551, 17240377, Exp.:02/2025		
Carvediol Tablets, USP, 12.5 mg, Rx only, a)500 Tablets, NDC 68462-164-05; b) 100 Tablets, NDC 68462-164-01, Manufactured for Glenmark Pharmaceuticals, NJ.	Class II	Drugs	Lot numbers: a) 17230658, Exp.: 02/2025; 17230814,17230822, Exp.: 03/2025; 17231004,17231009,17231022, Exp.: 04/2025; 17231393,17231392, Exp.: 05/2025; 17231538, 17231541,17231542, Exp.: 06/2025; 17231710,17231718,17231721,17231722,17231730, Exp': 07/2025; 17232169, Exp.: 09/2025; 17232253, Exp.: 10/2025; 17240220,17240240, Exp.: 01/2026; 17240459, Exp.: 02/2026 b) 17230814, Exp.: 03/2025; 17231392, Exp.:05/2025; 17232260, Exp.: 10/2025.	CGMP Deviations:N-Nitroso Carvedilol I impurity (NNCI-I) were found to be failing per current FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA
Carvedilol 25 mg Tablet, QTY: 30 Tablets per Blister Pack (3 x 10 blister cards), Rx Only, MFG by: Glenmark, Mahwah, NJ 07430, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC: 70518-3945-00.	Class II	Drugs	Lot #s: J0777493050824, Exp. 5/31/2025; J0787856062124, Exp. 7/31/2025.	CGMP deviations: presence of N-Nitroso Carvedilol Impurity-1 (NNC 1), above the FDA recommended acceptable intake limit.	RemedyRepack Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
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#: 083J033, Exp. Date 09/2025	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
Potassium Chloride Extended-Release Tablets, USP, 10 mEq (750 mg), 100 Tablets per carton (10 x 10 unit dose blisters), Rx Only, Distributed by: Aurobindo Pharma USA< INC., 279 Princeton-Hightstown Road, East Windsor, NJ 08520. Made in India. Distributed by: MAJOR PHARMACEUTICALS, Livonia, MI 48152. NDC: 0904-7216-61	Class II	Drugs	Lot# T05224; Exp. 02/2026	Failed Dissolution Specifications.	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
Irbesartan Tablets USP, 300 mg, 50 Tablets (5 x 10) Unit Dose per carton, Manufactured for: AvKARE, Pulaski, TN 38478. NDC 50268-442-15	Class II	Drugs	Lot 45279, Exp 03/31/2025	Out of Specification for Dissolution	AvKARE
Lorazepam Tablets, USP, 0.5mg, Unit Dose, 100 tablets per carton (10 x 10 blister packs), Rx only, The drug product contained in this package is from NDC # 69315-904 Leading Pharma, LLC., Packaged and Distributed by: Major Pharmaceuticals, Indianapolis, IN 26268 USA, NDC: 0904-6007-61	Class II	Drugs	Lot #s: N01424, N01425, Exp 03/31/2025; N01659, N01660, Exp 08/31/2025; N01668, 09/2025; N01679, N01704, N01745, Exp 10/31/2025; N01856, Exp 02/28/2026; N01973, Exp 05/31/2026; N02079, Exp 08/31/2026.	Failed impurities/degradation specifications and Sub-potent Drug: Out-of-specification results were obtained during routine stability testing for Assay and Impurities.	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
Lorazepam Tablets, USP, 1mg, Unit Dose, 100 tablets per carton (10 x 10 blister packs), Rx only, The drug product contained in this package is from NDC # 69315-905 Leading Pharma, LLC.,	Class II	Drugs	Lot #s: N01419, N01420, N01421, Exp 03/31/2025; N01663, Exp 06/30/2025; N01664, Exp 08/31/2025; N01673, Exp 09/30/2025;	Failed impurities/degradation specifications and Sub-potent Drug: Out-of-specification results were obtained during	The Harvard Drug Group LLC dba Major Pharmaceutical

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Packaged and Distributed by: Major Pharmaceuticals, Indianapolis, IN 26268 USA, NDC: 0904-6008-61.			N01688, Exp 08/31/2025; N01747, N01748, N01749, Exp 11/30/2025; N01792, Exp 12/31/2025; N01857, Exp 02/28/2026; N01974, Exp 05/31/2026; N02081, Exp 08/31/2026.	routine stability testing for Assay and Impurities.	s and Rugby Laboratories
Lorazepam Tablets, USP, 2mg, Unit Dose, 100 tablets per carton (10 x 10 blister packs), Rx only, The drug product contained in this package is from NDC # 69315-906 Leading Pharma, LLC., Packaged and Distributed by: Major Pharmaceuticals, Indianapolis, IN 26268 USA, NDC: 0904-6009-61.	Class II	Drugs	Lot #s: N01422, N01423, Exp 03/31/2025; N01661, N01662, Exp 09/30/2025; N01746, N01750, Exp 10/31/2025; N01876, N01877, Exp 03/31/2026; N01899, N01900, N01975, Exp 04/30/2026.	Failed impurities/degradation specifications and Sub-potent Drug: Out-of-specification results were obtained during routine stability testing for Assay and Impurities.	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
Atomoxetine Capsules, USP, 10 mg, 30 capsule bottles, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ, USA, Product of India, NDC 68462-265-30.	Class II	Drugs	Lot Numbers: 19232368, Exp:5/2025; 19235088, Exp.: 11/2025; 19241447, Exp.: 3/2026; 19243146, Exp.: 7/2026.	CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA
Atomoxetine Capsules, USP, 18 mg, 30 capsule bottles, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ, USA, Product of India, NDC 68462-266-30.	Class II	Drugs	Lot Numbers: 19233756, Exp.: 8/2025; 19235111, Exp.: 11/2025; 19242167, Exp.: 5/2026; 19242180, Exp.: 5/2026.	CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA
Atomoxetine Capsules, USP, 25 mg, 30 capsule bottles, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ, USA, Product of India, NDC 68462-267-30.	Class II	Drugs	Lot Numbers: 19233792, Exp.: 8/2025; 19233795, Exp.: 8/2025; 19234258, Exp.: 9/2025; 19240912, Exp.: 2/2026; 19241476, 19241477, Exp.: 3/2026; 19242599, Exp.: 6/2026; 19243163, 19243162,	CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp.:7/2026;19243884, 19243887, Exp.:9/2026.		
Atomoxetine Capsules, USP, 40 mg, 30 capsule bottles, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ, USA, Product of India, NDC 68462-268-30.	Class II	Drugs	Lot Numbers: 19234109, Exp.: 9/2025; 19234897, Exp.: 11/2025; 19240501, Exp.: 1/2026; 19241489, Exp.: 3/2026; 19241806, Exp.: 4/2026.	CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA
Atomoxetine Capsules, USP, 60 mg, 30 capsule bottles, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ, USA, Product of India, NDC 68462-269-30.	Class II	Drugs	Lot Numbers: 19234630, Exp.: 10/2025; 19240528, 19240529, Exp.: 1/2026.	CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA
Atomoxetine Capsules, USP, 80 mg, 30 capsule bottles, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ, USA, Product of India, NDC 68462-270-30.	Class II	Drugs	Lot Numbers: 19234153, Exp.: 9/2025; 19234900, 19234929, Exp.: 11/2025; 19240936, 19240942, Exp.: 2/2026; 19243199, 19243190, Exp.:7/2026; 19244013, 19244014, Exp.: 9/2026.	CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA
Atomoxetine Capsules, USP, 100 mg, 30 capsule bottles, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ, USA, Product of India, NDC 68462-271-30.	Class II	Drugs	Lot Numbers: 19234955, 19234956, Exp.: 11/2025; 19240971, Exp.: 2/2026; 19241864, Exp.: 4/2026.	CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA
Atomoxetine Capsules, USP, 10 mg, 30 capsule bottles, Rx Only, Manufactured for: Northstar Rx LLC., Memphis, TN 38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Goa, India, NDC 16714-755-01.	Class II	Drugs	Lot Numbers: 19232356, Exp.: 5/2025; 19233198, Exp.: 7/2025; 19234213, 19234232, Exp.: 9/2025; 19241445, Exp.: 3/2026; 19243033, 19243121, Exp.: 7/2026.	CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA
Atomoxetine Capsules, USP, 18 mg, 30 capsule bottles, Rx Only, Manufactured for: Northstar Rx LLC., Memphis, TN 38141, Manufactured by: Glenmark	Class II	Drugs	Lot Numbers: 19233228, 19233227, Exp.: 7/2025; 19233757, Exp.: 8/2025; 19234229, Exp.: 9/2025;	CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pharmaceuticals Ltd., Goa, India, NDC 16714-756-01.			19235090, Exp.: 11/2025; 19241471, Exp.:3/2026; 19242180, Exp.: 5/2026.		
Atomoxetine Capsules, USP, 25 mg, 30 capsule bottles, Rx Only, Manufactured for: Northstar Rx LLC., Memphis, TN 38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Goa, India, NDC 16714-757-01.	Class II	Drugs	Lot Numbers: 19232506, 19232397, 19232415, Exp.: 5/2025; 19233791, Exp.: 8/2025; 19234248, Exp.: 9/2025; 19240909, Exp.: 2/2026; 19242598, Exp.:6/2026; 19243163, 19243122, Exp.: 7/2026; 19243884, Exp.: 9/2026.	CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA
Atomoxetine Capsules, USP, 40 mg, 30 capsule bottles, Rx Only, Manufactured for: Northstar Rx LLC., Memphis, TN 38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Goa, India, NDC 16714-758-01.	Class II	Drugs	Lot Numbers: 19232540, 19232524, 19232553, Exp.: 5/2025; 19240510, Exp.: 1/2026; 19241489, Exp.: 3/2026; 19243905, 19243935, Exp.: 9/2026.	CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA
Atomoxetine Capsules, USP, 60 mg, 30 capsule bottles, Rx Only, Manufactured for: Northstar Rx LLC., Memphis, TN 38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Goa, India, NDC 16714-759-01.	Class II	Drugs	Lot Numbers: 19234630, Exp.: 10/2025; 19240529, Exp.: 1/2026.	CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA
Atomoxetine Capsules, USP, 80 mg, 30 capsule bottles, Rx Only, Manufactured for: Northstar Rx LLC., Memphis, TN 38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Goa, India, NDC 16714-760-01.	Class II	Drugs	Lot Numbers: 19233234, 19233253, Exp.: 7/2025; 19234154, Exp.: 9/2025; 19243185, Exp.: 7/2026; 19243951, 19243974, Exp.: 9/2026.	CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA
Atomoxetine Capsules, USP, 100 mg, 30 capsule bottles, Rx Only, Manufactured for: Northstar Rx LLC., Memphis, TN	Class II	Drugs	Lot Numbers: 19233270, 19233278, 19233285, Exp.: 7/2025; 19233806, Exp.:	CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity	Glenmark Pharmaceuticals Inc., USA

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Goa, India, NDC 16714-761-01.			8/2025; 19240954, Exp.: 2/2026; 19241854, Exp.: 4/2026.	above the FDA recommended limit.	
fentaNYL Citrate In Sodium Chloride 1600mcg/100mL (16 mcg per mL) CII, Single use 100mL IV Bag, Fagron Sterile Services, 8710 E 34th St N, Wichita, KS 67726 Bar Code 71266-5060-01	Class II	Drugs	Lot # C274-000040409, Exp 03/22/2025	Lack of Assurance of Sterility	Fagron Compounding Services
Silodosin Capsules, 8mg, 90-count bottle, Rx only, Manufactured for: AvKare, Pulaski, TN 38478, Manufactured by: Amneal Pharmaceuticals of NY, LLC, NY 11719, NDC 42291-778-90	Class II	Drugs	Lot#: BC20223A, Exp. March 31, 2025.	Subpotent Drug: Out of Specification (OOS) result for De hydro Impurity (0.654%) for 18 M Stability sample and low assay 94.9% (specification of NLT 95.0% NMT 105%)	AvKARE
BADGER 50, ADVENTURE SPORT MINERAL SUNSCREEN WITH CLEAR ZINC, (uncoated 25% zinc oxide), 2.4 oz., Tin, W.S. Badger Company, Inc, 768 Route 10, Gilsum NH, 03448 UPC 6 34084 47150 2	Class III	Drugs	LOT# 091923A, Exp. Date 09/19/26	Labeling: Missing Label: The finished product potentially missing the labeling with the drug facts panel, bar code and directions for use.	The W.S. Badger Company, Inc.
Guaifenesin and Codeine Phosphate Oral Solution USP, 100mg/10 mg per 5 mL, 16 fl oz (473 ml) bottles, PAI Pharmaceutical Associates, Inc., Greenville, SC 29605, NDC 0121-0775-16	Class III	Drugs	Lot number 4B07, Exp Date: 2026-OCT-31	Superpotent; sodium benzoate preservative	PAI Holdings, LLC. dba Pharmaceutical Associates 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

Amino Acid Injection

Amoxicillin Powder, For Suspension

Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet

Atropine Sulfate Injection

Azacitidine Injection

Bumetanide Injection

Bupivacaine Hydrochloride Injection

Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection

Carboplatin Injection

Cefotaxime Sodium Powder, for Solution

Clindamycin Phosphate Injection

Clonazepam Tablet

Conivaptan Hydrochloride Injection

Cromolyn Sodium Concentrate

Desmopressin Acetate Spray

Dexamethasone Sodium Phosphate Injection

Dexmedetomidine Hydrochloride Injection

Dextrose Monohydrate 10% Injection

Dextrose Monohydrate 5% Injection

Dextrose Monohydrate 50% Injection

Dextrose Monohydrate 70% Injection

Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection

Dobutamine Hydrochloride Injection

Dopamine Hydrochloride Injection

Dulaglutide Injection

Echothiophate Iodide Ophthalmic Solution

Epinephrine Bitartrate, Lidocaine Hydrochloride Injection

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

Ketamine Hydrochloride Injection

Ketorolac Tromethamine Injection

Lactated Ringers 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 Film, Extended Release

Methylphenidate Hydrochloride Tablet, Extended Release

Methylprednisolone Acetate Injection

Metronidazole Injection

Midazolam Hydrochloride Injection

Morphine Sulfate Injection

Naltrexone Hydrochloride Tablet

Nitroglycerin Injection

Oxazepam Capsule

Parathyroid Hormone Injection

Peginterferon alfa-2a Injection

Penicillin G Benzathine Injection

Peritoneal Dialysis Solution

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

Sodium Acetate Injection

Sodium Bicarbonate Injection

Sodium Chloride 0.9% Injection

Sodium Chloride 0.9% Irrigation

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

Triamcinolone Acetonide Injection

Triamcinolone Hexacetonide Injection

Valproate Sodium Injection

Vecuronium Bromide Injection