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Drug Information Update

September 2024

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Newly Available Generics

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Lofexidine HCl Oral Tablet 0.18 MG	Lucemyra	Florida Pharmaceutical Product	• The mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.
Oxcarbazepine ER oral tablet extended release 24 hour 150mg, 300mg, 600mg	Oxtellar XR	Apotex	• For the treatment of partial-onset seizures in patients 6 years of age and older.
Dasatinib oral tablet 20mg, 50mg, 70mg, 80mg, 100mg, 140mg	Sprycel	Apotex	• For the treatment of newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. • For the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib. • For the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy. • For the treatment of pediatric patients 1 year of age and older with Ph+ CML in chronic phase. • For the treatment of pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy.
Tazarotene 0.05% Cream	Tazorac	Padagis	• For the topical treatment of plaque psoriasis.

New Drug Entities/Strengths/Combinations

Drug Name	Generic Name	Description
Vabysmo Intravitreal Solution Prefilled Syringe 6 MG/0.05ML	faricimab-svoa	New dosage form. Approved July 2024, just now launching. Injectable VEGF andangiopoietin-2 inhibitor for the treatment of wet, or neovascular, age-related macular degeneration (AMD) and diabetic macular edema (DME).
Lazcluze Oral Tablet 80 MG, 240 MG	lazertinib mesylate	New entity. Oral EGFR kinase inhibitor indicated in combination with Rybrevant (amivantamab-vmjw) for first-line treatment of locally advanced or metastatic non–small cell lung cancer (NSCLC) with certain EGFR mutations.
Tevimbra Intravenous Solution 100 MG/10ML	tislelizumab-jsgr	New entity. Approved March 2024, just now launching. IV PD-(L)1 inhibitor indicated for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor. Dosed every 3 weeks.
Moderna COVID-19 Vac 6m-11y Intramuscular Suspension Prefilled Syringe 25 MCG/0.25ML	COVID-19mRNA vac 6m-11y moderna	COVID-19 vaccine. Targets the KP.2 variant of SARS-CoV-2 to help prevent COVID-19 in individuals 6 months of age and older.
Onyda XR Oral Suspension Extended Release 0.1 MG/ML	clonidine hydrochloride	New entity. Once a day extended-release oral suspension for the treatment of ADHD as monotherapy or as adjunctive therapy to approved CNS stimulant medications in patients six years and older. Approved in May 2024 and just launching. 505b2 approval.
Glimepiride Oral Tablet 3 MG	glimepiride	New strength. Previously only available in 1mg, 2mg, and 4mg tablets.
Yorvipath Subcutaneous Solution Pen-injector 168 MCG/0.56ML, 294 MCG/0.98ML, 420 MCG/1.4ML	palopegteriparatide	New entity. Prodrug of parathyroid hormone (PTH[1-34]) for the treatment of hypoparathyroidism in adults. Developed under the name TransCon PTH. The only other approved PTH analog for hypoparathyroidism is Natpara; however, the product was recalled in 2019 and Takeda announced that it will discontinue manufacturing of Natpara by the end of 2024.
Tryvio Oral Tablet 12.5 MG	aprocitentan	Endothelin receptor antagonist indicated for the treatment of hypertension in combination with other antihypertensive drugs to lower blood pressure in adult patients who are not adequately controlled on other drugs. Includes a Boxed Warning regarding embryo-fetal toxicity. Due to this risk, Tryvio will only be made available through a Risk Evaluation and Mitigation Strategy (REMS) program. Approved in March 2024, just now launching.

Drug Name	Generic Name	Description
Novavax COVID-19 Vaccine Intramuscular Suspension Prefilled Syringe 5 MCG/0.5ML	COVID-19 Subunit Vacc-Novavax	COVID-19 vaccine
Rytelo Intravaneous Solution Reconstituted 47 MG, 188 MG	imetelstat	New entity. Indicated for the treatment of adult patients with low- to intermediate-risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring four or more red blood cell (RBC) units over 8 weeks who have not responded to, have lost response to, or are ineligible for erythropoiesis-stimulating agents. Rytelo will compete with Reblozyl (luspatercept) for the treatment of lower risk-MDS with anemia.
Veltassa Oral Packet 1 GM	patiromer sorbitex calcium	New dosage strength. Approved in 2023, just now launching. Already available in 8.4 gram, 16.8 gram, and 25.2 gram packets. Potassium binder indicated for the treatment of hyperkalemia. Veltassa will compete with Lokemla and SPS.
Potassium Chloride ER Oral Tablet Extended Release 15 MEQ	Potassium chloride	New dosage form of 15 MEQ. Already available in potassium chloride CRYSTAL 15MEQ tablets. Indicated for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient.
Ebglyss Subcutaneous Solution Auto-injector 250 MG/2ML	lebrikizumab	New entity. IL13 inhibitor for the treatment of adults and children 12 years of age and older who weigh at least 88 pounds (40 kg) with moderate to severe atopic dermatitis (AD) that is not well controlled with topical prescription therapies. Subcutaneous injection that can be used with or without topical corticosteroids
Tecentriq Hybreza Subcutaneous Solution 1875-30000 MG-UT/15ML	atezolizumab and hyaluronidase-tqjs	Subcutaneous (SC) formulation of Tecentriq. Anti-programmed cell death-ligand 1 (PD-L1) cancer immunotherapy used for the same indications as the IV version, including non–small cell lung cancer (NSCLC), small cell lung cancer (SCLC), hepatocellular carcinoma (HCC), melanoma, and alveolar soft part sarcoma (ASPS). The SC administration of Tecentriq Hybreza is notably quicker, taking approximately 7 minutes, compared to the 30–60 minutes required for IV infusion.
Tremfya Intravenous Solution 200 MG/20ML, Auto-injector 200 MG/2ML, Prefilled Syringe 200 MG/2ML	guselkumab	New dose and formulation. Tremfya 200 mg formulations are indicated for ulcerative colitis induction and maintenance doses (100mg formulations used for plaque psoriasis and psoriatic arthritis).
Femlyv Oral Tablet Disintegrating 1-0.02 MG	norethindrone acetate-ethinyl estradiol	First and only orally disintegrating tablet for contraception. 505b2 approval.
Ocrevus Zunovo Subcutaneous Solution 920-23000 MG-UT/23ML	ocrelizumab & hyaluronidase-ocsq	Anti CD20 antibody for the treatment of adults with relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active

Drug Name	Generic Name	Description
		secondary progressive disease, and adults with primary progressive multiple sclerosis (PPMS). Ocrevus Zunovo is administered every 6 months by a healthcare provider, like the intravenous (IV) formulation of Ocrevus. However, the SC administration of Ocrevus Zunovo is notably faster, taking approximately 10 minutes, compared to the 2 hours or more required for IV infusion of Ocrevus.
Miplyffa Oral Capsule 47 MG, 62 MG, 93 MG, 124 MG	arimoclomol	New entity. Approved in combination with the enzyme inhibitor miglustat to treat neurological symptoms associated with Niemann-Pick Disease Type C (NPC) in adults and children 2 years of age and older. First approved agent for treatment of NPC, mechanism of action is unknown.
Dolobid Oral Tablet 250 MG	diflunisal	New/relaunch of the 250mg tablet. Analgesic indicated for pain and osteoarthritis.

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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†
Tremfya	guselkumab 200 mg/2ml subcutaneous prefilled syringe, 200mg/2ml subcutaneous pen-injector, 200 mg/2ml vial	Janssen Biotech, Inc.	• For the treatment of moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy • For the treatment of active psoriatic arthritis • **For the treatment of moderately to severely active ulcerative colitis**
Dupixent	dupilumab 200 mg/1.14 ml, 300 mg/2 ml subcutaneous syringe; dupilumab 200 mg/1.14 ml, 300 mg/2 ml subcutaneous pen-injector	Sanofi/Regeneron	• Atopic Dermatitis: for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids. • Asthma: as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. *Limitations of Use:* Not for the relief of acute bronchospasm or status asthmaticus. • Chronic Rhinosinusitis with Nasal Polyps: as an add-on maintenance treatment in adult **and pediatric patients aged 12 years and older** with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP). • Eosinophilic Esophagitis: for the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE). • Prurigo Nodularis: for the treatment of adult patients with prurigo nodularis (PN)**.** • **Chronic Obstructive Pulmonary Disease (COPD): as an add-on maintenance treatment of adult patients with inadequately**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			controlled COPD and an eosinophilic phenotype. Limitations of Use: Not for the relief of acute bronchospasm.
Fasenra	benralizumab 10mg/0.5ml prefilled syringe, 30mg/ml prefilled syringe, 30mg/ml autoinjector	AstraZeneca	• Add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype • **Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)**
Kisqali	ribociclib 200mg tablets	Novartis	• **In combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence** • For the treatment of adults with HR-positive, HER2-negative advanced or metastatic breast cancer in combination with: ○ an aromatase inhibitor as initial endocrine-based therapy; or ○ fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy
Keytruda	pembrolizumab 100 mg/4 ml intravenous vial	Merck	• **In combination with pemetrexed and platinum chemotherapy, as first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma (MPM)** *Note: Keytruda 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. • **In combination with carboplatin and pemetrexed for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor. • 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.
Sarclisa	isatuximab-irfc 100mg/5ml vial, 500mg/25ml vial	Sanofi-Aventis	• In combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor • In combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy • **In combination with bortezomib, lenalidomide and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant (ASCT)**
Bimzelx	bimekizumab-bkzx 160mg/ml prefilled syringe and single-dose prefilled autoinjector	UCB	• Treatment of moderate to severe plaque psoriasis (PSO) in adults who are candidates for systemic therapy or phototherapy • **Treatment of adults with active psoriatic arthritis (PsA)** • **Treatment of adults with active non-radiographic axial spondyloarthritis (nraxSpA) with objective signs of inflammation** • **Treatment of adults with active ankylosing spondylitis (AS)**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Tagrisso	osimertinib 40 mg, 80 mg oral tablets	AstraZeneca	• Adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test • **Treatment of adult patients with locally advanced, unresectable (stage III) NSCLC whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test** • First-line treatment of adult patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test • In combination with pemetrexed and platinum-based chemotherapy, for first-line treatment of adult patients with locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test • Treatment of adult patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy

Recalls

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Heparin (Heparin Sodium in 0.9% Sodium Chloride Injection), 2,000 units per 1,000 mL (2 units/mL), 1000 mL Sterile Single Dose Container, Rx Only, Baxter USA, NDC 0338-0433-04	Class I	Drugs	Lot # N008235, Exp 8/31/2024	Microbial Contamination of Sterile Products; out of limit results obtained for endotoxin testing.	Baxter Healthcare Corporation
Indomethacin Extended-Release Capsules, USP, 75 mg, packaged in a) 60-count bottle (NDC 68462-325-60) and b) 90-count bottle (NDC 68462-325-90), Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Plot No. 2 Phase-2, Pharma Zone, SEZ, Pithampur, Dist-Dhar, Madya Pradesh - 454775, India Mfg Llc. No: 25/9/2010, Manufactured for Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430.	Class II	Drugs	Lot#: 17240105, Exp 12/31/2025	Failed Dissolution Specifications: below specification results	Glenmark Pharmaceuticals Inc., USA
IBU Ibuprofen Tablets, USP, 800 mg, Rx Only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, Made in India, a)NDC 55111-684-01 - 100 Tablets per bottle, b)NDC 55111-684-05 - 500 Tablets per bottle.	Class II	Drugs	a) NDC 55111-684-01 Lots C2207525, Exp 5/31/2026; C2212902, Exp 11/30/2026. b) NDC 55111-684-05 Lots C2207526, Exp 5/31/2026; C2210751, C2210752, Exp 9/30/2026; C2212765, C2212766, Exp 11/30/2026; C2301027, C2301063, C2301187, C2301188, C2301247, Exp 12/31/2026; C2301356, C2301388, C2301494, C2301478, C2301617, Exp	Failed impurities/degradation specifications: results for unknown impurity, were 0.13% and 0.11% respectively, exceeding the 0.10% specification limit.	Dr. Reddy's Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			1/31/2027; C2303381, C2303432, C2303565, C2303630, C2303643, C2303710, Exp 2/28/2027; C2303879, C2303806, C2303895, C2303963, C2304263, C2304264, C2304130, C2304163, C2304427, Exp 3/31/2027.		
IBU Ibuprofen Tablets, USP, 600 mg, Rx Only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, Made in India, a)NDC 55111-683-01 - 100 Tablets per bottle, b)NDC 5511-683-05 - 500 Tablets per bottle.	Class II	Drugs	a)NDC 55111-683-01 Lots C2207527, Exp 5/31/2026; C2210864, Exp 9/30/2026; C2213018, Exp 11/30/2026. b)NDC 5511-683-05 Lots C2207528, Exp 5/31/2026; C2210860, Exp 9/30/2026; C2213016, C2213017, Exp 11/30/2026; C2301852, C2302056, C2302057, Exp 1/31/2027.	Failed impurities/degradation specifications: results for unknown impurity, were 0.13% and 0.11% respectively, exceeding the 0.10% specification limit.	Dr. Reddy's Laboratories, Inc.
IBU Ibuprofen Tablets, USP, 400 mg, Rx Only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, Made in India, a) NDC 55111-682-01 - 100 Tablets per bottle, b) NDC 55111-682-05 - 500 Tablets per bottle.	Class II	Drugs	a)NDC 55111-682-01 Lots C2207529, Exp 5/31/2026; C2210993, Exp 9/30/2026. b)NDC 55111-682-05 Lots C2207530, Exp 5/31/2026; C2210992, C2210994, Exp 9/30/2026; C2213304, C2213305, Exp 11/30/2026.	Failed impurities/degradation specifications: results for unknown impurity, were 0.13% and 0.11% respectively, exceeding the 0.10% specification limit.	Dr. Reddy's Laboratories, Inc.
Ibuprofen Tablets, USP 400mg, Generic for Motrin, Pkg Size: 30 tablets per bottle, Mfg:	Class II	Drugs	Lot: B0223H, Exp: 5/31/2026; C3023H, Exp: 9/30/2026.	Failed Impurities/Degradation Specifications - at 18-month Stability testing	Preferred Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Dr. Reddy's Laboratories, Louisiana, Shreveport, NDC 68788-9110-03.					
Cefixime for Oral Suspension USP, 100 mg/5 mL, 50 mL bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202, Manufactured by: Lupin Limited, Mandideep 462 046 INDIA, NDC 68180-405-01	Class II	Drugs	Lot #: F201517, Exp 11/30/2024	Subpotent Drug- An out of specification (OOS) result observed in assay test during 18-month long term stability study.	Lupin Pharmaceuticals Inc.
Semaglutide, 2 mL (2.5mg/mL), Compounded RX Product, Multidose SC inj, glass vial, ProRx, 267-565-7008, NDC 84139-225-01	Class II	Drugs	Lot #: ProRx031924, BUD 09/18/2024 ProRx032624, BUD 09/25/2024 ProRx041324, BUD 10/12/2024	Lack of Assurance of Sterility	ProRx LLC
Tirzepatide 2 mL (10 mg/mL) and 20 mg/mL, 2mL Multidose SC Injection vials, Compounded Rx Product, ProRx 267-565-7008, NDC 84139-210-01	Class II	Drugs	Lot # ProRx040924-1, BUD 10/08/2024	Lack of Assurance of Sterility	ProRx LLC
SEMAGLUTIDE 5mg/2mL (2.5mg/mL), Rx Only 2 mL Multiple Dose Vial, Rx Only, Compounded Drug, Mfd by: ProRX Exton, PA19341, NDC 84139-225-01	Class II	Drugs	Lot #: ProRx052424, BUD 11/23/2024 ProRx060724, BUD 12/06/2024 ProRx061124, BUD 12/10/2024 ProRx061924, BUD 12/18/2024	Lack of Assurance of Sterility	ProRx LLC
SEMAGLUTIDE 10mg/4mL (2.5mg/mL), 4 mL Multiple Dose Vial, Rx Only, Compounded Drug, Mfd by: ProRX Exton, PA19341, NDC 84139-225-04	Class II	Drugs	ProRx061424, BUD 12/13/2024	Lack of Assurance of Sterility	ProRx LLC
Semaglutide / Cyanocobalamin Injection: 2.5/0.5 mg/mL, 2 mL Multiple Dose Vial, Compounded Rx Product, ProRX 267-565-7008, NDC 84139-225-02	Class II	Drugs	Lot # ProRx031924-1, BUD 09/18/2024	Lack of Assurance of Sterility	ProRx LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
TIRZEPATIDE 20 mg/2mL (10/mg/mL), Rx Only, 2mL Multiple Dose Vial, Mfd by: ProRx Exton, PA, 19341, NDC 84139-210-01	Class II	Drugs	Lot # ProRx051424, BUD 11/13/2024	Lack of Assurance of Sterility	ProRx LLC
TIRZEPATIDE 60 mg/3mL (20/mg/mL), Rx Only, 3mL Multiple Dose Vial, Mfd by: ProRx Exton, PA, 19341, NDC 84139-210-02	Class II	Drugs	Lot# ProRx052224, BUD 11/21/2024 ProRx061024, BUD 12/09/2024	Lack of Assurance of Sterility	ProRx LLC
BARRIER THERAPY SKIN PROTECTANT CREAM (1% colloidal oatmeal), 10 FL OZ/296 ML-tube, Distributed By: Prequel, LOS ANGELES, CA 90069. UPC 8 10129 11007 4	Class II	Drugs	Lot: X4054A, Exp: 2/2026; X4136A, X4137A, X4138A, Exp: 5/2026	Microbial contamination of non-sterile Products -	PREQUEL SKIN
Just Right 5000, 1.1% Sodium Fluoride, Candy Apple Flavor, Net Wt. 3.4oz (97g), Rx Only, Manufactured for Elevate Oral Care, LLC in the U.S.A with imported pump, 346 Pike Rd, Suite 5, West Palm Beach, FL 33411, NDC 57511-002-1	Class III	Drugs	Lot #G073DC, Exp 3/31/2026	LABELING: LABEL MIX-UP.	Elevate Oral Care
AcetaZOLAMIDE Tablets, USP, 125 mg, 100 count bottled, Rx Only, Distributed by: Advagen Pharma Limited, Plainsboro, NJ, Manufactured by Rubicon Research Private Limited, Thane, India NDC 72888-047-01	Class III	Drugs	Lot # 30575HF1, exp. date, Nov 2026 NDC# 72888-047-01	Discoloration	Rubicon Research Private Limited

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

FDA Drug Safety Communications

[9/12/2024] FDA adds warning about rare occurrence of serious liver injury with use of Veozah (fezolinetant) for hot flashes due to menopause

The U.S. Food and Drug Administration (FDA) is warning that Veozah (fezolinetant), a medicine used to treat hot flashes due to menopause, can cause rare but serious liver injury. If there are signs and symptoms suggesting liver injury, stopping the medicine could prevent worsening liver injury and potentially return liver function to normal.

We added a warning about the risk of liver injury to the existing warning about elevated liver blood test values and required liver blood testing in the prescribing information for Veozah. We made this update after reviewing a postmarketing report of a patient with elevated liver blood test values and signs and symptoms of liver injury after taking the medicine for about 40 days. We also added new recommendations for patients and health care professionals about increasing the frequency of liver blood testing, adding monthly testing for the next 2 months after starting Veozah, and then at months 3, 6, and 9 of treatment as already recommended. The updated prescribing information also instructs patients to stop the medicine immediately and contact the health care professional who prescribed the medicine if signs and symptoms of liver injury occur.

Veozah (fezolinetant) is a nonhormonal prescription medicine approved in May 2023 to reduce the frequency and severity of moderate to severe hot flashes caused by menopause. The medicine is in a drug class called neurokinin 3 (NK3) receptor antagonists. It works to restore the balance between estrogen hormones and a brain chemical called neurokinin B (NKB) by blocking the activities of the NK3 receptor, which plays a role in the brain's control of body temperature.

Patients should stop taking Veozah immediately and contact your health care professional who prescribed the medicine if you experience signs and symptoms that suggest liver problems. These include feeling more tired than usual; nausea; vomiting; unusual itching; light-colored stools; yellowing of the eyes or skin, called jaundice; dark urine; swelling in the stomach or belly area, called the abdomen; or pain in the right upper abdomen. Your health care professional will do blood tests before starting Veozah and during treatment to check and monitor how well your liver is working. Talk to your health care professional about the risks and benefits of taking Veozah and discuss any questions or concerns you may have, including about possible alternative treatments.

Health care professionals should conduct hepatic laboratory testing before prescribing Veozah, then every month for the first three months after patients start treatment, and then at months 6 and 9 of treatment. When prescribing Veozah, inform patients about the risk of elevated liver blood test values that may occur during treatment and the rare but serious risk of liver injury, and advise them of the need for regular liver blood testing. Discuss the signs and symptoms of liver injury and instruct patients to stop Veozah immediately and contact the health care professional who prescribed the medicine if they develop these any time during treatment.

We reviewed a postmarketing case* of serious liver injury in a patient who experienced symptoms of fatigue, nausea, itching, yellow eyes and skin, light-colored stools, and dark urine within 40 days of starting Veozah. The patient's liver blood test values were elevated, including abnormal liver enzymes and bilirubin levels. After stopping the medicine, the patient's symptoms gradually went away, and blood test values slowly returned to normal.

*The case was reported to the FDA Adverse Event Reporting System (FAERS) database.

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

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

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

Triamcinolone Acetonide Injection

Triamcinolone Hexacetonide Injection

Valproate Sodium Injection

Vecuronium Bromide Injection

Vinblastine Sulfate Injection

Vitamin A Palmitate Injection