MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

December 2023

MC-Rx is dedicated to improved drug therapy vigilance, continuity of care, patient safety and effective formulary management. This edition is developed by our clinical team, which is comprised of registered clinical pharmacists, to provide you with continuous evaluation and insights of the drugs market and its impact as it evolves.

Here you will find

Drug pipeline

FDA drug approvals

New indications

Patent expirations

Generic approvals

FDA safety updates/recalls

Drug shortages

Updated through December 18, 2023.

Importance of Prevention Strategies to Lower Healthcare Cost

Chronic diseases contribute significantly to health and economic costs in the United States. The leading chronic diseases, heart disease, stroke, cancer, and diabetes, account for $4.1 trillion in annual healthcare expenditures[1]. Approximately one third of the deaths in the U.S. are caused by heart disease or stroke, which adds approximately $216 billion annually in healthcare system costs, and $147 billion[2] in job productivity losses. In 2017, diabetes diagnoses cost an estimated $327 billion[2]. In addition, almost 600,000 people die from cancer each year, which is expected to add $240 billion to healthcare system expenses by 2030. To decrease the burden on healthcare costs, at MC-Rx we strive to create awareness by educating our community regarding the importance of prevention. Prevention is the effort to improve health, such as screening, health education, adherence to therapy, and adopting an overall healthy lifestyle. There are three different types of prevention[8]:

Prevention Strategy	Definition[8]	Example
Primary	Intervention before health effects occur	Immunizations, healthy eating, ceasing cigarette use
Secondary	Screening to identify diseases in the earliest stages, before the onset of sign and symptoms	Colorectal cancer screening, mammography, Diabetes Prevention Programs (DPP)
Tertiary	Managing the disease after diagnosis; to slow or stop the disease progression	Implementing clinically-driven prevention initiatives (ex. Pharmacist-driven medication education and intervention program)
		Wellness programs, Digital therapeutics

Prevention can be accomplished individually, however, managed care organizations, health plans and employers can contribute by establishing strategies to help the insured adhere to prevention and treatment regimens to manage their health conditions. For the insured, this may represent a better quality of life, better health, and improved work performance.

One strategy that may help the insured optimize their treatment and help lower healthcare costs is a *Diabetes Prevention Program (DPP)*. These programs have proven to reduce risk of diabetes, especially in people with pre-diabetes, via management of lifestyle changes[4]. A DPP is a lifestyle management program proven to reduce the risk of diabetes among people with pre-diabetes through improved eating patterns, physical activity, and weight loss. For example, DPP has shown to cost effectively reduce diabetes by 58% and demonstrate healthcare savings of more than $3,000 in 3 years[4]. DPP participants have lost an average weight of 4.3%, and program participation is associated with preventing other health conditions such as obesity, hypertension, and dyslipidemia. Another tool in the arsenal of prevention includes wellness programs. A wellness program is a social/lifestyle program intended to improve and promote health and fitness, usually offered through the workplace or through insurance plans directly to their enrollees[10]. This has many benefits – for example, more productivity, increased employee morale, reduced absenteeism, and improved recruitment and retention of employees.

Updated through December 18, 2023.

"Hot Topic"

For **primary prevention strategies**, MC-Rx promotes access and appropriate utilization of immunizations, such as influenza, Covid-19, and pneumonia vaccines. Every year the U.S. spends approximately $27 billion treating diseases that could have been prevented by vaccinations[3]. For every $1 spent on childhood vaccinations, there is a cost avoidance of $10.90[3]. According to the CDC, by 2021, 2.9 million medical visits, 65,000 hospitalizations, and 3,900 deaths were prevented by influenza vaccination[6]. Most recently, Covid-19 vaccines have prevented 18.5 million hospitalizations, and 3.2 million deaths in the United States[9]. As for **secondary prevention**, MC-Rx supports screening, early detection, and management of diseases via educational platforms and health fairs. In addition, MC-Rx provides educational material aimed at patients, providers, health plans, employers, and other insurers to promote health literacy and commitment to a healthy lifestyle. You may visit the company webpage and view our comprehensive educational program including videos and blogs on the latest health topics (https://www.mc-rx.com/).

Finally, for **tertiary prevention**, MC-Rx ensures appropriate and timely access to important cost-effective, first-line, preventative medications such as statins, to prevent kidney disease in patients with diabetes. We also promote the integration of disease management programs into the pharmacy benefit. These programs exist for a variety of health conditions, including diabetes, hypertension, and obesity. To increase access and convenience, disease management programs can be available through digital platforms. For example, digital therapeutics are innovative applications aimed to treat or alleviate a disease, disorder, condition, or injury, by generating and delivering a medical intervention. It may benefit payers by reducing the overall cost of care by enhancing and optimizing current medical treatments, improving provider communication efficiency, and support value and outcome-based care initiatives[5]. Data from digital wellness programs have shown a 9.3% reduction in healthcare utilization, 23.5% reduction in hospitalizations, and $5,077 reduction in cost for cardio metabolic conditions like diabetes[5].

At MC-Rx, we are committed to providing innovative care solutions that support patient access to treatment. One example of our commitment to provide access to affordable, cost-effective care was the early onset adoption of our Biosimilar/Biologic Program. Based on MC-Rx drug utilization data, after one year of implementing this program, the annual savings for our client was approximately 25% and beneficiaries experienced approximately 40% lower out-of-pocket costs.

In conclusion, prevention efforts at the primary, secondary, and tertiary levels help reduce development of chronic conditions and prevent complications of existing medical conditions. At MC-Rx, we challenge ourselves to constantly look for strategic innovation, but keep our focus on the basic clinical principles of patient care, service, and individualized attention. The MC-Rx clinical team of experts is composed of pharmacy doctors that partner with clients to develop drug formularies and clinical programs which focus on delivering access to evidence-based, cost-effective care.

Updated through December 18, 2023.

References:

1. Health and Economic Benefits of Chronic Diseases. (2023). Centers for Disease Control and Prevention. https://www.cdc.gov/chronicdisease/about/costs/index.htm.
2. Health and Economic Benefits of Chronic Disease Interventions. (2023). Center for Disease Control and Prevention. https://www.cdc.gov/chronicdisease/programs-impact/pop/index.htm
3. Vaccines Are Cost Saving. (2020). Vaccinate Your Family. https://vaccinateyourfamily.org/why-vaccinate/vaccine-benefits/costs-of-disease-outbreaks/
4. Cost Savings and Reduced Health Care Utilization Associated with Participation in a Digital Diabetes Prevention Program in an Adult Workforce Population. (2020). Journal of health economics and outcomes research. https://doi.org/10.36469/jheor.2020.14529
5. Value of DTx. Digital Therapeutic Alliance. https://dtxalliance.org/
6. Estimated influenza illnesses, medical visits, hospitalizations, and deaths prevented by vaccination in the United States – 2022-2023 influenza season. (2023). Centers for Disease Control and Prevention. https://www.cdc.gov/flu/about/burden-averted/2022-2023.htm
7. Prevention. Centers for Disease Control and Prevention. https://www.cdc.gov/pictureofamerica/pdfs/picture_of_america_prevention.pdf
8. Use of updated COVID-19 vaccines 2023–2024 formula for persons aged ≥6 months: Recommendations of the Advisory Committee on Immunization Practices. (2023). Centers for Disease Control and Prevention. https://www.cdc.gov/mmwr/volumes/72/wr/mm7242e1.htm#:~:text=Introduction,the%20United%20States%20(1)
9. Wellness Program. Healthcare.gov. https://www.healthcare.gov/glossary/wellness-programs/

Updated through December 18, 2023.

Specialty Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Arimoclomol (Miplyffa - Orphazyme)	Complete response	2024	Molecular chaperone activator that stimulates the normal cellular protein repair pathway for the treatment of Niemann-Pick Disease Type C (NPC); oral
Atidarsagene autotoemcel (Libmeldy- Orchard Therapeutics)	BLA Filed	03/18/2024	Ex-vivo stem cell gene therapy for the treatment of early onset metachromatic leukodystrophy (MLD); IV infusion
Concizumab (Novo Nordisk)	Complete response	2024	A humanized monoclonal antibody against tissue factor pathway inhibitor (TFPI) for the prevention and treatment of bleeding in patients with haemophilia A and B with inhibitors; subcutaneous therapy.
Crovalimab (Genentech)	BLA Filed	07/27/2024	C5 inhibitor for the treatment of paroxysmal nocturnal hemoglobinuria; SC injection
Danicopan (AstraZeneca)	NDA Filed	07/27/2024	Complement factor D (CFD) inhibitor for treatment-naïve paroxysmal nocturnal hemoglobinuria (PNH) patients; oral
Donanemab (Eli Lilly)	BLA Filed	Q1: 2024	Antibody that targets a modified form of beta amyloid called N3pG for the treatment of patients with early symptomatic Alzheimer's disease; IV infusion
Eladocagene exuparvovec (Upstaza - PTC Therapeutics)	Phase 3	2024	Recombinant, adeno-associated virus, containing the human cDNA encoding the AADC enzyme for the treatment of AADC deficiency; intracerebral infusion
Eplontersen (Ionis Pharmaceuticals/ AstraZeneca)	NDA Filed	12/22/2023	Antisense medicine designed to inhibit production of transthyretin (TTR) for the treatment of hereditary transthyretin-mediated amyloid polyneuropathy (hATTR-PN); subcutaneous injection
Exagamglogene autotemcel (Vertex Pharmaceuticals/ CRISPR Therapeutics)	BLA Filed	12/08/2023	Gene edited therapy utilizing CRISPR-Cas9 of primary human hematopoietic stem and progenitor CD34+ cells that have undergone ex vivo editing of the erythroid specific enhancer region of BCL11A, for the treatment of sickle cell disease and transfusion dependent beta thalassemia; intravenous (single dose)
Fidanacogene elaparvovec (Pfizer)	BLA Filed	04/27/2024	Bio-engineered adeno-associated virus (AAV) capsid expressing a codon-optimized, high-activity human factor IX variant for the treatment of hemophilia B; IV infusion (one time)

Updated through December 18, 2023.

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Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Garadacimab CSL (Behring)	Phase 3	2024	Fully human recombinant FXIIa antagonist monoclonal antibody for the prevention and treatment of hereditary angioedema (HAE); subcutaneous injection
Givinostat (Italfarmaco)	BLA Filed	12/23/2023	Histone deacetylase (HDAC) inhibitor for the treatment of Duchenne muscular dystrophy; oral
Iptacopan (Novartis)	NDA Filed	Dec. 2023	Low molecular weight factor B inhibitor for the treatment of paroxysmal nocturnal hemoglobinuria; oral
Lebrikizumab (Eli Lilly)	Complete Response	2024	Humanized monoclonal antibody targeting interleukin 13 (IL-13) for the treatment of atopic dermatitis; subcutaneous injection
Lovotibeglogene autotemcel (lovocel - bluebird bio)	BLA Filed	12/20/2023	Lenti-D gene therapy for the treatment of sickle cell disease (SCD) in patients 12 years of age and older with history of vaso-occlusive events; IV infusion
Olezarsen (Ionis Pharmaceuticals)	Phase 3	2024	Antisense drug that targets the ApoC-III protein to reduce serum triglycerides for the treatment of familial chylomicronemia syndrome (FCS); SC (weekly)
Resmetirom (Madrigal Pharmaceuticals)	NDA Filed	03/14/2024	Thyroid hormone receptor (THR) ß -selective agonist for the treatment of nonalcoholic steatohepatitis (NASH) with liver fibrosis; oral
Sotatercept (Merck)	BLA Filed	03/26/2024	Soluble receptor fusion protein comprised of extracellular domain of the human activin receptor type IIA (ActRIIA) fused to human immunoglobulin for the treatment of pulmonary arterial hypertension; subcutaneous injection
Tovorafenib (Day One Biopharmaceuticals)	NDA Filed	04/30/2024	Type 2 pan-RAF inhibitor for the treatment of patients with relapsed/refractory BRAF+ pediatric low grade glioma (pLGG); oral

Updated through December 18, 2023.

Biosimilar Pipeline

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Generic Name Investigational Name	Manufacturer(s)	Reference Biological	Possible FDA approval date	Potential launch date
Pegfilgrastim-cbqv (Udenyca Onbody)	Coherus Biosciences	Neulasta Onpro (pegfilgrastim)	12/5/2023	TBD. New on-body device
Denosumab biosimilar	Sandoz	Prolia (denosumab)	12/6/2023	TBD (Feb 2025?)
Trastuzumab biosimilar (Zercepac)	Henlius/Accorda	Herceptin (trastuzumab)	12/14/2024	TBD (Pending FDA Approval)
Tocilizumab biosimilar (Tyenne)	Fresenius/Merck KgaA	Actemra (tocilizumaab)	2H 2023	TBD (Settlement agreement)
Aflibercept biosmilar (Yesafili)	Momenta/Biocon	Eylea (aflibercept)	2023-2024	TBD (2024?)
Bevacizumab biosimilar (Equidacent)	Centus	Avastin (bevacizumab)	2023-2024	TBD (Pending FDA Approval)
Bevacizumab biosimilar (Aybintio)	Samsung Bioepis/ Organon	Avastin (bevacizumab)	2023-2024	TBD (Pending FDA Approval)
Bevacizumab biosimilar	Biothera/Sandoz	Avastin (bevacizumab)	2023-2024	TBD (Pending FDA Approval)
Pegfilgrastim biosimilar (Lupifil-P)	Lupin	Neulasta (pegfilgrastim)	2023-2024	TBD (Pending FDA Approval)
Filgrastim biosimilar	Tanvex BioPharma	Neupogen (filgrastim)	2023/2024	TBD (Pending FDA Approval)
Eculizumab biosimilar	Amgen/Daiichi Sankyo	Soliris (eculizumab)	2/28/2024	Settlement: March 1, 2025
Adalimumab biosimilar (Simlandi)	Teva/Alvotech	Humira (adalimumab)	1Q 2024	TBD (Pending FDA Approval)
Insulin aspart biosimilar	Sandoz/Gan & Lee	Novolog (insulin aspart)	4/1/2024	TBD (Pending FDA Approval)
Insulin lispro biosimilar (Prandilin)	Sandoz/Gan & Lee	Humalog (insulin lispro)	4/1/2024	TBD (Pending FDA Approval)
Insulin glargine biosimilar (Basalin)	Sandoz/Gan & Lee	Lantus (insulin glargine)	4/3/2024	TBD (Pending FDA Approval)
Ranibizumab biosimilar (Xlucane)	Xbrane Biopharma	Lucentis (ranibizumab)	4/21/2024	TBD (upon approval?)
Aflibercept biosimilar	Celtrion	Eylea (aflibercept)	4/29/2024	TBD (2024?)

Updated through December 18, 2023.

Biosimilar Pipeline

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Generic Name Investigational Name	Manufacturer(s)	Reference Biological	Possible FDA approval date	Potential launch date
Aflibercept biosimilar	Coherus Biosciences	Eylea (aflibercept)	6/29/2024	TBD (2024?)
Ustekinumab biosimilar	Celtrion	Stelara (ustekinumab)	6/30/2024	Settlement: Mar. 7, 2024
Rituximab biosimilar	Dr. Reddy's/Fresenius	Rituxan (rituximab)	7/12/2024	TBD (Pending FDA Approval)
Trastuzumab biosimilar	Tanvex BioPharma	Herceptin (trastuzumab)	2024	TBD (Pending FDA Approval)
Ustekinumab biosimilar	Alvotech/Teva	Stelara (ustekinumab)	2024	Settlement: Feb. 21, 2025
Adalimumab biosimilar (Simlandi)	Teva/Alvotech	Humira (adalimumab)	2024	TBD (Pending FDA Approval)
Bevacizumab biosimilar (abevmy)	Biocon	Avastin (bevacizumab)	2024	TBD (Pending FDA Approval)

Updated through December 18, 2023.

New Drug Entities

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New Drug Entities	Details
Cipaglucosidase alfa-atga (Pombiliti)/Miglustat (Opfolda)	**Dosage form:** For injection: 105 mg of cipaglucosidase alfa-atga as a lyophilized powder in a single-dose vial for reconstitution. Miglustat Capsules: 65 mg. **Indication:** Orphan: Is a hydrolytic lysosomal glycogen-specific enzyme indicated, in combination with Opfolda, an enzyme stabilizer, for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT). **Comparables:** Lumizyme (alglucosidase alfa) and Nexviazyme (avalglucosidase alfa-ngpt). **Guidelines:** • Pompe Disease (2021). National Organization of Rare Disorders https://rarediseases.org/rare-diseases/pompe-disease/
Gepirone (Exxua)	**Dosage form:** Extended-release tablets: 18.2 mg, 36.3 mg, 54.5 mg, and 72.6 mg. **Indication:** Is indicated for the treatment of major depressive disorder (MDD) in adults. **Comparables:** None **Guidelines:** • Clinical Practice Guideline for the Treatment of Depression Across Three Age Cohorts (2021). Clinical Guidelines Practice for the Treatment of Depression. https://www.apa.org/depression-guideline
Nedosiran (Rivfloza)	**Dosage form:** Injection 160 mg/mL is a clear, colorless-to-yellow solution available as follows: • 80 mg (0.5 mL) single-dose vial • 128 mg (0.8 mL) single-dose Pre-filled Syringe • 160 mg (1 mL) single-dose Pre-filled Syringe. **Indication:** Is an LDHA-directed small interfering RNA indicated to lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR ≥ 30 mL/min/1.73 m2. **Comparables:** Oxlumo™ (lumasiran) **Guidelines:** • Primary Hyperoxaluria (2020). National Organization of Rare Disease. https://rarediseases.org/rare-diseases/primary-hyperoxaluria/

Updated through December 18, 2023.

New Drug Entities

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

New Drug Entities	Details
Taurolidine and heparin (Defencath)	**Dosage form:** DEFENCATH is a sterile catheter lock solution available in singledose vials in the following strengths: o 3 mL containing taurolidine 40.5 mg/3 mL (13.5 mg/mL), and heparin 3,000 USP Units/3 mL (1,000 USP Units/mL) o 5 mL containing taurolidine 67.5 mg/5 mL (13.5 mg/mL), and heparin 5,000 USP Units/5 mL (1,000 USP Units/mL) **Indication:** Is a combination of taurolidine, a thiadiazinane antimicrobial, and heparin, an anti-coagulant, indicated to reduce the incidence of catheter-related bloodstream infections (CRBSI) in adult patients with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC). This drug is indicated for use in a limited and specific population of patients. **Comparables:** **Guidelines:**
Tocilizumab-bavi (Tofidence)	**Dosage form:** Intravenous Infusion Injection: 80 mg/4 mL (20 mg/mL), 200 mg/10 mL (20 mg/mL), 400 mg/20 mL (20 mg/mL) in single-dose vials for further dilution prior to intravenous infusion. **Indication:** is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of: Rheumatoid Arthritis (RA) • Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs). Polyarticular Juvenile Idiopathic Arthritis (PJIA) • Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis. Systemic Juvenile Idiopathic Arthritis (SJIA) • Patients 2 years of age and older with active systemic juvenile idiopathic arthritis. **Comparables:** Actemra **Guidelines:** • Rheumatoid Arthritis Guideline (2021). American College of Rheumatology. https://rheumatology.org/rheumatoid-arthritis-guideline
Vamorolone (Agamree)	**Dosage form:** Oral Suspension: 40 mg/mL. **Indication:** Is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older. **Comparables:** Deflazacort (Emflaza) **Guidelines:** • Corticosteroid treatment of Duchenne muscular dystrophy (2016). Neurology. https://www.bing.com/

Updated through December 18, 2023.

New Drug Entities

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New Drug Entities	Details
Zilucoplan (Zilbrysq)	**Dosage form:** Injection: 16.6 mg/0.416 mL, 23 mg/0.574 mL, or 32.4 mg/0.81 mL zilucoplan in single-dose prefilled syringes. **Indication:** indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive **Comparables:** Zilbrysq is the first targeted C5 complement inhibitor for gMG that is administered subcutaneously once daily and that can be self-administered. Zilbrysq will compete with several other therapies approved for the treatment of gMG: argenx's Vyvgart and Vyvgart Hytrulo, both FcRn antagonists, and Alexion/AstraZeneca's Soliris and Ultomiris, both complement inhibitors administered as intravenous infusions. Unlike Zilbrysq, all of these treatments are administered by a healthcare professional. **Guidelines:** International Consensus Guidance for Management of Myasthenia Gravis (2020). Neurology. https://n.neurology.org/content/neurology/96/3/114.full.pdf

Updated through December 18, 2023.

New Drug Formulations

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New Drug Formulations	Details
Acetaminophen and Ibuprofen (Combogesic IV)	**New Dosage form:** Injection: 1,000 mg/100 mL (10 mg/mL) of acetaminophen and 300 mg/100 mL (3 mg/mL) of ibuprofen in single-dose vial **Indication:** Is indicated in adults where an intravenous route of administration is considered clinically necessary for: • the relief of mild to moderate pain • the management of moderate to severe pain as an adjunct to opioid analgesics. **Comparables:** Combogesic tablet **Guidelines:** • Pain Management (2019). Pain Management Best Practices. https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf
Infliximab-dyyb (Zymfentra)	**New Dosage form:** Injection: 120 mg/mL in a single-dose prefilled syringe. 120 mg/mL in a single-dose prefilled syringe with needle shield. 120 mg/mL in a single-dose prefilled pen. **Indication:** Is a tumor necrosis factor (TNF) blocker indicated in adults for maintenance treatment of: • moderately to severely active ulcerative colitis following treatment with an infliximab product administered intravenously. • moderately to severely active Crohn's disease following treatment with an infliximab product administered intravenously. **Comparables:** Infliximab products **Guidelines:** • AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis (2020). Gastroenterology. https://www.gastrojournal.org/article/S0016-5085(20)30018-4/fulltext • Crohn's Disease: Diagnosis and Management (2018). American Familly Physician. https://www.aafp.org/pubs/afp/issues/2018/1201/p661.html#afp20181201p661-t7
Metronidazole (Likmez)	**New Dosage form:** Oral Suspension: 500 mg/5 mL **Indication:** New Dosage Form, New Formulation: is a nitroimidazole antimicrobial indicated for: Trichomoniasis in adults, Amebiasis in adults and pediatric patients, Anaerobic Bacterial Infections in adults. To reduce the development of drug-resistant bacteria and maintain the effectiveness of LIKMEZ and other antibacterial drugs, LIKMEZ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria. **Comparables:** generic metronidazole oral capsule **Guidelines:** • IDSA Practice Guidelines (year). Infectious Diseases Society of America. https://www.idsociety.org/practice-guideline/practice-guidelines/#/+/0/date_na_dt/desc/

Updated through December 18, 2023.

New Drug Formulations

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

New Drug Formulations	Details
Oxaprozin (Coxanto)	**New Dosage form:** Capsules: 300 mg. **Indication:** Is a non-steroidal anti-inflammatory drug indicated for: • Relief of signs and symptoms of Osteoarthritis (OA), • Relief of signs and symptoms of Rheumatoid Arthritis (RA), • Relief of signs and symptoms of Juvenile Rheumatoid Arthritis (JRA). **Comparables:** Oxaprozin (Daypro) **Guidelines:** • Clinical Practice Guidelines (2015). American College of Rheumatology. https://rheumatology.org/clinical-practice-guidelines
Pilocarpine Hydrochloride (Qlosi)	**New Dosage form:** Ophthalmic solution: pilocarpine hydrochloride 0.4% (4 mg/mL) in a single-patient-use vial. **Indication:** indicated for the treatment of presbyopia in adults. **Comparables:** Pilocarpine (Vuity) **Guidelines:** • Care of the Patient with Presbyopia (2010). Optometric Clinical Practice Guideline. https://www.aoa.org/AOA/Documents/CPG-17.pdf
Potassium Chloride (Pokonza)	**New Dosage form:** Oral Solution, USP) 10 mEq: Each pouch contains 0.75 g of Potassium Chloride providing potassium 10 mEq and chloride 10 mEq. Pokonza 10 mEq oral packet. **Indication:** New Formulation: Is a potassium salt 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. **Comparables:** Packet, Oral: Klor-Con: 20 mEq (1 ea, 30 ea, 100 ea), Generic: 20 mEq (1 ea, 30 ea, 50 ea, 100 ea) **Guidelines:** • Clinical manifestations and treatment of hypokalemia in adults (2023). UpToDate. https://www.uptodate.com/contents/clinical-manifestations-and-treatment-of-hypokalemia-in-adults?search=hypokalemia&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#

Updated through December 18, 2023.

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New Drug Formulations	Details
Sitagliptin (Zituvio)	**New Dosage form:** Tablets: 100 mg, 50 mg, and 25 mg (a freebase form of sitagliptin), Zituvio was approved as a new drug, not as a generic to Januvia (sitagliptin) tablets, which uses a phosphate salt of sitagliptin. They are not interchangeable. **Indication:** is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Comparables:** Sitagliptin phosphate (Januvia), other DPP4 **Guidelines:** • Standards of Care in Diabetes (2023). American Diabetes Association. https://diabetesjournals.org/clinical/article/41/1/4/148029/Standards-of-Care-in-Diabetes-2023-Abridged-for
Sitagliptin and Metformin hydrochloride (Zituvimet)+	**New Dosage form:** ZITUVIMET Tablets: sitagliptin 50 mg and metformin HCl 500 mg tablets sitagliptin 50 mg and metformin HCl 1,000 mg tablets **Indication:** ZITUVIMET is a combination of sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, and metformin hydrochloride (HCl), a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Comparables:** Other DPP4-metformin combinations **Guidelines:** • Standards of Care in Diabetes (2023). American Diabetes Association. https://diabetesjournals.org/clinical/article/41/1/4/148029/Standards-of-Care-in-Diabetes-2023-Abridged-for
Tirzepatide (Zepbound)	**New Dosage form:** Injection: 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg per 0.5 mL in single-dose pen **Indication:** as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: • 30 kg/m2 or greater (obesity) or • 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea or cardiovascular disease). **Comparables:** Wegovy, Saxenda **Guidelines:** • A Review of Current Guidelines for the Treatment of Obesity (2022). AJMC. https://www.ajmc.com/view/review-of-current-guidelines-for-the-treatment-of-obesity

Updated through December 18, 2023.

New Drug Formulations

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New Drug Formulations	Details
Ustekinumab-auub (Wezlana)	**New Dosage form:** Subcutaneous Injection • 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 Infusion • Injection: 130 mg/26 mL (5 mg/mL) solution in a single-dose vial. **Indication:** Is a human interleukin -12 and -23 antagonist indicated for the treatment of: Adult patients with: • moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy. • active psoriatic arthritis (PsA). • moderately to severely active Crohn's disease (CD). • moderately to severely active ulcerative colitis. Pediatric patients 6 years and older with: • moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy. • active psoriatic arthritis (PsA). **Comparables:** Ustekinumab (Stelara) **Guidelines:** • 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis (2018). https://journals.sagepub.com/doi/full/10.1177/2475530318812244 • Crohn's Disease: Diagnosis and Management (2018). American Familly Physician. https://www.aafp.org/pubs/afp/issues/2018/1201/p661.html#afp20181201p661-t7 • AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis (2020). Gastroenterology. https://www.gastrojournal.org/article/S0016-5085(20)30018-4/fulltext

Updated through December 18, 2023.

New Indications

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

New Indications	Details
Abatacept (Orencia	For expansion of the indication for the subcutaneous use to include treatment of patients age 2 years and older with active psoriatic arthritis (PsA).
Adalimumab-aacf (Idacio)	For the inclusion of treatment of non-infectious intermediate, posterior and panuveitis in adult patients.
Empagliflozin (Jardiance)	For the addition of the indication to reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression.
Encorafenib (Braftovi)	For the addition of the indication of encorafenib, in combination with binimetinib, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation, as detected by an FDA-approved test.
Enzalutamide (Xtandi)	For the addition of the indication for the treatment of Non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis.
Etanercept (Enbrel)	For the addition of the indication for the treatment of active juvenile psoriatic arthritis (JPsA) in patients 2 years of age and older.
Ivosidenib (Tibsovo)	For the addition of the indication for the treatment of adult patients with relapsed or refractory myelodysplastic syndromes (MDS) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.
Nivolumab (Opdivo)	For the addition of the indication to include Stage IIB and Stage IIC melanoma. The approved indication now reads: OPDIVO is indicated for the adjuvant treatment of adult and pediatric patients 12 years and older with completely resected Stages IIB, IIC, III, or IV melanoma.
Patiromer (Veltassa)	For the addition of the indication Efficacy-New Patient Population: a potassium binder indicated for the treatment of hyperkalemia in adults and pediatric patient's ages 12 years and older.
Pegfilgrastim-fpgk (Stimufend) is biosimilar* to NEULASTA (pegfilgrastim)	For the addition of the indication to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome (H-ARS)).

Updated through December 18, 2023.

New Indications

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

New Indications	Details
Pembrolizumab (Keytruda)	For the addition of the indication: • For the treatment of patients with resectable (tumors ≥4 cm or node positive) NSCLC in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery. • In combination with gemcitabine and cisplatin, is indicated for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer. • For the conversion of the Merkel cell carcinoma (MCC) indication in both adult and pediatric patients from accelerated approval to regular approval. • Food and Drug Administration revised the existing indication of pembrolizumab (Keytruda, Merck) with trastuzumab, fluoropyrimidine, and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma. This updated indication, which remains approved under accelerated approval regulations, restricts its use to patients whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test.
Roflumilast (Zoryve)	For the addition of the indication for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.
Secukinumab (Cosentyx)	For the addition of the indication for the treatment of adult patients with moderate to severe hidradenitis suppurativa.
Vabysmo (faricimab-svoa)	For the addition of the indication for the treatment of macular edema following retinal vein occlusion (RVO).

Updated through December 18, 2023.

In Market Brand

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

In-Market-Brands	Details
Bimekizumab-bkzx (Bimzelx)	**Dosage form:** Injection: 160 mg/mL in a single-dose prefilled syringe or single-dose prefilled auto-injector. **Indication:** indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. **Comparables:** Multiple other injected, oral and topical drugs, including biologics such as adalimumab (Humira® and biosimilars), Enbrel® (etanercept) and Skyrizi® (risankizumab), are FDA approved to treat psoriasis. Bimzelx is the only one that specifically blocks IL-17A and IL-17F, however. **Guidelines:** • Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021 Publisher: GRAPPA Publication Date: 2022 • Joint AAD-NPF Psoriasis Clinical Guidelines Publisher: American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) Publication Dates: Range from 2019 to 2020
Capivasertib (Truqap)	**Dosage form:** Tablets: 160 mg and 200 mg **Indication:** TRUQAP is a kinase inhibitor indicated, in combination with fulvestrant, for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy. **Comparables:** No comparables **Guidelines:** • Breast Cancer (2023). NCCN. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
Clindamycin phosphate, adapalene, and benzoyl peroxide (Cabtreo)	**New Dosage form:** Topical gel: 1.2% clindamycin phosphate, 0.15% adapalene, and 3.1% benzoyl peroxide. CABTREO is supplied in 20-gram and 50-gram tubes and 20-gram and 50-gram pumps. Indication: indicated for the topical treatment of acne vulgaris in adult and pediatric patients 12 years of age and older. **Comparables:** first product to combine antibacterial, retinoid and bactericidal ingredients **Guidelines:** • Guidelines of care for the management of acne vulgaris (2016). Journal of the American Academy of Dermatology. https://www.jaad.org/article/S0190-9622(15)02614-6/fulltext

Updated through December 18, 2023.

In Market Brand

In-Market-Brands	Details
Etrasimod (Velsipity)	**Dosage form:** Tablets: 2 mg of etrasimod **Indication:** VELSIPITY is a sphingosine 1-phosphate receptor modulator indicated for the treatment of moderately to severely active ulcerative colitis in adults **Comparables:** Ozanimod (Zeposia) **Guidelines:** • AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis (2020). Gastroenterology. https://www.gastrojournal.org/article/S0016-5085(20)30018-4/fulltext
Fruquintinib (Fruzaqla)	**Dosage form:** Capsules: 1 mg and 5 mg. **Indication:** is a kinase inhibitor indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy. **Comparables:** Stivarga and Lonsurf +/- bevacizumab **Guidelines:** • Colon Cancer (2023). NCCN. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf
Mirikizumab-mrkz (Omvoh)	**Dosage form:** Intravenous Infusion • Injection: 300 mg/15 mL (20 mg/mL) solution in a single-dose vial, Subcutaneous Injection, • Injection: 100 mg/mL solution in a single-dose prefilled pen. **Indication:** Is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults. **Comparables:** Ustekinumab (Stelara) Risankizumab-rzaa (Skyrizi); approval of Skyrizi for UC is expected in June 2024. Other FDA-approved IL-23 inhibitors are indicated for treating psoriasis and other inflammatory conditions, but not UC or Crohn's disease. **Guidelines:** • AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis (2020). Gastroenterology. https://www.gastrojournal.org/article/S0016-5085(20)30018-4/fulltext • American Gastroenterological Association Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis Publication Date: 2020 • American Gastroenterological Association Clinical Practice Guideline on the Role of Biomarkers for the Management of Ulcerative Colitis Publication Date: 2023 • American College of Gastroenterology Clinical Guideline on Ulcerative Colitis in Adults Publication Date: 2019

Updated through December 18, 2023.

In Market Brand

In-Market-Brands	Details
Momelotinib (Ojjaara)	**Dosage form:** Tablets: 100 mg, 150 mg, 200 mg. **Indication:** Is a kinase inhibitor indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia. **Comparables:** Inrebic® (fedratinib) capsules, Jakafi® (ruxolitinib) tablets, and Vonjo® (pacritinib) capsules **Guidelines:** • Badri T, Gandhi GR. Molluscum Contagiosum. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK441898/ • Molluscum Contagiosum. (2015). Centers for Disease Control and Prevention. https://www.cdc.gov/poxvirus/molluscum-contagiosum/index.html
Repotrectinib (Augtyro)	**Dosage form:** Capsules: 40 mg **Indication:** Select patients for the treatment of locally advanced or metastatic NSCLC based on the presence of ROS1 rearrangement(s) in tumor specimens **Comparables:** Entrectinib, Crizotinib **Guidelines:** • Non Small Cell Lung Cancer (2023). NCCN. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
Toripalimab-tpzi (Loqtorzi)	**Dosage form:** Injection: 240 mg/6 mL (40 mg/mL) solution in a single-dose vial **Indication:** • in combination with cisplatin and gemcitabine, for first-line treatment of adults with metastatic or with recurrent locally advanced nasopharyngeal carcinoma (NPC). • as a single agent for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy. **Comparables:** Currently, NPC is treated primarily with radiation and various chemo regimens. The epidermal growth factor receptor (EGFR) blocker, Erbitux® (cetuximab) injection and PD-1 blockers, such as Keytruda® (pembrolizumab) and Opdivo® (nivolumab), are FDA approved to treat head and neck cancers, but Loqtorzi is the first drug specifically indicated for NPC. **Guidelines:** waiting for NCCN guideline update

Updated through December 18, 2023.

In Market Brand

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

In-Market-Brands	Details
Tenapanor (Xphozah)	**New Dosage form:** Tablets 10, 20, 30 mg "New Dosage Formulation" marketed for a new indication under another brand name **Indication:** indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. **Comparables:** first-in-class mechanism of action that blocks phosphate absorption through its primary pathway **Guidelines:** • Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD) (2017). KDIGO. https://kdigo.org/wp-content/uploads/2017/02/2017-KDIGO-CKD-MBD-GL-Update.pdf
Vedolizumab (Entyvio)	**New Dosage form:** NDF: Subcutaneous injection: 108 mg/0.68 mL solution in a single-dose prefilled syringe with needle safety device, Injection: 108 mg/0.68 mL solution in a single-dose prefilled pen (ENTYVIO PEN). Other: Intravenous infusion For injection: 300 mg vedolizumab in a single-dose vial. **Indication:** Is an integrin receptor antagonist indicated in adults for the treatment of • Moderately to severely active ulcerative colitis (UC). • Moderately to severely active Crohn's disease (CD). **Comparables:** Entyvio IV **Guidelines:** • AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis, CLINICAL PRACTICE GUIDELINE|VOLUME 158, ISSUE 5, P1450-1461, APRIL 2020 • AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease, CLINICAL PRACTICE GUIDELINE| VOLUME 160, ISSUE 7, P2496-2508, JUNE 2021
Vonoprazan (Voquezna)	**New Dosage form:** Tablets: 10 mg and 20 mg of vonoprazan. **Indication:** is a potassium-competitive acid blocker indicated: • for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults. • to maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults. • in combination with amoxicillin and clarithromycin for the treatment of Helicobacter pylori (H. pylori) infection in adults. • in combination with amoxicillin for the treatment of H. pylori infection in adults. **Comparables:** Voquezna is a first-in-class potassium-competitive acid blocker (P-CAB); other H. pylori regimes (PPI). **Guidelines:** • ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease (2022). The American Journal of Gastroenterology. https://journals.lww.com/ajg/fulltext/2022/01000/acg_clinical_guideline_for_the_diagnosis_and.14.aspx

Updated through December 18, 2023.

New Generics

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Halobetasol Propionate Topical Foam, 0.05%	Padagis Israel Pharmaceuticals Ltd.	Lexette (Halobetasol Propionate) Topical Foam	8/11/2023	For the topical treatment of plaque psoriasis in patients twelve (12) years of age and older
Levonorgestrel and Ethinyl Estradiol Tablets, USP and Ferrous Fumarate Tablets, 0.1 mg/0.02 mg and 75 mg	Xiromed Pharma Espana, S.L.	Balcoltra (Levonorgestrel and Ethinyl Estradiol and Ferrous Bisglycinate) Tablets	8/16/2023	For use by females of reproductive potential to prevent pregnancy
Lifitegrast Ophthalmic Solution, 5%	Micro Labs Limited	Xiidra (Lifitegrast) Ophthalmic Solution	8/4/2023	For the treatment of the signs and symptoms of dry eye disease
Lisdexamfetamine Dimesylate Capsules, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg	Ascent Pharmaceuticals, Inc, Alkem Laboratories Limited, Ascent Pharmaceuticals Inc, Apotex Inc, Prinston Pharmaceutical Inc., Lannett Company, Inc., Teva Pharmaceuticals USA, Inc., Rhodes Pharmaceuticals, L.P.Norwich Pharmaceuticals, Inc., Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries, Inc., SpecGx LLC, Mylan Pharmaceuticals Inc., Amneal Pharmaceuticals LLC, Hikma Pharmaceuticals USA Inc., Actavis Elizabeth LLC	Vyvanse (Lisdexamfetamine Dimesylate) Capsules	8/25/2023	For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older; moderate to severe binge eating disorder (BED) in adults

Updated through December 18, 2023.

New Generics

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Palbociclib Tablets, 75 mg, 100 mg, and 125 mg	Synthon Pharmaceuticals, Inc.	Ibrance (Palbociclib) Tablets	8/28/2023	For the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy, or fulvestrant in patients with disease progression following endocrine therapy
Spironolactone Oral Suspension, 25 mg/5 mL	Amneal Pharmaceuticals LLC	Carospir (Spironolactone) Oral Suspension	9/5/2023	For the treatment of NYHA Class III-IV heart failure and reduced ejection fraction; to use as an add-on therapy for the treatment of hypertension, to lower blood pressure; for the management of edema in adult cirrhotic patients when edema is not responsive to fluid and sodium restrictions
Tretinoin Gel (Microsphere), 0.08%	Encube Ethicals Private Limited	Retin-A-Micro (Tretinoin) Gel Microsphere	8/22/2023	For the topical treatment of acne vulgaris
Tofacitinib Oral Solution, 1 mg/mL	Slayback Pharma LLC	Xeljanz (Tofacitinib) Oral Solution	9/25/2023	For the treatment of Rheumatoid Arthritis; Psoriatic Arthritis; Ankylosing Spondylitis; Ulcerative Colitis; Polyarticular Course Juvenile Idiopathic Arthritis

Updated through December 18, 2023.

Recall Notifications

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

Date	Drug Name	Reason for Recall	Company name
12/11/2023	Vigabatrin 500 mg	Due to seal integrity issues allowing for powder leakage from the pouch	InvaGen Pharmaceuticals Inc.
11/27/2023	Sandimmune (cyclosporine oral solution)	Undeclared Sildenafil	Meta Herbal
11/24/2023	2% Miconazole Nitrate Athlete's Foot Spray	Presence of Benzene	Insight Pharmaceuticals
11/21/2023	Vitrakvi (larotrectinib)	Microbial contamination identified as Peniciliim brevicompactum	Bayer
11/15//2023	SugarMD Advanced Glucos Support	Undeclared Glyburide and Metformin	SugarMDs, LLC
10/03/2023	Betaxolol	Potential presence of Oxycodone HCL tablet	KVK-Tech, Inc
9/28/2023	Brexafemme	Potential cross contamination with non-antibacterial beta-lactam drug substance	Scynexis, Inc

Updated through December 18, 2023.

Safety Notifications

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

The FDA is warning that the antiseizure medication levetiratecam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan) can cause a rare but serious reaction that can be life-threatening. This reaction is called Drug Reaction with Eosinophilia and Systemic Symptoms.

Updated through December 18, 2023.

Shortages (New)

There are no new drug shortages

References:

FDA Approved Drugs. Food and Drug Administration (FDA). Retrieved from https://www.access.fda.gov/

FDA: Drug Shortages. https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages

FDA: First Generic Drug Approvals. https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals

FDA: Recalls, Market Withdrawals, & Safety Alerts. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

Updated through December 18, 2023.

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