MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

October 2022

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/ withdrawals/ recalls

Drug shortages/ discontinuations

Information has been updated through October 6, 2022.

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

Therapy Topic

2022-2023 Flu Season Update: Influenza & COVID-19 Vaccine Options and Guidance:

CDC Recommendations on Influenza:

The CDC recommends annual vaccination against seasonal influenza, or flu, for everyone 6 months of age and older. Vaccination reduces the incidence and the risk of serious complications and death associated with influenza illness in children and adults.

This year, the CDC is preferentially recommending three specific vaccines for people 65 years of age and older. These specific vaccines were recommended because they may provide better and longer durations of protection in older patients.

- Fluzone High-Dose Quadrivalent which was FDA-approved in 2019 specifically for use in adults 65 years of age and older. It contains four times the antigens of a standard-dose inactivated flu vaccine. The higher dose of antigens is intended to stimulate a better immune response, and therefore, better protection against flu.
- Flublok Quadrivalent is also a higher dose vaccine. It is approved for use in people 18 years of age and older and contains three times the antigen dose of standard-dose inactivated flu vaccines.
- Fluad Quadrivalent is an inactivated influenza vaccine with an adjuvant approved for use in people 65 years of age and older. It contains the same amount of antigen as other standard-dose inactivated flu vaccines plus MF59 adjuvant, which is intended to trigger a greater immune response, and therefore, better protection against flu.

During the 2021–2022 flu season, the rate of influenza was lower than pre-pandemic levels, but it was significantly higher than the previous (2020–2021) season, which was historically mild, due to COVID-19–related precautions like masking and social distancing. In the past, influenza activity in the United States typically began to increase in the fall and peaked in February. During last year's season, the majority of the United States had two separate peaks in activity. The first wave peaked in mid-December, earlier than normal, and the timing of the second peak ranged from mid-March in parts of the south to May in New England and the Pacific Northwest. Experts are uncertain what this could mean for the 2022–2023 flu season.

Information has been updated through October 6, 2022.

What's New

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

Influenza Vaccines Available for the 2022-2023 Season

Product Name, Manufacturer	How Supplied	FDA Approved Age	Comment
Inactivated, High-Dose			
Fluzone High-Dose Quadrivalent, Sanofi Pasteur	0.7 mL	≥65 years	Preservative-free
Live Attenuated, for intranasal use			
FluMist Quadrivalent, AstraZeneca	0.2 mL intranasal sprayers	2–49 years	Intranasal
Inactivated			
Afluria Quadrivalent, Seqirus	0.5 mL	≥36 months	Preservative-free
Fluad Quadrivalent, Seqirus	0.5 mL	≥65 years	Adjuvanted Preservative-free
Fluarix Quadrivalent, GSK	0.5 mL	≥6 months	Preservative-free
Flublok Quadrivalent, Sanofi Pasteur	0.5 mL	≥18 years	Recombinant Egg-free Preservative-free Antibiotic-free
Flucelvax Quadrivalent, Seqirus	0.5 mL	≥6 months	Egg-free Preservative-free Antibiotic-free
Flulaval Quadrivalent, GSK	0.5 mL	≥6 months	Preservative-free
Fluzone Quadrivalent, Sanofi Pasteur	0.5 mL	≥6 months	Preservative-free

*Although there are many forms of flu vaccines there is no one vaccine that is preferred over another.
Information is current as of 10/06/2022

Information has been updated through October 6, 2022.

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

Can the Influenza Vaccine be Coadministered with the COVID-19 Vaccine?

COVID-19 is expected to continue to circulate in the United States during the 2022–2023 influenza season, and COVID-19 vaccinations (both primary series and boosters) will continue to be used. Recently, the CDC and the FDA cleared Pfizer-BioNTech's and Moderna's bivalent COVID-19 vaccines targeting Omicron BA.4/BA.5 for use as single booster doses. According to CDC research, broad uptake of the updated COVID-19 boosters early this fall could prevent >100,000 hospitalizations compared with a later rollout and could save billions of dollars in direct medical costs. This early booster rollout will coincide with the optimal timing for influenza vaccine administration for most people.

Current guidance from the CDC for the administration of COVID-19 vaccines indicates that these vaccines can be administered with influenza vaccines during the same provider visit. Studies have demonstrated similar levels of immunogenicity when the vaccines are co-administered, and no safety concerns have been identified. Additional information regarding influenza and routine vaccination during the COVID-19 pandemic can be obtained on the CDC website. (https://www.cdc.gov/flu/season/faq-flu-season-2022-2023.htm)

CDC Update on COVID-19 Vaccination:

On August 31, 2022, the FDA issued a statement granting emergency use authorization (EUA) for updated booster doses by the companies Pfizer and Moderna. The use of these new booster doses is also endorsed by the CDC and by the CDC's Advisory Committee on Immunization Practices (ACIP).

Both vaccine boosters add the spike protein Omicron BA.4 and BA.5 to their respective original components to mitigate the most transmissible variants.

- The Moderna COVID-19 vaccine, bivalent, is authorized for use as a single booster dose in persons 18 years of age or older. Vaccine-eligible patients must have waited at least two months since their last dose of the primary series or their last monovalent booster dose.
- The Pfizer-BioNTech COVID-19 vaccine, bivalent, is authorized for use as a single booster dose in people 12 years of age and older. Vaccine-eligible patients must wait at least two months since their last dose of the primary series or their last monovalent booster dose.

Important note: The administration, dosage and handling of these vaccines are the same as their monovalent versions. For patients 12 years of age and older, the recommendation for a booster dose is, overwhelmingly, the new bivalent formulation. To ensure appropriateness of administration for patients, we have summarized the ages and quantities of doses per vaccine below for non-immunocompromised patients:

Information has been updated through October 6, 2022.

What's New

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Vaccine	Doses	Age
Viral Vector Vaccine		
Janssen	**Primary Vaccination Series**	
	One Dose	18 years and older
	Booster Dose	
	First Booster Dose	18 years and older one booster dose, two months after initial dose
	Second Booster Dose	50 years and older: 4 months after first booster dose
mRNA Vaccines		
Moderna	**Primary Vaccination Series - Monovalent**	
	Two Doses	6 months and older: Second dose, 4-8 weeks after first dose.
	Booster Dose - Monovalent	
	First Booster Dose	18 years and older one booster dose, 5 months after the last dose of the primary vaccination series
	Second Booster Dose	50 years and older: 4 months after first booster dose
	Booster Dose - Bivalent	
	Booster Dose	18 years and older, 2 months after the last dose of the primary series or last monovalent booster dose.

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What's New

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Vaccine	Doses	Age
Pfizer	**Primary Vaccination Series - Monovalent**	
	Three Doses	6 months – 4 years of age: Second dose, 3-8 weeks after first dose. Third dose, at least 8 weeks after second dose
	Two Doses	5 years and older: Second dose, 3-8 weeks after first dose
	Booster Dose - Monovalent	
	First Booster Dose	5 years or older, 5 months after the last dose of the primary vaccination series.
	Second Booster Dose	50 years and older: 4 months after first booster dose
	Booster Dose - Bivalent	
	Booster Dose	12 years and older, 2 months after the last dose of the primary series or last monovalent booster dose.
Protein Subunit Vaccine		
Novavax	**Primary Vaccination Series**	
	Two Doses	18 years and older

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Specialty Pipeline

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

There is a growing trend of specialty drugs in the market. Therapeutic areas where the specialty drug pipeline could yield new approvals in the coming years include treatments for dermatologic conditions, hemophilia, genetic disorders, among others.

Pipeline Drug	Current Status	Anticipated Approval	Indication
Adagrasib	NDA Filled	12/14/2022	KRAS G12C specific inhibitor for the treatment of KRAS G12C- mutated locally advanced or metastatic non-small cell lung cancer (NSCLC); oral.
Arimoclomol	Complete Response	2023	Molecular chaperone activator that stimulates the normal cellular protein repair pathway for the treatment of Niemann Pick Disease Type C (NPC); oral.
Bimekizumab	Complete Response	2023	Monoclonal antibody that blocks the effects of IL-17A and IL-17F for the treatment of moderate-to-severe plaque psoriasis; SC injection.
Cipaglucosidase alfa	BLA Filed	10/29/2022	Recombinant human acid α-glucosidase (rhGAA) enzyme replacement therapy/chaperone therapy for the treatment of late-onset Pompe disease; IV infusion.
Deucravacitinib	NDA Filed	09/10/2022	Tyrosine Kinase 2 (TYK2) inhibitor for use in patients with moderate to severe plaque psoriasis.
Donanemab	BLA Filed	2023	Antibody that targets a modified form of beta amyloid called N3pG for the treatment of patients with early symptomatic Alzheimer's disease; IV infusion.
Etranacogene dezaparvovec	BLA Filed	11/24/2022	Gene therapy in patients with severe hemophilia B. *Single IV infusion*
Futibatinib	NDA Filed	09/30/2022	Fibroblast growth factor (FGFR) 1-4 inhibitor for the treatment of patients with previously treated locally advanced or metastatic cholangiocarcinoma harboring FGFR2 gene rearrangements, including gene fusions; oral.
Lecanemab	BLA Filed	01/09/2023	Humanized IgG1 monoclonal antibody that binds selectively to large, soluble Aß protofibrils and is thought to lead to their clearance or neutralize their toxicity for treatment of Alzheimer's Disease; IV infusion.

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Specialty Pipeline

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

Pipeline Drug	Current Status	Anticipated Approval	Indication
Mirikizumab	BLA Filed	04/28/023	Monoclonal antibody targeting IL-23p19 for the treatment of moderate-severe ulcerative colitis (UC); IV infusion and SC injection.
Obeticholic acid	Complete Response	2023	Farnesoid X receptor (FXR) agonist for the treatment of nonalcoholic steatohepatitis (NASH); oral.
Olipudase alfa	Approved	08/31/2022	Enzyme (acid sphingomyelinase) replacement therapy for the long-term treatment of non-central nervous system (CNS) manifestations of acid sphingomyelinase deficiency (ASMD); IV.
Pegunigalsidase alfa	Complete Response	2023	Plant cell-expressed, recombinant alpha-galactosidase-A enzyme for the treatment of Fabry disease; IV infusion (monthly).
Spesolimab	BLA Filed	09/01/2022	Humanized monoclonal antibody that blocks activation of the interleukin-36 receptor for the treatment of generalized pustular psoriasis (GPP) flares; IV.
Teclistamab	BLA Filed	08/29/2022	BCMA/CD3 bispecific antibody for the treatment of relapsed or refractory multiple myeloma; SC.
Teplizumab	BLA Filed	08/17/2022	Humanized monoclonal antibody engineered to alter the function of the T lymphocytes that mediate the destruction of the insulin-producing beta cells of the islets of the pancreas to delay or prevent the onset of type 1 diabetes in at-risk individuals; IV.
Valoctocogene roxaparvovec	Complete Response	2023	Adenovirus-associated virus vector-mediated the transfer of Human Factor VIII gene in patients with severe hemophilia A; IV Infusion.

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Biosimilar Pipeline

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

Below is a list of biosimilars that are currently under FDA review. Approval of a biosimilar does not imply availability and allocation in the market. Additional patent, exclusivities, settlement agreements, etc. may result in a delay in launch of a biosimilar.

Pipeline Biosimilar	Manufacturer	Reference Biologic	Possible FDA Approval Date	Potential Launch Date
Adalimumab	Fresenius Kabi	Humira (adalimumab)	1Q 2023	Settlement: 09/30/2023
Adalimumab (Hukyndra)	Teva/Alvotech	Humira (adalimumab)	Dec. 2022	Settlement: 07/01/2023
Adalimumab, CF(Yuflyma)	Celltrion	Humira (adalimumab)	2022	Settlement: 07/01/2023
Adalimumab-adaz (Hyrimoz HCF, CF) - new formulation	Sandoz	Humira (adalimumab)	5/21/2023	Settlement: 07/01/2023
Adalimumab-afzd (Abrilada)	Pfizer	Humira (adalimumab)	4Q 2022	Settlement: 07/01/2023
Aflibercept	Momenta/Viatris	Eylea (aflibercept)	Oct. 2022	TBD (2024)
Bevacizumab	Biothera	Avastin (bevacizumab)	2022	TBD (Pending FDA Approval)
Bevacizumab (Abevmy)	Viatris/Biocon	Avastin (bevacizumab)	2022	TBD (Pending FDA Approval)
Bevacizumab (Aybintio)	Samsung Bioepis/ Merck	Avastin (bevacizumab)	2022	TBD (Pending FDA Approval)
Bevacizumab (Vegzelma)	Actinium/ Celltrion	Avastin (bevacizumab)	10/1/2022	TBD (Pending FDA Approval)
Filgrastim	Tanvex BioPharma	Neupogen (filgrastim)	2022	TBD (Pending FDA Approval)
Natalizumab	Sandoz	Tysabri (Natalizumab)	May 2023	TBD (Pending FDA Approval)
Pegfilgrastim (Lupifil-P)	Lupin	Neulasta (pegfilgrastim)	4/2/2022	TBD (Pending FDA Approval)

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Biosimilar Pipeline

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

Pipeline Biosimilar	Manufacturer	Reference Biologic	Possible FDA Approval Date	Potential Launch Date
Tocilizumab	Fresenius Kabi/ Merck	Actemra (Tocilizumab)	2Q: 2023	TBD (Pending FDA Approval)
Trastuzumab	EirGenix/Sandoz	Herceptin (trastuzumab)	10/20/2022	TBD (Pending FDA Approval)
Trastuzumab	Tanvex BioPharma	Herceptin (trastuzumab)	2022	TBD (Pending FDA Approval

FDA Approvals

In-Market Brand

Drug Name	Information
Ranibizumab-eqrn (Cimerli)	**Dose:** Single-dose glass vial designed to provide 0.05 mL for intravitreal injections: 10 mg/mL solution (CIMERLI 0.5 mg) 6 mg/mL solution (CIMERLI 0.3 mg). **Indication:** A vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of patients with: Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema Following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), Myopic Choroidal Neovascularization (mCNV). **Comparables:** Lucentis, Byooviz, Susvimo, Eylea, Bevacizumab **Guidelines:** • American Academy of Ophthalmology, Age-Related Macular Degeneration Preferred Practice Pattern http://dx.doi.org/10.1016/j.ophtha.2019.09.024 • Guidelines for the Management of Diabetic Macular Edema by the European Society of Retina Specialists (EURETINA) Ophthalmologica 2017; 237:185-222 https://doi.org/10.1159/000458539

This information is up-to-date as of May 17th, 2022.

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

New Drug Entities

Drug Name	Information
Betibeglogene autotemcel (Zynteglo)	**Dose:** Cell suspension for intravenous infusion. A single dose of ZYNTEGLO contains a minimum of 5.0 × 106 CD34+ cells/kg of body weight, in one or more infusion bags. **Indication:** Is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of adult and pediatric patients with β-thalassemia who require regular red blood cell (RBC) transfusions. **Comparables:** None **Guidelines:** • Thalassemia International Federation (TIF): Guidelines for the management of transfusion dependent thalassemia (TDT), 4th edition (2021) • American Society of Hematology (ASH): Guidelines for sickle cell disease – Stem cell transplantation (2021)
Olipudase alfa (Xenpozyme)	**Dose:** For injection: 20 mg of olipudase alfa-rpcp as a lyophilized powder in a single-dose vial for reconstitution. **Indication:** A hydrolytic lysosomal sphingomyelin-specific enzyme indicated for treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients. Acid Sphingomyelinase Deficiency (ASMD), a rare genetic disease that causes premature death. **Comparables:** None (Xenpozyme is the first approved medication to treat symptoms that are not related to the central nervous system in patients with ASMD). **Guidelines:** https://rarediseases.org/rare-diseases/acid-sphingomyelinase-deficiency/#:~:text=Acid%20sphingomyelinase%20deficiency%20(ASMD)%20is,substance%20(lipid)%20called%20sphingomyelin
Spesolimab-sbzo (Spevigo)	**Dose:** Injection: 450 mg/7.5 mL (60 mg/mL) solution in a single-dose vial **Indication:** Is an interleukin-36 receptor antagonist indicated for the treatment of generalized pustular psoriasis flares in adults. **Comparables:** None **Guidelines:** https://www.aad.org/member/clinical-quality/guidelines/psoriasis

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New Drug Entities

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

Drug Name	Information
Pegfilgrastim-fpgk (Stimufend)	**Dose:** Injection: 6 mg/0.6 mL solution in a single-dose pre-filled syringe for manual use only **Indication:** Is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. **Comparables:** Fulphila, Nyvepria, Udenyca and Ziextenzo, Fylnetra **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf
Eflapegrastim-xnst (Rolvedon)	**Dose:** Injection: 13.2 mg/0.6 mL solution in a single-dose prefilled syringe. **Indication:** Is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. **Comparables:** None **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf
Deucravacitinib tablets (Sotyktu)	**Dose:** 6mg oral tablets **Indication:** Indicated to treat adults who have moderate-to-severe plaque psoriasis treatable by systemic therapy or phototherapy, **Comparables:** Otezla **Guidelines:** https://www.aad.org/member/clinical-quality/guidelines/psoriasis
Terlipressin (Terlivaz)	**Dose:** For injection: Terlivaz 0.85 mg (1 vial) as a lyophilized powder in a single-dose vial for reconstitution. **Indication:** Is a vasopressin receptor agonist indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function. **Comparables:** None **Guidelines:** • Kidney Disease: Improving Global Outcomes (KDIGO): Clinical practice guideline update for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder (CKD-MBD) (2017) • National Institute for Health and Care Excellence (NICE): Clinical guideline on chronic kidney disease – Assessment and management (2021)

Information has been updated through October 6, 2022.

New Drug Formulations

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

Drug Name	Information
Roflumilast (Zoryve)	**Dose:** Cream, 0.3%: 3 mg of roflumilast per gram in 60-gram tubes. **Indications:** Is a phosphodiesterase 4 inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older. **Comparables:** Eucrisa, Apremilast **Guidelines:** • American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF): Joint guidelines of care for the management and treatment of psoriasis in pediatric patients (2020) • Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures
Acalabrutinib (Calquence)	**Dose:** 100 mg tablet **Indication:** Is a kinase inhibitor indicated for the treatment of adult patients with: Mantle cell lymphoma (MCL) who have received at least one prior therapy. Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). **Comparables:** Tyvaso inhalation for nebulizer **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf
Testosterone undecanoate (Kyzatrex)	**Dose:** Capsules: 100 mg, 150 mg, 200 mg. **Indication:** Is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. **Comparables:** Tlando, Jatenzo **Guidelines:** American Urological Association (AUA): Guidelines for the evaluation and management of testosterone deficiency (2018)
Tadalafil (Tadliq)	**Dose:** Oral Suspension: 20 mg/5 mL **Indication:** Is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability. **Comparables:** Adcirca, Revatio **Guidelines:** CHEST: Guideline and expert panel report on therapy for pulmonary arterial hypertension in adults, update (2019)

Information has been updated through October 6, 2022.

New Drug Formulations

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

Drug Name	Information
Drospirenone chewable tablets	**Dose:** Chewable Tablets consists of 28 tablets in the following order: 24 white active chewable tablets each containing 3.5 mg of drospirenone, 4 green inert chewable tablets. **Indication:** Is a progestin indicated for use by females of reproductive potential to prevent pregnancy. **Comparables:** Slynd **Guidelines:** • American College of Obstetricians and Gynecologists (ACOG): Birth control (contraception) – Resources for Ob-Gyns and women's health care providers • American Society of Reproductive Medicine (ASRM): Contraception
Dextromethorphan hydrobromide and Bupropion hydrochloride (Auvelity)	**Dose:** Extended-release tablets: 45 mg/105 mg dextromethorphan hydrobromide/ bupropion hydrochloride. **Indication:** Is a combination of dextromethorphan, an uncompetitive N-methyl D-aspartate (NMDA) receptor antagonist and sigma-1 receptor agonist, and bupropion, an aminoketone and CYP450 2D6 inhibitor, indicated for the treatment of major depressive disorder (MDD) in adults. **Comparables:** Bupropion sustained-release tablets **Guidelines:** https://www.apa.org/depression-guideline
Ibrutinib (Imbruvica)	**Dose:** New Formulation: Oral suspension: 70 mg/mL. Other: Capsules: 70 mg and 140 mg, Tablets: 140 mg, 280 mg, 420 mg, and 560 mg. **Indication:** For Adult and pediatric patients age 1 year and older with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy. **Comparables:** None **Guidelines:** https://ashpublications.org/hematology/article/2021/1/648/482938/Updates-in-chronic-graft-versus-host-disease
Omeprazole and sodium bicarbonate (Konvomep)	**Dose:** For Oral Suspension: 2 mg omeprazole and 84 mg sodium bicarbonate per mL after reconstitution in 90 mL, 150 mL, or 300 mL bottles. **Indication:** Is a combination of omeprazole, a proton pump inhibitor (PPI) and sodium bicarbonate, indicated in adults for: • Treatment of active benign gastric ulcer • Reduction of risk of upper gastrointestinal (GI) bleeding in critically ill patients. **Comparables:** Omeprazole-Sodium Bicarbonate, Zegerid **Guidelines:** American College of Gastroenterology (ACG): Clinical guideline for the treatment of Helicobacter pylori infection (2017)

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Drug Name	Information
Stiripentol (Diacomit)	**Dose:** Capsule: 250 mg or 500 mg and powder for Oral Suspension: 250 mg or 500 mg. **New Indication:** For the treatment of seizures associated with Dravet syndrome in patients taking clobazam who are 6 months of age and older and weighing 7 kg or more. There are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome. **Comparables:** Epidiolex, Fintepla **Guidelines:** https://rarediseases.org/rare-diseases/dravet-syndrome-spectrum/
Relugolix, estradiol, and norethindrone (Myfembree)	**Dose:** Tablets: fixed-dose combination containing relugolix 40 mg, estradiol 1 mg and norethindrone acetate 0.5 mg. **New Indication:** To expand the use for the management of moderate to severe pain associated with endometriosis. **Comparables:** Oriahnn **Guidelines:** American College of Obstetricians and Gynecologists (ACOG): Committee option on dysmenorrhea and endometriosis in the adolescent (2018)

New Generics

First-Time Generic Approval

Generic Name	Applicant	Brand Name	Approval Date	Indication
Empagliflozin and Metformin Hydrochloride Tablets, 5 mg/500 mg, 5 mg/1000 mg, 12.5 mg/500 mg, and 12.5 mg/1000 mg	Zydus Pharmaceuticals (USA) Inc.	Synjardy (Empagliflozin and Metformin Hydrochloride) Tablets	7/7/2022	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease

Information has been updated through October 6, 2022.

Recall

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Date	Brand Name(s)	Product Description	Recall Reason Description	Company Name
08/04/2022	Multiple brand names	Magnesium Citrate Saline Laxative Oral Solution	Microbial contamination with Gluconacetobacter liquefaciens	Multiple Manufacturers
08/04/2022	Major	Milk of Magnesia, Magnesium Hydroxide/ Aluminum Hydroxide/ Simethicone Oral Suspension	Microbial contamination	Plastikon Healthcare, LLC
08/03/2022	Launch Sequence	Launch Sequence Aphrodisia and Euphoria Capsules	Contains Tadalafil	Loud Muscle Science, LLC
07/25/2022	Sustango	Dietary Supplement for Male Enhancement	Contains Tadalafil	Ultra Supplement LLC

Shortages (New)

Date	Drug Name (Shortage Reason)
08/21/2022	Conjugated Estrogens/Bazedoxifene (DUAVEE) Tablet, Film Coated (Currently in Shortage)
08/20/2022	Risankizumab-rzaa Injection (Discontinuation)
08/15/2022	Fluconazole (Diflucan) Tablets (Discontinuation)

Information has been updated through October 6, 2022.

References

For the most up to date list of drug shortages visit:

- https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

Sources

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AUGUST 2022

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