Drug Information Update

January 2025

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Newly Available Generics

Brand Name	Generic Name/ Dosage Form	Manufacturer	Indication
Motegrity	prucalopride succinate oral tablet 1 mg, 2 mg	Ani Pharmaceuticals	For the treatment of chronic idiopathic constipation (CIC) in adults
Nymalize	nimodipine Oral Solution 60 MG/20ML	Camber Pharmaceuticals	For the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in adult patients with subarachnoid hemorrhage (SAH) from ruptured intracranial berry aneurysms regardless of their post-ictus neurological condition (i.e., Hunt and Hess Grades I to V).
Mesnex	mesna 400mg oral tablet	Ingenus Pharmaceuticals	Indicated as a prophylactic agent in reducing the incidence of ifosfamide-induced hemorrhagic cystitis Limitations of use: Mesna is not indicated to reduce the risk of hematuria due to other pathological conditions such as thrombocytopenia
Namzaric	memantine hcl-donepezil hcl oral capsule extended release 24 hour 14-10 mg, 28-10mg	Amneal Pharmaceuticals	For the treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on 10 mg of donepezil hydrochloride once daily
Entresto	sacubitril-valsartan Oral Tablet 24-26mg, 49-51mg, 97-103mg	AvKARE	• To reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure and reduced ejection fraction • For the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older. Sacubitril and valsartan tablets reduces NT-proBNP and is expected to improve cardiovascular outcomes
Spritam	levetiracetam oral tablet disintegrating soluble 250mg	Prasco Laboratories	• For the treatment of partial-onset seizures in patients 4 years of age and older weighing more than 20 kg • For adjunctive therapy for the treatment of: o Myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy o Primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy

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Brand Name	Generic Name/ Dosage Form	Manufacturer	Indication
Nexium	esomeprazole magnesium oral packet 2.5mg, 5mg	Cipla USA	• Short-term treatment in the healing of erosive esophagitis (EE) in adults and pediatric patients 1 year to 17 years of age • Maintenance of healing of EE in adults Short-term treatment of heartburn and other symptoms associated GERD in adults and pediatric patients 12 years to 17 years of age • Risk reduction of nonsteroidal anti-inflammatory drugs (NSAID)-associated gastric ulcer in adults at risk for developing gastric ulcers due to age (60 years and older) and/or documented history of gastric ulcers • Helicobacter pylori eradication in adult patients to reduce the risk of duodenal ulcer recurrence in combination with amoxicillin and clarithromycin • Long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome in adults • Short-term treatment in the healing of EE in pediatric patients 1 year to 11 years of age and of EE due to acid-mediated GERD in pediatric patients 1 month to less than 1 year of age • Short-term treatment of heartburn and other symptoms associated with GERD in pediatric patients 1 year to 11 years of age
Metronidazole	metronidazole oral tablet 125 mg	Method Pharmaceuticals	• Symptomatic Trichomoniasis • Asymptomatic Trichomoniasis • Treatment of Asymptotic Sexual Partners • Amebiasis • Anaerobic Bacterial Infections • Intra-abdominal Infections • Skin and Skin Structure Infections • Gynecologic Infections • Bacterial Septicemia • Bone and Joint Infections • CNS Infections • Endocarditis *See package insert for full details.*

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New Drug Entities/Strengths/Combinations

Drug Name	Generic Name	Description
Alyftrek Oral Tablet 4-20-50 MG, 10-50-125 MG	vanzacaftor/tezacaftor/deutivacaftor	Once-daily next-in-class triple combination cystic fibrosis transmembrane conductance regulator (CFTR) modulator for the treatment of cystic fibrosis (CF) in people 6 years and older who have at least one F508del mutation or another mutation in the CFTR gene that is responsive to Alyftrek. Alyftrek has efficacy in 31 additional CFTR gene mutations compared to Trikafta.
Crenessity Oral Capsule 50 MG, 100 MG, 50 MG/ML Oral Solution	crinecerfont	First in class adjunctive treatment to glucocorticoid replacement to control androgens in adult and pediatric patients four years of age and older with classic congenital adrenal hyperplasia (CAH).
Bizengri (750 MG Dose) Intravenous Solution Therapy Pack 375 MG/18.75ML	zenocutuzumab-zbco	Indicated for adults with pancreatic adenocarcinoma or non–small cell lung cancer (NSCLC) that are advanced unresectable or metastatic and harbor a neuregulin 1 (NRG1) gene fusion who have disease progression on or after prior systemic therapy. This approval marks the first systemic therapy for NRG1 fusion-positive (NRG1+) NSCLC or pancreatic adenocarcinoma.
Tryngolza Subcutaneous Solution Auto-injector 80 MG/0.8ML	olezarsen	APOC-III-directed antisense oligonucleotide (ASO) indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS). Currently, there are no FDA-approved therapies for the treatment of FCS and standard triglyceride lowering therapies are generally ineffective in patients with FCS.
Opdivo Qvantig Subcutaneous Solution 600-10000 MG-UT/5ML	nivolumab and hyaluronidase-nvhy	Combination subcutaneous product indicated in most previously approved adult, solid tumor Opdivo indications as monotherapy, monotherapy maintenance following completion of Opdivo plus Yervoy (ipilimumab) combination therapy, or in combination with chemotherapy or cabozantinib.
Kebilidi Injection Suspension 280000000000 VG/0.5ML	eladocagene exuparvovec-tneq	Adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of adult and pediatric patients with aromatic 13 L-amino acid decarboxylase (AADC) deficiency. The indication covers the full spectrum of disease severity and the approval constitutes the first gene therapy for direct administration to the brain to be approved in the US. Approved in the UK and Europe under the name Upstaza.
Gabarone Oral Tablet 100 MG, 400 MG	gabapentin	New brand name and tablet strength of gabapentin. Already available in 600mg and 800mg tablets, and 100mg, 300mg, and 400mg capsules.

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Drug Name	Generic Name	Description
Adalimumab-adaz Subcutaneous Solution Auto-injector 80 MG/0.8ML	adalimumab-adaz	New strength of Humira biosimilar. Unbranded version of Hyrimoz.
Adalimumab-adaz Subcutaneous Solution Prefilled Syringe 20 MG/0.2ML	adalimumab-adaz	New strength of Humira biosimilar. Unbranded version of Hyrimoz.
Prevymis Oral Packet 20 MG, 120 MG	letermovir	New dosage form approved in September 2024, just now launching. Indicated for CMV prophylaxis in transplant recipients. Already available in IV solution and oral tablets (240mg, 480mg).
Jivi Intravenous Solution Reconstituted 4000 UNIT	antihemophilic factor (recombinant), PEGylated-aucl	New strength of recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A. Already available in 500, 1000, 2000, and 3000 unit.
Fenopron Oral Capsule 300 MG	fenoprofen	New brand name and strength of fenoprofen. Available generic in 200mg and 400mg capsules, and 600mg tablets.
Topiramate Oral Capsule Sprinkle 50 MG	topiramate	New generic strength of existing product.
Metformin HCl Oral Tablet 750 MG	metformin	New generic strength of existing product.
Alhemo Subcutaneous Solution Pen-injector 60 MG/1.5ML, 150 MG/1.5ML	concizumab-mtci	Once-daily treatment for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A with factor VIII inhibitors or hemophilia B with factor IX inhibitors. This approval marks the first subcutaneous injection treatment of its kind for use in this patient population.
Metronidazole Oral Tablet 125 MG	metronidazole	Relaunch of existing generic. No other NDCs for 125mg tablet available. Also available in 250mg and 500mg tablets.
Datroway Intravenous Solution Reconstituted 100 MG	datopotamab deruxtecan-dlnk	Trophoblast cell-surface antigen 2 (TROP2)–directed antibody and topoisomerase inhibitor conjugate, for adult patients with unresectable or metastatic hormone receptor (HR)–positive, human epidermal growth factor receptor 2 (HER2)–negative (HR+/HER2–) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease. Will primarily compete with Trodelvy (sacituzumab govitecan-hziy).
Steqeyma Subcutaneous Solution Prefilled Syringe 45 MG/0.5ML, 90 MG/ML	ustekinumab-stba	Stelara biosimilar. Approved in December, just now launching. Will compete with the other Stelara biosimilars (Selarsdi, Pyzchiva, Otulfi, Imuldosa, and Wezlana). Wezlana has launched, others expected to launch within the next few months.

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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†
Omvoh	mirikizumab-mrkz intravaenous solution 300mg/15ml, subcutaneous injection 100mg/ml (auto injector and prefilled syringe)	Eli Lilly	• Treatment of moderately to severely active ulcerative colitis in adults • **Treatment of moderately to severely active Crohn's disease in adults**
Calquence	acalabrutinib 100mg tablet	AstraZeneca	• **In combination with bendamustine and rituximab for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are ineligible for autologous hematopoietic stem cell transplantation (HSCT)** • For the treatment of adult patients with MCL who have received at least one prior therapy • For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
Lumakras	sotorasib 120mg, 240mg, 320mg oral tablets	Amgen Inc.	<u>KRAS G12C-mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC):</u> • As a single agent, for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, who have received at least one prior systemic therapy. This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). **<u>KRAS G12C-mutated Metastatic Colorectal Cancer (mCRC):</u>**

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Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• **In combination with panitumumab, for the treatment of adult patients with KRAS G12C-mutated mCRC as determined by an FDA approved-test, who have received prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy.**
Spravato	esketamine 28mg nasal spray	Janssen	• Treatment-resistant depression (TRD) in adults, **as monotherapy or in conjunction with an oral antidepressant** • Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant.
Enhertu	fam-trastuzumab deruxtecan-nxki 100mg intravenous solution	Daiichi Sankyo, Inc.	Treatment of adult patients with unresectable or metastatic: • **Hormone receptor (HR)-positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining) breast cancer, as determined by an FDA-approved test, that has progressed on one or more endocrine therapies in the metastatic setting.** • HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer, as determined by an FDA-approved test, who have received a prior chemotherapy in the metastatic setting; or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy. **Enhertu has many approved indications. See package insert for full details.*
Ozempic	semaglutide injection: • 2 mg/3 mL (0.68 mg/mL) available in: Single-patient-use pen that delivers 0.25 mg or 0.5 mg per injection • 4 mg/3 mL (1.34 mg/mL) available in: Single-	Novo Nordisk	• As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus • To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease

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Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
	patient-use pen that delivers 1 mg per injection • 8 mg/3 mL (2.68 mg/mL) available in: Single-patient-use pen that delivers 2 mg per injection		• **To reduce the risk of sustained eGFR decline, end-stage kidney disease and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease**

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Recalls

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
FORCE FOREVER 400mg Tablets, Huesos y articulaciones sin dolor, SUPLEMENTO ALIMENTICIO, 60-count bottles	Class I	Drugs	All lots, Exp. Date: 03/27/2030	Marketed without an approved NDA/ANDA. FDA analysis found the product to be tainted with Diclofenac and Dexamethasone.	GNMart LLC
Clonazepam Orally Disintegrating Tablet, USP, 2 mg, C-IV, Rx Only, 60 Tablets per carton, 10 blister cards containing 6 tablets each, Distributed by: PAR Pharmaceutical, Chestnut Ridge, NY 10977, NDC#: 49884-310-02 (carton), NDC#: 49884-310-52 (blisters).	Class I	Drugs	Lot # 550176501, 550176601, Exp 02/28/2027.	Labeling: Label Error on Declared Strength; Some cartons were incorrectly labeled. The blister strips inside the product carton reflect the correct strength.	Endo USA, Inc.
Clonazepam Orally Disintegrating Tablets, USP, 0.125 mg, C-IV, Rx Only, 60 tablets per carton (10 blister cards containing 6 tablets each), Distributed by: PAR Pharmaceutical, Chestnut Ridge, NY 10977, NDC#: 49884-306-02 (carton), NDC #: 49884-306-52 (blisters).	Class I	Drugs	Lot #: 550174101, Exp. 01/31/2027.	Labeling: Label Error on Declared Strength; Some cartons were incorrectly labeled. The blister strips inside the product carton reflect the correct strength.	Endo USA, Inc.
Clonazepam Orally Disintegrating Tablets, USP, 0.25 mg, C-IV, Rx Only, 60 tablets per carton (10 blister cards containing 6 tablets each), Distributed by: PAR Pharmaceutical, Chestnut Ridge, NY 10977, NDC#: 49884-307-02 (carton), NDC #: 49884-307-52 (blisters).	Class I	Drugs	Lot #s: 550142801, 550142901, 550143001, 550143101, 550143201, 550143301, 550143401, 550147201, 550147401, Exp. 08/31/2026.	Labeling: Label Error on Declared Strength; Some cartons were incorrectly labeled. The blister strips inside the product carton reflect the correct strength.	Endo USA, Inc.
Clonazepam Orally Disintegrating Tablets, USP, 1 mg, C-IV, Rx Only, 60 tablets per carton (10 blister cards containing 6 tablets each), Distributed by: PAR Pharmaceutical, Chestnut Ridge, NY	Class I	Drugs	Lot #s: 550145201, Exp. 08/31/2026; 550175901, 550176001, 550176201, Exp. 02/28/2027	Labeling: Label Error on Declared Strength; Some cartons were incorrectly labeled. The blister strips inside the product carton reflect the correct strength.	Endo USA, Inc.

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
10977, NDC#: 49884-309-02 (carton), NDC #: 49884-309-52 (blisters).					
Nhan Sam Tuyet Lien Truy Phong Hoan, Capsules, 30-Count Bottles, Manufactured by Yee Hong Pharmaceuticals, SDN, Penang, Malasia.	Class I	Drugs	All codes, unknown expiration dates all before 05/2030.	Marketed without an Approved NDA/ANDA: FDA analysis found the products to be tainted with undeclared Furosemide, Dexamethasone and Chlorpheniramine	Buy-Herbal
Systane Lubricant Eye Drops, Ultra PF, Sterile, 25 Vials (0.7mL Each), Manufactured for: Alcon Laboratories, Inc. Forth Worth, TX 76134	Class I	Drugs	Lot 10101; Exp.09/30/2025	Non-Sterility	Alcon Research LLC
FOUZEE SugarLin HERBAL FORMULA capsules, 180 capsules per bottle, Sold and Distributed by Shoppers-Plaza, Hawthorne, CA 90250. Product of India. UPC 8 26656 69047 7	Class I	Drugs	Batch # 001, exp. date 09/10/2026	Marketed without an Approved NDA/ANDA; FDA laboratory analysis confirmed product tainted with undeclared metformin and glyburide	SHOPPERS-PLAZA
UMARY ACID HYALURONIC, 850 MG CAPLETS, 30-count bottle, UPC7502265120323	Class II	Drugs	Lot#: 24183, Exp 07/01/28	cGMP Deviations: the firm initiated a recall after notification from the distributor that product may be tainted with undeclared diclofenac and omeprazole, however there is no analytical data confirming that product distributed by the firm is tainted.	MXBBB
Kit for the Preparation of Technetium Tc 99m Sestamibi Injection, Each Kit contains: 30 sterile and non-pyrogenic reaction vials each containing Tetrakis (2-methoxy isobutyl isonitrile) Copper (I) tetratluoroborate - 1 mg; Stannous Chloride Dihydrate - 0.D75 mg; L-Cysteine	Class II	Drugs	Lot 092-24006, Catalog # N092D0, Exp 06/15/2026	Lack of Assurance of Sterility; Improper crimps on vials impacting the integrity of the product	Curium US, LLC

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Hydrochloride Monohydrate - 1 mg; Sodium Citrate Dihydrate - 2.6 mg; Mannitol - 20 mg. The pH is adjusted to 5.6 to 5.7 with HCl or NaOH prior to lyophilization. Sealed under nitrogen. 30 Radioassay Information Labels with radiation warning symbol. 1 package insert, Rx only, Manufacture by: Curium US LLC, Maryland Heights, MO 63043, 69945-092-40					
Duloxetine Delayed-Release Capsules, USP, 30mg, Rx Only, 90-count bottles (NDC 51991-747-90) Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922.	Class II	Drugs	Lot # 222205C, exp. date 11/2025	CGMP Deviations: presence of N-nitroso-duloxetine impurity above FDA recommended interim limit.	Breckenridge Pharmaceutical , Inc
Duloxetine Delayed-Release Capsules, USP, 60 mg, Rx Only, 90-count bottles (NDC 51991-748-90) Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922.	Class II	Drugs	Lot # 230077C, exp. date 11/2025	CGMP Deviations: presence of N-nitroso-duloxetine impurity above FDA recommended interim limit.	Breckenridge Pharmaceutical , Inc
Duloxetine Delayed-Release Capsules, 60 mg, a) 30 count blister cards (NDC 70518-0937-04), b) 30 count bottles (NDC 70518-0937-03), Rx only, Source NDC 57237-0019-99, MFG: Rising Pharma, Inc., Allendale, NJ, Repackaged by: RemedyRepack Inc., Indiana, PA	Class II	Drugs	a) NDC 70518-0937-04, Lot # J0786744-061724, Exp. 06/30/2025 b) NDC 70518-0937-03, Lot # B3002625-060524, Exp. 10/31/2025	CGMP Deviations; presence of N-nitroso-duloxetine impurity above recommended interim limit.	RemedyRepack Inc.

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
DULoxetine DR USP, 30 mg, 90-count bottle, Rx Only, Packaged by: PD Rx Pharmaceuticals Inc, Oklahoma City, OK 73127, NDC: 43063-877-90	Class II	Drugs	Lot # I24E77, A24E49, Exp Date: 04/30/25; J23C50, J23C97, L23B39, L23E98, Exp Date: 01/31/2025	CGMP Deviations: the presence of a Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Duloxetine above the interim acceptable intake limit	PD-Rx Pharmaceuticals, Inc.
chlorproMAZINE Hydrochloride Tablets, USP, 10mg, 100-count bottle, RX only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ; Product of India, NDC 68462-861-01	Class II	Drugs	Lot#: 17230132, Exp 12/2024; 17230449, Exp 01/2025	CGMP Deviations: N-Nitroso-Desmethyl Chlorpromazine impurity (NNDCI) were found to be failing per current FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA
chlorproMAZINE Hydrochloride Tablets, USP, 25 mg, 100-count bottle, RX only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ; Product of India, NDC 68462-862-01	Class II	Drugs	Lot#: 17230133, Exp 12/31/2024	CGMP Deviations: N-Nitroso-Desmethyl Chlorpromazine impurity (NNDCI) were found to be failing per current FDA recommended limit.	Glenmark Pharmaceuticals Inc., USA
Duloxetine Delayed-Release Capsules USP, 30 mg, Rx only, 30 count bottles, Manufactured by: Aurobindo Pharma Limited, Hyderabad-500 090, India, For BluePoint Laboratories NDC 68001-414-04	Class II	Drugs	Lot DT3023029A Exp 02/28/2025	CGMP Deviations: Presence of N-nitroso-duloxetine impurity above the recommended interim limit.	Amerisource Health Services LLC
Duloxetine Delayed-Release Capsules, USP, 30 mg, Rx only, 90 count bottles, Manufactured by: Aurobindo Pharma Limited, Hyderabad-500 090, India, For BluePoint Laboratories NDC 68001-414-05	Class II	Drugs	Lot DT3023030A Exp 2/28/2025	CGMP Deviations: Presence of N-nitroso-duloxetine impurity above the recommended interim limit.	Amerisource Health Services LLC
Duloxetine Delayed-Release Capsules USP, 60 mg, Rx only, 30 count bottles, Manufactured by: Aurobindo Pharma Limited, Hyderabad-500 090, India, For BluePoint Laboratories NDC 68001-415-04	Class II	Drugs	Lot DT6023061B Exp 01/31/2025	CGMP Deviations: Presence of N-nitroso-duloxetine impurity above the recommended interim limit.	Amerisource Health Services LLC
Duloxetine Delayed-Release Capsules, USP, 60 mg, Rx only, 1,000 count bottles, Manufactured by: Aurobindo Pharma	Class II	Drugs	Lots, expiry: Lot DT6022166A, exp 11/30/2024; Lot DT6023071A, exp 2/28/2025	CGMP Deviations: Presence of N-nitroso-duloxetine impurity	Amerisource Health Services LLC

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Limited, Hyderabad-500 090, India, For BluePoint Laboratories NDC 68001-415-08				above the recommended interim limit.	
Levothyroxine Sodium Tablets, Lupin, 75 mcg (0.075mg), 1000 Tablets, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 United States, Manufactured by: Lupin Limited, Pithampur (M.P)- 454 775 INDIA, NDC# 68180-967-03	Class II	Drugs	Lot# LA01276, Exp Date: 07/2026	Failed Impurities/Degradation Specifications: Out of specifications result observed in the drug substance for impurity test during 3-month long term stability study.	Lupin Pharmaceuticals Inc.
Nitrofurantoin Capsules, USP, 100 mg, 50 Capsules (5 x 10) Unit Dose per carton, Rx Only, Manufactured for: AvKARE, Inc., Pulaski, TN 38478. NDC#: 50268-625-15.	Class II	Drugs	Lot # 47101; Exp. 02/2026	Failed Dissolution Specifications	AvKARE
Dapsone Gel 7.5%, 60 g, Rx Only, Manufactured by: Zydus Lifesciences Ltd., Ahemedabad, India, Distributed by: Viona Pharmaceuticals Inc., Cranford, NJ 07016, NDC 72578-094-02. packaged in an Airless pump pack	Class II	Drugs	Lots T400513, Exp Date 02/2026; T400807, Exp Date 03/2026; T401152, Exp Date 06/2026; T401303, Exp Date 07/2026; T401304, Exp Date 07/2026; T401399, Exp Date 07/2026 & T401696 Exp Date 08/2026.	Crystallization	VIONA PHARMACEUTICALS INC
Dapsone Gel 7.5%, 90 g, Rx Only, Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India, Distributed by: Viona Pharmaceuticals Inc., Cranford, NJ 07016, NDC 72578-094-03. packaged in an Airless pump pack	Class II	Drugs	Lots T400514, Exp Date 02/2026 & T400808, Exp Date 03/2026	Crystallization	VIONA PHARMACEUTICALS INC
ketamine inj 50 mg per 1 mL, Rx Only, 1 mL fill in a 3mL pre-filled syringe, For IV or IM Use, Hikma Injectables USA Inc., 36 Stults Road, Dayton, NJ 08810, This is a Compounded Drug. Hospital/Office Use Only. NDC 63037-137-25	Class II	Drugs	Lot number: 242560008D, Use by Date 01/15/2025; 242970002D, Use by Date 02/25/2025	Lack of Assurance of Sterility: The tamper-evident seal on several of the syringes are not attached upon receipt of shipment.	Hikma Injectables USA Inc

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
phenylephrine in 0.9% Sodium Chloride Inj, 1mg per 10 mL (100 mcg/mL), Rx only, Hikma Injectables USA Inc., 36 Stults Road, Dayton, NJ 08810, NDC 63037-173-25	Class II	Drugs	Lot number: 243120003D, Use by Date: 03/11/2025	Lack of Assurance of Sterility: The tamper-evident seal on several of the syringes are not attached upon receipt of shipment.	Hikma Injectables USA Inc
Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection, 10 mL Multi-Dose Reaction Vial, 5 vial Box, Rx Only, Manufactured for: Jubilant Draximage Inc., dba Jubilant Radiopharma, Kirkland , Quebec, H9H, 4J$, Canada, NDC# 65174-179-05.	Class II	Drugs	LOT C2300070 and C2300070E;Exp. May 31, 2025	Failed Stability Specifications	Jubilant Draximage Inc., dba Jubilant Radiopharma
Ciprofloxacin Ophthalmic Solution USP, 0.3% as base, Sterile, package in 5 mL bottles, Rx Only, Distributed by: Leading Pharma LLC, Fairfield, NJ. Manufactured by: FDC Limited, Maharashtra, India, NDC 69315-308-05	Class II	Drugs	Lot: 083L111, Exp. 11/30/2025; 084A032, Exp. 12/31/2025	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
Clobazam Tablets, 10 mg, packaged in 30 tablets per carton (3x10 blister cards each), Rx Only, Amneal Pharmaceuticals LLC, Distributed by: American Health Packaging, Columbus, Ohio 43217, NDC 60687-423-21	Class II	Drugs	Lot #: 1019594, Exp. Date 12/31/2025	Presence of Foreign Tablets/Capsules	Amerisource Health Services LLC
medroxyPROGESTERone Acetate Injectable Suspension, USP, 150mg per mL, Rx only, 1 mL Single-Dose Vial, Mfd in India for: Eugia US LLC, NJ 08520 NDC 55150-329-01 Shipper label: medroxyPROGESTERone Acetate Injectable Suspension, USP, 150 mg per mL, Distributed by: Eugia US LLC, NJ,	Class II	Drugs	Lot No.: 1MP24069, Exp.: 08/2026	CGMP Deviations	Eugia US LLC

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Manufactured by: Eugia Pharma Specialties Limited, India					
Colchicine Capsules 0.6 mg, 30-count bottles, Rx only, Manufactured by: Granules Pharmaceuticals Inc. Chantilly, VA 20151 NDC 70010-001-03	Class II	Drugs	Lot#: GPC240763B, Exp. Date 6/17/2026	Out of specification observed during the accelerated stability conditions for the 30 count bottles.	Granules Pharmaceuticals Inc.
Progesterone Injection USP, 500mg 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	Batch # 1PR24010, Expiry: 02/28/2027	Presence of Particulate Matter: A market complaint was received of a glass piece in the vial.	Eugia US LLC
Duloxetine Delayed-Release Capsules USP 30 mg, a) 30 count (NDC 57237-018-30) and b) 1000 count (NDC 57237-018-99) bottles, Rx only, Distributed by: Rising Pharm Holdings, Inc., East Brunswick, NJ	Class II	Drugs	a) Lot# DT3023051A, exp. date Apr-25; b) DT3023025A, exp. date Jan-25	CGMP Deviations; Presence of N-nitroso-duloxetine impurity above recommended interim limit.	Rising Pharma Holding, Inc.
Duloxetine Delayed-Release Capsules USP 20 mg, 60 count bottles, Rx only, Distributed by: Rising Pharm Holdings, Inc., East Brunswick, NJ NDC 57237-017-60	Class II	Drugs	Lot # DT2023003A, DT2023007A, DT2023008A, exp. date Jan-25	CGMP Deviations; Presence of N-nitroso-duloxetine impurity above recommended interim limit.	Rising Pharma Holding, Inc.
Duloxetine DR Capsules USP 60 mg, a) 30 count (NDC 57237-019-30) and b) 1000 count (NDC 57237-019-99) bottles; Distributed by: Rising Pharm Holdings, Inc., East Brunswick, NJ	Class II	Drugs	Lot # a) DT6023053A, DT6023061A, DT6023068A, DT6023074A, exp. date Jan-25; DT6023078A, DT6023076A, exp. date Feb-25; DTC24043A, DTC24044A, exp. date Dec-25 b) DT6023002A, DT6023016A, DT6023036A, exp. date Dec-24; DT6023048A, exp. date Jan-25	CGMP Deviations; Presence of N-nitroso-duloxetine impurity above recommended interim limit.	Rising Pharma Holding, Inc.
Metformin Hydrochloride Extended-Release Tablets, USP, 500 mg, 1000-count bottles, Rx Only, Manufactured by:	Class II	Drugs	Lot #: 4911311A, Exp. Date: 11/2025	Presence of Foreign Tablets/Capsules: A Paracetamol 500 mg tablet was found in a	Granules Pharmaceuticals Inc.

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Granules India Limited, Hyderabad- 500 081, India, Manufactured for: Quallent Pharmaceuticals Health LLC, Grand Cayman, Grand Cayman Islands, NDC 82009-117-10				1000-count bottle of Metformin HCL ER Tablets USP, 500 mg.	
glipiZIDE, Extended-Release Tablets, 2.5 mg, 30-count (3x10 blister cards) carton, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217, Carton NDC: 60687-480-21, Unit Dose NDC: 60687-480-11	Class II	Drugs	Lot # 1012910, Exp Date: 04/30/2025	Failed Dissolution Specifications:	Amerisource Health Services LLC
Cardura XL (doxazosin) extended release tablets 8 mg, 30-count bottle, Rx only, Distributed by Viatris Specialty LLC, Morgantown, WV 26505, NDC 58151-079-93	Class II	Drugs	Lot # 8181625, Exp 12/31/2025	Failed Impurities/Degradation Specifications: Out of specification results observed for the impurity compound B during stability testing.	Viatris Inc
Cardura XL (doxazosin) extended release tablets 4 mg, 30 -count bottle, Rx only, Distributed by Viatris Specialty LLC, Morgantown, WV 26505, NDC 58151-078-93	Class II	Drugs	Lot# 8182298, Exp 10/31/2025	Failed Impurities/Degradation Specifications: Out of specification results observed for the impurity compound B during stability testing.	Viatris Inc
Clobazam Tablets, 10 mg, packaged in 30 tablets per carton (3x10 blister cards each), Rx Only, Amneal Pharmaceuticals LLC, Distributed by: American Health Packaging, Columbus, Ohio 43217, NDC 60687-423-11	Class II	Drugs	Lot #: 1018598, Exp. Date 10/31/2025	Presence of Foreign Tablets/Capsules	Amerisource Health Services LLC
Kissable Diabetics Foot Cream, NET WT 4 oz (113 g) per tube, Manufactured By: Brands International Corp., Newmarket, ON, L3X 2S2. UPC 6 72008 80925 3	Class II	Drugs	Lots: 23319025, 23318024, 23313023, 23311022, 23310021, 23222021, 23220020, 23215019, 23215018, 23214017, 23213016, 23208015,	CGMP Deviations: lack of adequate release testing.	Brands International Corporation

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			2313014, 2312213, 2312212, 2312111, 2312110, 2311709, 2311708, 2311607, 2311506, 2311405, 2307904, 23073003, 23072002, 2306901 and 24135003. All expiration dates within expiry.		
First Aid Beauty Ultra Repair Cream, colloidal oatmeal 0.5%, Coconut Vanilla, Net Wt. 396.8 g (14 OZ), DISTR. BY: First Aid Beauty LTD, Newton, MA, 02458, UPC 8 15517 02955 6	Class II	Drugs	Lots 24D44, Exp 4/10/2026 & 24D45, 4/11/2026	CGMP Deviations; product intended for quarantine was inadvertently distributed	First Aid Beauty Ltd
Atropine Sulfate Ophthalmic Solution, USP 1%, 5 mL bottles, Rx only, Manufactured for: Somerset Therapeutics, LLC. Somerset, NJ 08873, NDC 70069-716-01	Class III	Drugs	Lot #: A240211, Exp. Date April 2026	Failed Impurities/Degradation Specifications	SOMERSET THERAPEUTICS LLC
Carboxymethylcellulose Sodium Ophthalmic Solution 0.5% Moisturizing Lubricant Eye Drops, 0.5 FL OZ (15 mL) bottles, Distributed by: AvKARE, Pulaski, TN, 38478, NDC 50268-068-15.	Class III	Drugs	Lot #: 0160, Exp. Date April 26 2026	LABELING: LABEL MIX-UP	AvKARE
Polyvinyl Alcohol Ophthalmic Solution 1.4%, Moisturizing Lubricant Eye Drops, 0.5 FL OZ (15 mL) bottles, Distributed by AvKARE, Pulaski, TN 38478, www.avkare.com, NDC 50268-678-15	Class III	Drugs	Lot #: 0160, Exp. Date April 26 2026	LABELING: LABEL MIX-UP	AvKARE
Methadone Hydrochloride Tablets, USP, 5mg, 10x10 Unit-Dose Tablets, Rx Only, Distributed by: Hikma Pharmaceuticals USA Inc., Berkeley Heights, NJ 07922, NDC 0054-0709-20	Class III	Drugs	Lot # AC2556A; Exp. 03/2027	Failed Tablet/Capsule Specifications: Illegible product identification for the unit dose configuration only.	West-Ward Columbus Inc

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Acetaminophen Extra Strength 500 mg, 100 Tablets per bottle, Akron Pharma, Inc., 373 RT US 46 W Building E, Suite 117, Fairfield, NJ 07004, NDC 71399-8022-01.	Class III	Drugs	Lot: KDT0224002A, Exp 09/30/2026	Labeling: Not Elsewhere Classified: Tablets/Capsules imprinted with wrong ID.	Akron Pharma, Inc.
Acetaminophen Regular Strength, 325 mg, 100 Tablets per bottle, Akron Pharma, Inc., 373 RT US 46 W Building E, Suite 117, Fairfield, NJ 07004, NDC 71399-8024-01 .	Class III	Drugs	Lot #: KDT0124001, Exp 08/31/2026	Labeling: Not Elsewhere Classified: Tablets/Capsules imprinted with wrong ID.	Akron Pharma, Inc.
Acetaminophen, 325 mg Tablets, 100 Tablets per bottle, Akron Pharma, Manufactured for: Akron Pharma Inc., Fairfield, NJ 07034, NDC 71399-8014-01.	Class III	Drugs	Lot #s: KDT0124004, KDT0124005, KDT0124006, Exp 08/31/2026	Labeling: Not Elsewhere Classified: Tablets/Capsules imprinted with wrong ID.	Akron Pharma, Inc.
Acetaminophen Extra Strength 500 mg, 1000 Tablets per bottle, Akron Pharma, Manufactured for: Akron Pharma Inc., 373 US RT 46 W Building E, Suite 117, Fairfield, NJ 07034, NDC 71399-8022-02	Class III	Drugs	Lot #s: KDT0224001B, Exp 08/31/2026; KDT0224002B, Exp 09/30/2026.	Labeling: Not Elsewhere Classified: Tablets/Capsules imprinted with wrong ID.	Akron Pharma, Inc.
Diphenhydramine HCl 25 mg, 100 capsules per bottle, Akron Pharma, Manufactured for: Akron Pharma, Inc., 373 RT US 46 W Building E, Suite 117, Fairfield, NJ 07004, NDC 71399-8028-1.	Class III	Drugs	Lot: KDC0124001A Exp 09/30/2026.	Labeling: Not Elsewhere Classified: Tablets/Capsules imprinted with wrong ID.	Akron Pharma, Inc.
Diphenhydramine HCl 25 mg, 1000 Capsules per bottle, Akron Pharma, Manufactured for: Akron Pharma, Inc., 373 RT US 46 W Building E., Suite 117, Fairfield, NJ 07004, NDC 71399-8028-2.	Class III	Drugs	Lot: KDC0124002B Exp 09/30/2026	Labeling: Not Elsewhere Classified: Tablets/Capsules imprinted with wrong ID.	Akron Pharma, Inc.
Diphenhydramine HCl 50 mg, 1000 capsules per bottle, Akron Pharma, Manufactured for: Akron Pharma, Inc. 373 Route US 46, Building E, Suite 117, Fairfield, NJ 07004, NDC 71399-8026-02.	Class III	Drugs	Lot: KDC0224001B Exp 09/30/2026	Labeling: Not Elsewhere Classified: Tablets/Capsules imprinted with wrong ID.	Akron Pharma, Inc.

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

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FDA Drug Safety Communications

[Posted 1-22-2025] FDA adds Boxed Warning about a rare but serious allergic reaction called anaphylaxis with the multiple sclerosis medicine glatiramer acetate (Copaxone, Glatopa)
Treat immediately if symptoms worsen or do not go away shortly after an injection

What safety concern is FDA announcing?
The U.S. Food and Drug Administration (FDA) is warning about the risk of a rare but serious allergic reaction with the medicine glatiramer acetate (Copaxone, Glatopa), which is used to treat patients with multiple sclerosis (MS). This serious allergic reaction, called anaphylaxis, can occur at any time while on treatment, after the first dose or after doses administered months or years after starting the medicine. For most patients who experienced anaphylaxis with glatiramer acetate use, the symptoms appeared within one hour of injection. In some cases, anaphylaxis resulted in hospitalization and death.

The initial symptoms of anaphylaxis can overlap with those of a common reaction called immediate post-injection reaction that is temporary and can start soon after a shot is given. While immediate postinjection reaction is common, anaphylaxis is rare and its symptoms are typically more severe, worsen over time, and require treatment. Patients experiencing a reaction after the medicine is administered should seek immediate medical attention if the symptoms are more than mild, get worse over time, or do not go away within a brief time. We are adding a new Boxed Warning about this risk to the glatiramer acetate prescribing information and patient Medication Guide.

What is FDA doing?
We are adding the risk of anaphylaxis to a new Boxed Warning, FDA's most prominent warning, and to the Warnings and Precautions section of the glatiramer acetate prescribing information. These warnings include information that anaphylaxis can occur at any time, from as early as after the first dose or after doses administered years after starting the medicine. We are also adding new recommendations for patients and health care professionals about the critical importance of quickly recognizing and treating symptoms of anaphylaxis. The updated prescribing information also instructs patients to stop taking the medicine and seek immediate medical attention by going to an emergency room or calling 911 if symptoms of anaphylaxis occur.

What is glatiramer acetate (Copaxone, Glatopa) and how can it help me?
Glatiramer acetate is an FDA-approved medicine to treat patients with relapsing forms of MS. It works by lessening the immune system's abnormal attack on nerves in the brain and spinal cord. This medicine helps decrease the number of MS relapses. Glatiramer acetate is available as an injectable medicine administered daily or three times per week, depending on dosage, under the brand name Copaxone, branded generic name Glatopa, and as other generic glatiramer acetate products. The first glatiramer acetate product, Copaxone, was approved in 1996.

What should patients and caregivers do?
Patients should stop taking glatiramer acetate and seek immediate medical attention by going to an emergency room or calling 911 if you experience symptoms of an anaphylactic reaction. Symptoms generally appear within one hour of injection and include wheezing or difficulty breathing, swelling of the face, lips, or throat, and hives. These symptoms can quickly progress to more serious symptoms, including severe rash or shock, which is a life-threatening condition. Anaphylaxis can occur at any point during glatiramer acetate treatment, including years after starting treatment. You

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should not restart glatiramer acetate if you have experienced anaphylaxis unless another clear cause for anaphylaxis is identified. Talk to your health care professional if you have any questions or concerns about glatiramer acetate.

Patients should be aware that the early symptoms of anaphylaxis can be similar to a temporary reaction that sometimes happens right after or within minutes after an injection of the medicine into the skin. This immediate post-injection reaction goes away on its own, usually within 15-30 minutes, with no specific treatment. This reaction can occur with the first dose, or after doses administered months or even years after starting the medicine. This immediate post-injection reaction may involve symptoms such as flushing, chest pain, palpitations, anxiety, shortness of breath, rash, or hives. Call the health care professional who prescribed the medicine if you have any of these immediate post-injection reaction symptoms. Do not continue taking more injections until your prescriber tells you to do so. Seek immediate medical attention by going to an emergency room or calling 911 if any of these symptoms worsen or do not go away.

What should health care professionals do?
Health care professionals should be aware that fatal anaphylaxis has occurred with glatiramer acetate, including years after treatment has been initiated and that the symptoms of these rare anaphylactic events may overlap with those of common immediate post-injection reactions. Symptoms such as flushing, chest pain, palpitations, anxiety, shortness of breath, rash, or hives typically occur within minutes after an injection and are generally transient, self-limited, and resolve without specific treatment within 30 minutes. Those associated with anaphylaxis are typically more severe, worsen, or last longer, requiring urgent medical attention.

Educate patients on the signs and symptoms of anaphylaxis and immediate post-injection reactions. Instruct them to seek immediate medical attention by going to an emergency room or calling 911 if they experience any symptoms of anaphylaxis, and to contact their prescriber if they experience an immediate post-injection reaction. Do not restart the medicine in patients who experience anaphylaxis unless a clear alternative etiology is identified.

What did FDA find?
We identified 82 worldwide cases of anaphylaxis associated with glatiramer acetate occurring from December 1996 through May 2024, including 19 cases that reported anaphylaxis more than one year after starting the medicine (see Data Summary). The 82 worldwide cases include only reports submitted to FDA* and found in the medical literature so there are likely additional cases about which we are unaware. While anaphylaxis in these cases appears to be rare compared to how often the medicine is used (see Facts about Glatiramer Acetate), these 82 patients reported serious outcomes that required emergency room visits or hospitalizations for medical treatment, and six died. A majority of the 82 patients experienced anaphylaxis within one hour of taking the medicine.

*The cases were reported to the FDA Adverse Event Reporting System (FAERS) database.

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

How do I report side effects from glatiramer acetate (Copaxone, Glatopa)?

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

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

Facts about Glatiramer Acetate (Copaxone, Glatopa)

- Glatiramer acetate is a prescription medicine approved by FDA to reduce the frequency of relapses in patients with multiple sclerosis (MS).
- Glatiramer acetate works by lessening the immune system's abnormal attack on nerves in the brain and spinal cord. This helps decrease the number of MS relapses.
- Glatiramer acetate is given as an injection under the skin and should be taken according to the prescribed dosing schedule to be effective.
- Common side effects that may occur seconds to minutes after injection, called immediate postinjection reactions, include flushing, rash, short-term difficulty breathing, and chest pain. These may overlap with signs and symptoms associated with the rare but serious anaphylaxis allergic reactions.
- In 2023, an estimated 240,000 glatiramer acetate prescriptions were dispensed and estimated 32,000 patients received a dispensed prescription from U.S. outpatient retail and mail order pharmacies.[1]

Additional Information for Patients and Caregivers

- FDA is warning that a rare but potentially life-threatening allergic reaction has been reported with the multiple sclerosis (MS) medicine glatiramer acetate. This serious allergic reaction, called anaphylaxis, can occur after the first dose or after doses administered months or even years after starting treatment. It can result in hospitalization and death.
- Initial symptoms of anaphylaxis may overlap with reactions that can happen shortly after an injection of the medicine into the skin, called immediate post-injection reactions. This could lead to a delay in recognizing and treating anaphylaxis, which can be life-threatening.
- If you experience symptoms of anaphylaxis, stop taking glatiramer acetate and seek immediate medical attention by going to an emergency room or calling 911. These symptoms include:
    - wheezing or difficulty breathing
    - swelling of the face, lips, or throat
    - hives
    - severe rash
- Immediate post-injection reactions, in contrast, are common, temporary reactions that usually go away within 15-30 minutes without lasting effects. These symptoms include the following, but if any of them get worse or persist, immediate medical attention may be necessary:
    - flushing or warmth
    - chest pain
    - fast heartbeat
    - anxiety
    - breathing problems or tightness in your throat

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  - swelling, rash, hives, or itching
- Be aware that immediate post-injection reactions are common, typically happen right after or within minutes after injection, and go away quickly, while anaphylactic reactions are rare, generally occur within one hour of an injection, and the symptoms are typically more severe, do not go away, get worse, and require treatment. Both reactions can occur after the first injection or after injections administered any time while on treatment, even after an injection given several years into treatment. However, anaphylaxis is a medical emergency needing immediate treatment.
- If you have had symptoms of anaphylaxis or an immediate post-injection reaction, do not give yourself more injections until your prescriber tells you to do so.
- Talk to your prescriber if you have any questions or concerns about glatiramer acetate.
- Read the patient Medication Guide that comes with your prescription because there may be new or important additional information about the medicine. The patient information leaflet explains the important things you need to know about the medicine. These include the side effects, what the medicine is used for, how to take and store it properly, and other things to watch out for when you are taking the medicine.
- To help FDA track safety issues with medicines, report side effects from glatiramer acetate or other medicines to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines and medical specialties of interest to you.

Additional Information for Health Care Professionals

- FDA is warning that cases of life-threatening anaphylaxis have been reported with multiple sclerosis medicine glatiramer acetate, resulting in hospitalization and death. This reaction can occur after the first dose or after injections administered any time while on treatment, even after an injection given several years after starting the medicine. In most of the reported cases, anaphylaxis occurred within an hour of administering the medicine.
- We are adding the risk of anaphylaxis and recommendations for patients and health care professionals to a new Boxed Warning, FDA's most prominent warning, and to the Warnings and Precautions section of the glatiramer acetate prescribing information.
- Be aware that initial symptoms of anaphylaxis might overlap with those of an immediate postinjection reaction, which could lead to a delay in recognizing and treating anaphylaxis.
- Educate patients on the signs and symptoms of immediate post-injection reactions, which are common, typically occur within minutes after the injection, and can involve symptoms such as flushing, chest pain, palpitations, anxiety, shortness of breath, rash, or hives. These symptoms are generally transient and resolve without specific treatment within 30 minutes. Instruct them to contact their prescriber if they experience any of these symptoms and discontinue taking the medicine until instructed to restart.
- Explain the signs and symptoms of anaphylaxis and instruct patients to stop taking glatiramer acetate and seek immediate medical attention by going to an emergency room or calling 911 if they develop these symptoms.
- Do not restart the medicine in patients that experience anaphylaxis unless a clear alternative etiology is identified.
- Encourage patients to read the patient Medication Guide that comes with their prescription because there may be new or important additional information about the medicine.

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- To help FDA track safety issues with medicines, report adverse events involving glatiramer acetate or other medicines to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines and medical specialties of interest to you.

Data Summary

FDA reviewed 82 serious cases of anaphylaxis worldwide associated with glatiramer acetate in the FAERS database and medical literature[2-8] since the product was approved in December 1996 through May 2024. Of the 82 patients, 51 were hospitalized for anaphylaxis, including 13 who required care in the intensive care unit, and six died. Most of these reactions occurred within one hour of injection. The median time to onset of anaphylaxis from starting glatiramer acetate was 5 months, ranging from one day to 72 months as follows: 12 patients within one month of starting the medicine, 48 patients between one and 12 months after starting, and 19 patients more than 12 months after starting it. One patient case described shock and sudden death after the first dose, and the duration of treatment was not reported for three patients. Treatments reported in patients who experienced anaphylaxis included epinephrine or adrenaline (n=32), corticosteroids (n=21), mechanical ventilation (n=5), and cardiopulmonary resuscitation (n=1). For context, there are more than 3 million patient-years of exposure to glatiramer acetate in the postmarket setting from 1996 through 2023.

References

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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

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

Cyclopentolate Hydrochloride Ophthalmic Solution

Desmopressin Acetate Spray

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Dexamethasone Sodium Phosphate Injection

Dexmedetomidine Hydrochloride Injection

Dextrose 50% 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

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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 Hydrochloride Tablet, Extended Release

Methylprednisolone Acetate Injection

Metronidazole Injection

Midazolam Hydrochloride Injection

Morphine Sulfate Injection

Naltrexone Hydrochloride Tablet

Nitroglycerin Injection

Oxazepam Capsule

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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

Semaglutide Injection

Sodium Acetate Injection

Sodium Bicarbonate Injection

Sodium Chloride 0.9% Injection

Sodium Chloride 0.9% Irrigation

Sodium Chloride 23.4% Injection

Somatropin Injection

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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

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