PharmNotes

Monthly Communications

May 2025

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Drug Safety Alert Notification

The Drug Safety Communications are provided by the U.S. Food and Drug Administration and are intended to offer important information to patients and health care providers about new safety issues regarding certain medications. This helps prescribers and health care professionals be informed so that decisions regarding the treatment of patients are made accordingly.

Safety Alert	Date	Additional Information
FDA and CDC Recommend Pause in Use of Ixchiq (Chikungunya Vaccine, Live) in Individuals 60 Years of Age and Older While Post Marketing Safety Reports are Investigated	5/9/2025	The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) are recommending a pause in the use of Ixchiq (Chikungunya Vaccine, Live) in individuals 60 years of age and older while the Agencies investigate postmarketing reports of serious adverse events, including neurologic and cardiac events, in individuals who have received the vaccine. FDA will conduct an updated benefit-risk assessment for the use of Ixchiq in individuals 60 years of age and older. In addition, FDA and CDC will continue the evaluation of postmarketing safety reports for Ixchiq. While the safety of Ixchiq for use in individuals 60 years of age and older is being further assessed, FDA and CDC are recommending a pause in use of the vaccine in this age group. FDA and CDC will update the public when the Agencies complete their evaluation of this safety issue.

FDA requires warning about rare but severe itching after stopping long-term use of oral allergy medicines cetirizine or levocetirizine (Zyrtec, Xyzal, and other trade names)	5/16/2025	The Food and Drug Administration (FDA) is warning that patients stopping the oral allergy medicines cetirizine (Zyrtec) or levocetirizine (Xyzal) after long-term use may experience rare but severe itching. These medicines are available in prescription and over-the-counter (OTC) forms. Reported cases were rare but sometimes serious, with patients experiencing widespread, severe itching that required medical intervention. As a result, they are revising the cetirizine and levocetirizine prescribing information to include a new warning about this risk. They will subsequently request that manufacturers add a warning about pruritus to the Drug Facts Label of the OTC versions.

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Avmapki Fakzynja™ Co-Pack (avutometinib capsules; defactinib tablets), co-packaged for oral use

FDA-Approved Indication

For the treatment of adult patients with KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) who have received prior systemic therapy.

Dosage & Administration

- Avmapki: 3.2 mg administered orally twice weekly (Day 1 and Day 4) for the first 3 weeks of each 4-week cycle.
- Fakzynja: 200 mg administered orally twice daily for the first 3 weeks of each 4-week cycle.

Dosage Forms & Strengths

- Avmapki Capsules: 0.8mg of avutometinib
- Fakzynja Tablets: 200mg of defactinib

Contraindications

None

Common Adverse Reactions

Increased creatine phosphokinase, nausea, fatigue, increased aspartate aminotransferase, rash, diarrhea, musculoskeletal pain, edema, decreased hemoglobin, increased alanine aminotransferase, vomiting, increased blood bilirubin, increased triglycerides, decreased lymphocyte count, abdominal pain, dyspepsia, dermatitis acneiform, vitreoretinal disorders, increased alkaline phosphatase, stomatitis, pruritus, visual impairment, decreased platelet count, constipation, dry skin, dyspnea, cough, urinary tract infection, and decreased neutrophil count.

Warnings & Precautions

- Ocular Toxicities
- Serious Skin Infections
- Hepatotoxicity
- Rhabdomyolysis
- Embryo-Fetal Toxicity

Drug Interactions

- Strong and moderate CYP3A4 inhibitors
- Strong and moderate CYP3A4 inducers
- Warfarin
- Gastric acid reducing agents

Use in Specific Population

- Lactation: Advise not to breastfeed
- Infertility: May impair fertility in males and females

Clinical Studies

The approval came from the open-label, phase 2 RAMP 201 study which included 57 adult patients with measurable KRAS-mutated recurrent LGSOC. Patients were required to have received at least one prior systemic therapy, including a platinum-based regimen. The major efficacy outcome measure was overall response rate. Findings showed a confirmed overall response rate of 44%. The duration of response ranged from 3.3 to 31.1 months.

Place in Therapy

Surgical cytoreduction is the preferred treatment option for LGSOC; however, when unresectable disease is present, systemic therapy is the option for treatment. Chemotherapy, especially platinum-based therapy, has been used in both the primary and recurrent treatment settings. Avmapki Fakzynja Co-Pack is the first FDA-approved novel treatment or novel combination treatment specifically for KRAS-mutated recurrent LGSOC. About 6000–8000 women in the United States are living with LGSOC.

New FDA-Approved Drug Products

New Molecular Entity

Specialty

Emrelis™ (telisotuzumab vedotin-tllv) for injection, for intravenous use

FDA-Approved Indication

For the treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression [≥50% of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy.

Dosage & Administration

1.9mg/kg administered every two weeks until disease progression or unacceptable toxicity.

Dosage Forms & Strengths

For injection: 20 mg or 100 mg of telisotuzumab vedotin-tllv as a lyophilized powder in a single-dose vial.

Contraindications

None

Common Adverse Reactions

Peripheral neuropathy, fatigue, decreased appetite, and peripheral edema.

Warnings & Precautions

- Peripheral Neuropathy
- Interstitial Lung Disease (ILD)/Pneumonitis
- Ocular Surface Disorders
- Infusion-Related Reactions (IRR)
- Embryo-Fetal Toxicity

Drug Interactions

- Strong CYP3A Inhibitors

Use in Specific Populations

- Severe or Moderate Hepatic Impairment: Avoid use.
- Lactation: Advise not to breastfeed.
- Infertility: May impair fertility.

Clinical Studies

The approval came from the ongoing open-label, single-arm, phase 2 LUMINOSITY study. This study evaluated telisotuzumab vedotin in patients with epidermal growth factor receptor (EGFR) wild-type, locally advanced or metastatic non-squamous NSCLC with high c-Met protein overexpression who had received no more than 1 line of prior chemotherapy. The primary endpoint was overall response rate (ORR). Results showed an ORR of 35%, all of which were partial responses, and a median duration of response of 7.2 months. Furthermore, 59% of responders had a response lasting at least 6 months and 21% of responders had a response lasting at least 12 months.

Place in Therapy

The NCCN Guidelines recommend that, if a driver mutation is identified, the best choice of therapy is a targeted therapy. Emrelis is a first-in-class c-Met-directed antibody and microtubule inhibitor conjugate and is also the first FDA-approved treatment specifically for tumors with c-Met overexpression.

New FDA-Approved Drug Products

New Molecular Entity

Tryptyr® (acoltremon ophthalmic solution) 0.003%

FDA-Approved Indication

For the treatment of the signs and symptoms of dry eye disease.

Dosage & Administration

Instill one drop in each eye twice daily (approximately 12 hours apart).

Dosage Forms & Strengths

Ophthalmic solution: 0.003% acoltremon in a single-dose vial.

Contraindications

None

Common Adverse Reactions

Instillation site pain.

Warnings & Precautions

- To avoid the potential for eye injury and contamination, do not touch the vial tip to the eye or other surfaces.

Clinical Studies

The approval came from two randomized, double-masked, vehicle-controlled studies (COMET-2 and COMET-3) in a total of 931 patients with dry eye disease. Patients were randomized to Tryptyr or placebo for 90 days. The primary endpoint was the percentage of patients achieving at least a 10 mm improvement from baseline in Schirmer score at day 14. In COMET-2, the percentage of patients meeting the primary endpoint was 42.6% and 8.2% with Tryptyr and vehicle, respectively, while in COMET-3, the percentage of patients meeting the primary endpoint was 53.2% and 14.4% with Tryptyr and vehicle, respectively.

Place in Therapy

Tryptyr is a first-in-class transient receptor potential melastatin 8 (TRPM8) thermoreceptor agonist. This mechanism of action appears to cause trigeminal nerve activation, resulting in increased tear production.

New FDA-Approved Drug Products

New Molecular Entity

mNexspike (COVID-10 Vaccine mRNA), injectable suspension for intramuscular use

FDA-Approved Indication

For active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). mNexspike is approved for use in individuals who have been previously vaccinated with any COVID-19 vaccine and are: 65 years of age and older, or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

Dosage & Administration

Administered by intramuscular injection as a single 0.2 mL dose at least 3 months after the last dose of COVID-19 vaccine.

Dosage Forms & Strengths

A single dose 0.2mL injectable suspension

Contraindications

Do not administer mNexspike to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of mNexspike or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of Spikevax (COVID-19 Vaccine, mRNA) or any Moderna COVID-19 vaccine authorized for emergency use.

Common Adverse Reactions

Pain in the injection site, headache, fatigue, myalgia, axillary swelling or tenderness, chills, arthralgia, nausea and vomiting.

Warnings & Precautions

Postmarketing data with authorized or approved mRNA COVID19 vaccines have demonstrated increased risks of myocarditis and pericarditis, with onset of symptoms typically in the first week following vaccination. The observed risk has been highest in males 12 years through 24 years of age.

Clinical Studies

The approval came from the NextCOVE study, a Phase 3, randomized, observer-blind, active-controlled trial, which included around 11,400 participants 12 years of age and older. Participants were randomized (1:1) to receive either mNexspike or Spikevax, Moderna's original COVID-19 vaccine. The primary outcome of the study was to demonstrate noninferior vaccine efficacy against COVID-19 starting 14 days after mNexspike compared with that after the comparator vaccine. Results demonstrated mNexspike had a 9.3% higher relative vaccine efficacy compared to Spikevax. Also, a 13.5% higher vaccine efficacy was observed with mNexspike.

Place in Therapy

In its trial, mNexspike had a greater immune response against omicron BA.4/BA.5 and the original strain of SARS-CoV-2 than Spikevax, particularly in older patients. Although mNexspike offers a lower-dose option when compared to Spikevax, it is only approved for older adults and patients at high risk for severe COVID-19. Spikevax is approved for vaccination against COVID-19 in all individuals 12 years of age and older.

New FDA-Approved Drug Products

New Biosimilar Product

Specialty

Starjemza™ (ustekinumab-hmny) injection, for subcutaneous or intravenous use

FDA-Approved Indication

For the treatment of adult and pediatric patients 6 years and older: [1] moderate to severe plaque psoriasis (PSO); [2] active psoriatic arthritis (PSA). For the treatment of adults with: [1] moderately to severely active Crohn's disease; [2] moderately to severe active ulcerative colitis.

Dosage & Administration

Refer to package insert for administration instructions.

Dosage Forms & Strengths

Subcutaneous:

- Injection: 45 mg/0.5 mL or 90 mg/mL solution in a single-dose prefilled syringe
- Injection: 45 mg/0.5 mL solution in a single-dose vial

Intravenous:

- Injection: 130 mg/26 mL (5 mg/mL) solution in a single-dose vial

Contraindications

Clinically significant hypersensitivity to ustekinumab products or to any of the excipients in Starjemza.

Common Adverse Reactions

Upper respiratory tract infection, headache, fatigue, vomiting, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, sinusitis, abdominal pain, influenza, fever, diarrhea and nausea.

Warnings & Precautions

- Infections
- Theorical Risk for Particular Infections
- Tuberculosis (TB)
- Malignancies
- Hypersensitivity Reactions
- Posterior Reversible Encephalopathy Syndrome (PRES)
- Immunizations
- Noninfectious Pneumonia

Clinical Studies

The FDA's decision is based on a comprehensive data package and the totality of evidence, including the results from a phase III study demonstrating biosimilarity between Starjemza and reference Stelara.

Place in Therapy

Starjemza is the eighth FDA-approved biosimilar to Stelara. Other ustekinumab biosimilars available include Wezlana (ustekinumab-auub), Selarsdi (ustekinumab-aekn), Pyzchiva (ustekinumab-ttwe), Otulfi (ustekinumab-aauz), Yesintek (ustekinumab-kfce), and Steqeyma (ustekinumab-stba).

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Brekiya® (dihydroergotamine mesylate) injection for subcutaneous use

FDA-Approved Indication

For the acute treatment of migraine with or without aura and the acute treatment of cluster headaches in adults.

Dosage & Administration

1mg administered subcutaneously as a single 1mL autoinjector. Do not exceed 3mg (3 doses) in a 24-hour period. Do not exceed 6mg (6 doses) in a week.

Dosage Forms & Strengths

Injection: 1 mg/mL dihydroergotamine mesylate as a 1 mL single-dose autoinjector.

Contraindications

- Concomitant use of strong CYP3A4 inhibitors
- Ischemic heart disease or coronary artery vasospasm
- Uncontrolled hypertension, peripheral arterial diseases, sepsis, following vascular surgery, or severe hepatic or renal impairment
- Concomitant use of other 5-HT_1 agonist or ergotamine-containing or ergo-type medications within 24 hours
- Hypersensitivity to dihydroergotamine, ergot alkaloids, latex or any of the ingredients in Brekiya
- Concomitant use with peripheral and central vasoconstrictors

Common Adverse Reactions

Coronary artery vasospasm, transient myocardial ischemia, myocardial infarction, ventricular tachycardia, ventricular fibrillation.

Drug Interactions

- Beta Blockers/Nicotine
- Selective Serotonin Reuptake Inhibitors

Warnings & Precautions

- ***BBW*:** Peripheral Ischemia following Coadministration with Strong CYP3A4 Inhibitors
- Myocardial Ischemia and/or Infarction, Other Cardiac Adverse Reactions, and Fatalities
- Cerebrovascular Adverse Reactions and Fatalities
- Other Vasospasm Related Adverse Reaction
- Medication Overuse Headache
- Preterm Labor
- Fibrotic Complication

Use in Specific Population

- Pregnancy: Based on animal data, may cause fetal harm.
- Lactation: Advise not to use during breastfeeding.

Clinical Studies

The efficacy of Brekiya was established based on previously reported drug data to support the use of this new formulation. Dihydroergotamine (DHE) has been approved since 1946 and is available in both injectable and intranasal formulations.

Place in Therapy

With this approval, Brekiya is now the first DHE autoinjector for patients to self-administer. This treatment is given subcutaneously and offers an alternative option to those who unable to respond to oral therapies adequately.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Specialty

Yutrepia™ (treprostinil) inhalation powder for oral use

FDA-Approved Indication

For the treatment of [1] Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability; [2] Pulmonary hypertension associated with interstitial lung disease (PHILD; WHO Group 3) to improve exercise ability.

Dosage & Administration

For oral inhalation only. Should be administered 3 to 5 times per day. The contents of each capsule can be inhaled in 2 breaths.

Dosage Forms & Strengths

Inhalation powder contained in capsules: 26.5 mcg, 53 mcg, 79.5 mcg, 106 mcg

Contraindications

None

Common Adverse Reactions

Cough, headache, throat irritation, and dizziness.

Warnings & Precautions

- Treprostinil may cause symptomatic hypotension.
- Treprostinil inhibits platelet aggregation and increases the risk of bleeding.
- Dosage adjustments may be necessary if inhibitors or inducers of CYP2C8 are added or withdrawn.
- May cause bronchospasm

Clinical Studies

The efficacy of Yutrepia was established from results of clinical studies conducted for Tyvaso (treprostinil) inhalation solution, which is approved to treat PAH and pulmonary hypertension (PH) associated with interstitial lung disease ([PH-ILD]; WHO Group 3). The approval of Yutrepia was also supported by safety and pharmacological data from the Phase 3, open-label INSPIRE trial, which evaluated Yutrepia in both patients naïve to treprostinil and those transitioning from Tyvaso. This trial found Yutrepia to be safe and well tolerated in both patient groups.

Place in Therapy

There are several drug products that are FDA-approved to treat PAH and are administered through different routes including oral, inhalation, IV, and SC. On the other hand, in the treatment of PH-ILD, Tyvaso and Tyvaso DPI were the only FDA-approved products specifically for the treatment of this disease. Treprostinil is currently available via several other formulations. With the approval of Yutrepia, Tyvaso DPI will most probably be the most direct competitor it will face since both of these products are dry-powder inhaler formulations of treprostinil.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Khindivi® (hydrocortisone) oral solution

FDA-Approved Indication

Replacement therapy in pediatric patients 5 years of age and older with adrenocortical insufficiency.

Dosage & Administration

The recommended starting replacement dosage is 8 to 10 mg/m^2 daily. Higher doses may be needed based on the patient's age and symptoms of the disease.

Dosage Forms & Strengths

Oral Solution: 1mg/mL

Contraindications

Hypersensitivity to hydrocortisone or any component of Khindivi.

Common Adverse Reactions

Fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite, and weight gain.

Warnings & Precautions

- Adrenal Crisis
- Systemic Adverse Reactions Due to Inactive Ingredients
- Immunosuppression and Increased Risk of Infection with Use of a Dosage Greater Than Replacement
- Growth Retardation
- Cushing's Syndrome Due to Use of Excessive Doses of Corticosteroids
- Decrease in Bone Mineral Density
- Psychiatric Adverse Reactions
- Ophthalmic Adverse Reactions
- Gastrointestinal Adverse Reactions

Drug Interactions

- CYP3A4 Inhibitors
- CYP3A4 Inducers
- Estrogen and Estrogen-Containing Products
- Antidiabetic agents
- NSAIDs

Place in Therapy

Khindivi is the first and only FDA-approved oral solution formulation of hydrocortisone. This ready to use liquid hydrocortisone does not require refrigeration, mixing, or shaking. Khindivi is a therapeutic option for patients who have difficulty swallowing tablets or with special administration needs.

Other notable new approvals include:

Nuvaxovid® (COVID-19 Vaccine, Adjuvanted) injectable suspension, for intramuscular use

The FDA approved the recombinant protein-based vaccine Nuvaxovid (COVID-19 Vaccine, Adjuvanted) for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adults 65 years and older. Nuvaxovid is also indicated for individuals 12 through 64 years of age who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19. This vaccine has been available in the United States since July 2022 under an emergency use authorization (EUA). With now its full approval, its use is more restrictive, limiting the use in patients younger than 64 years of age to those at high risk of severe outcomes.

New First-Time Generic Approvals

First-Time Generics are the first generic forms of brand name drugs. The generic version is formulated to work in the same way as the brand-name product and provides the same clinical benefit.

Product	Manufacturer	Generic For	Therapeutic Class	Indication(s)	Market Release Date
Ticagrelor Tablets 60mg and 90mg	Several, including Teva among others	Brilinta	Hematological Agents	Prevention of Blood Clots	5/1/2025
Eslicarbazepine Acetate Oral Tablet 200mg, 400mg, 600mg and 800mg	Several including Apotex among others	Aptiom	Anticonvulsants	Adjunctive treatment of partial – onset seizures	5/6/2025
Phentermine Hydrochloride; Topiramate ER Oral capsules Extended Release 24 Hour 11.25-69mg, 15-92mg, 3.75 – 23mg and 7.5-46mg	Teva Pharmaceutical	Qsymia	ADHD/Anti-Narcolepsy/Anti-Obesity/ Anorexiants	Reduce excess body weight	5/7/2025
Halobetasol Propionate and Tazarotene Topical Lotion 0.01% / 0.045%	Taro Pharmaceutical	Duobrii	Dermatologicals	Plaque Psoriasis	2034-2035
Eltrombopag Olamine 12.5mg, 25mg, 50mg and 75mg	Camber Pharma	Promacta	Hematopoietic Agents	Thrombocytope-nia	5/13/2025
Raltegravir Potassium Tablets 600mg (base)	Lupin Pharmaceutical	Isentress HD	Antivirals	HIV Infection	2028-2029
Rivaroxaban Tablets 10mg, 15mg and 20mg	Several including Lupin, Dr. Reddy's Labs, among others	Xarelto	Anticoagulants	Treatment and Prevention of Blood Clots	2027
Emtricitabine, Rilpivirine and Tenofovir	Mylan Pharmaceuticals Inc	Complera	Antivirals	HIV Infection	Late 2025

Disoproxil Fumarate Tablets 200mg / 25mg (base) / 300mg					
Bosutinib Monohydrate Tablets 100mg (base) and 500mg (base)	Alembic Pharmaceutical Limited	Bosulif 100mg (base) and 500mg (base)	Antineoplastics and Adjunctive Therapies	Chronic Myelogenous Leukemia	Late 2025
Nilotinib Hydrochloride	Apotex	Tasigna	Antineoplastics and Adjunctive Therapies	Leukemia	5/27/2025

*Note: Various legal factors may come into play, affecting the estimated availability date.

New FDA-Approved Indications for Existing Drugs

The following table contains drugs that have gained FDA approval for the treatment of additional diseases or conditions.

Drug Name and Manufacturer	Previous Indication(s)	New Indication
Welireg (belzutifan) From: Merck Sharp Dohme	[1] Von Hippel-Lindau (VHL) disease; [2] Advanced renal cell carcinoma.	[3] For the treatment of adult and pediatric patients 12 years and older with locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma (PPGL).
Zynyz (retifanlimab-dlwr) From: Incyte Corp	For the treatment of metastatic or recurrent locally advanced Merkel cell carcinoma (MCC).	[1] In combination with carboplatin and paclitaxel, for the first-line treatment of adult patients with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC); [2] As a single agent, for the treatment of adult patients with locally recurrent or metastatic SCAC with disease progression on or intolerance to platinum-based chemotherapy.
Jivi (antihemophilic factor [recombinant] PEGylated-aucl) From: Bayer	For use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for: [1] On-demand treatment and control of bleeding episodes; [2] Perioperative management of bleeding; [3] Routine prophylaxis to reduce the frequency of bleeding episodes.	For use in previously treated adults and pediatric patients 7 years of age and older with hemophilia A (congenital Factor VIII deficiency) for: [1] On-demand treatment and control of bleeding episodes; [2] Perioperative management of bleeding; [3] Routine prophylaxis to reduce the frequency of bleeding episodes.
Susvimo (ranibizumab) From: Neurelis, Inc	[1] Neovascular (wet) Age-related Macular Degeneration who have previously responded to at least two intravitreal injections of a VEGF inhibitor; [2] Diabetic Macular Edema who have previously responded to at least two intravitreal injections of a VEGF inhibitor.	For the treatment of patients with diabetic retinopathy who have previously responded to at least two intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor medication.
Nucala (mepolizumab) From: GlaxoSmithKline LLC	[1] Severe asthma; [2] Chronic rhinosinusitis with nasal polyps; [3] Eosinophilic granulomatosis with polyangiitis; [4] Hypereosinophilic syndrome.	For the add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease

		(COPD) and an eosinophilic phenotype.
Zoryve (roflumilast) foam From: Arcutis	Seborrheic dermatitis in adult and pediatric patients 9 years of age and older.	For the treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older.

Pipeline

The goals of the NDA (or BLA) are to provide enough information to permit FDA approval of a new pharmaceutical for sale and marketing in the U.S.

Drug Name and Manufacturer	Indication(s)	Additional Information	Impact
Sibeprenlimab From: Otsuka Pharmaceutical	Immunoglobulin A Nephropathy	BLA accepted	High

Pipeline Generics

This section describes generics that may possibly be available on the market in the next month. Various legal factors may come into play, affecting the date.

Generic Name	Brand Name	Brand Manufacturer
Rivaroxaban (oral suspension)	Xarelto	Johnson & Johnson (Janssen)
Sacubitril; Valsartan	Entresto	Novartis
Carbidopa-Levodopa ER	Rytary	Amneal