MC-Rx

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# Insights on the Drugs Pipeline

## Exploring the changes in the drugs market.

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**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

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

## Booster Shots - *Data Supporting Need for a Booster Shot* -

- Studies show that after getting vaccinated against COVID-19, protection against the virus may decrease over time and be less able to protect against the Delta variant. Although COVID-19 vaccination for adults aged 65 years and older remains effective in preventing severe disease, recent data suggest vaccination is less effective at preventing infection or milder illness with symptoms. Emerging evidence also shows that among healthcare and other frontline workers, vaccine effectiveness against COVID-19 infections is decreasing over time. This lower effectiveness is likely due to the combination of decreasing protection as time passes since getting vaccinated (e.g., waning immunity) as well as the greater infectiousness of the Delta variant. Data from a small clinical trial show that a Pfizer-BioNTech booster shot increased the immune response in trial participants who finished their primary series six months earlier. With an increased immune response, people should have improved protection against COVID-19, including the Delta variant.

## Pfizer-BioNTech Vaccine Booster Recipients

- Only certain populations initially vaccinated with the Pfizer-BioNTech vaccine can get a booster shot at this time.
- People aged 65 years and older
- People with medical conditions aged 50-64 years old
  - Adults 50–64 years with underlying medical conditions(i.e.) should get a booster shot
- People with medical conditions aged 18-49 years
  - People aged 18–49 years with underlying medical conditions (i.e.) may get a booster shot based on their benefits and risks. However, that risk is likely not as high as for adults aged 50 years and older who have underlying medical conditions. This recommendation may change in the future as more data becomes available.
- Long-term care setting residents aged 18 years and older
  - Residents aged 18 years and older in long-term care settings should get a booster shot. Because residents in long-term care settings live closely together in group settings and are often older adults with underlying medical conditions, they are at increased risk of infection and severe illness from COVID-19.
- Employees and residents at increased risk for COVID-19 exposure and transmission
  - Adults aged 18–64 years who work or reside in certain occupational or institutional settings (e.g., health care, schools, correctional facilities, homeless shelters) may be at increased risk of being exposed to COVID-19, which could be spreading where they work or reside. This recommendation may change in the future as more data becomes available.

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## Moderna Vaccine Booster Recipients

- A Food and Drug Administration advisory panel voted unanimously in favor of authorizing booster shots of the Moderna COVID-19 vaccine to:
- People 65 and older, those
- People aged 18 to 64 with risk factors for severe COVID-19, and
- People whose jobs put them at high risk for severe complications of COVID-19, such as health care workers. The Vaccines and Related Biological Products Advisory Committee voted 19-to-0 that the Moderna booster should be authorized for these groups at least six months after receiving their second dose.
- The FDA is not bound by the votes of its advisory committees, which it convenes to ask for guidance, but it generally follows their advice. The booster shot would be granted an emergency use authorization, used to speed the approval of products during public health emergencies, not a traditional approval.

## J&J COVID-19 Booster Recipients

- A Food and Drug Administration advisory panel voted unanimously to recommend Johnson & Johnson booster shots, most likely clearing the way for all 15 million people who got the company's one-dose coronavirus vaccine to receive a second shot. If the FDA and the CDC accept the recommendation, as expected, boosters could be offered soon. However, many committee members made clear that they believed Johnson & Johnson recipients might benefit from the option of a booster of the Pfizer-BioNTech or Moderna Vaccine, something a top FDA official said the agency was considering. FDA advisers cited growing evidence that J&J recipients are more vulnerable to infection than people who got vaccines from competitors Pfizer or Moderna – and that most got their single-dose many months ago.

**References:**


- https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html
- https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-9-23/03-COVID-Oliver.pdf

# 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 immune-related, inflammatory conditions (especially TNF-inhibitors and biosimilars), Alzheimer's, hemophilia, genetic disorders, among others.

| Pipeline Drug | Current Status | Anticipated Approval | Indication |
|---|---|---|---|
| Abrocitinib (Pfizer) | NDA Filed | 2021/2022 | Janus kinase 1 (JAK1) inhibitor for the treatment of patients with moderate-to-severe atopic dermatitis (AD); oral<br>*Breakthrough Therapy* |
| Adagrasib (Mirati Therapeutics) | Phase 2 | 2022 | KRAS G12C specific inhibitor for the treatment of KRAS G12C- mutated locally advanced or metastatic non-small cell lung cancer (NSCLC); oral<br>*Breakthrough Therapy* |
| Bimekizumab (UCB) | BLA Filed | 2021 11/15/2021 | Monoclonal antibody that blocks the effects of IL-17A and IL-<br>17F for the treatment of moderate-to-severe plaque psoriasis; SC injection |
| Futibatinib (Taiho Oncology) | Phase 3 | 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<br>*Breakthrough Therapy/Orphan Drug* |
| Tezepelumab (Amgen/ Astrazeneca) | BLA Filed | 01/10/2022 | Anti-thymic stromal lymphopoietin (anti-TSLP) monoclonal antibody for the treatment of severe, uncontrolled asthma; SC<br>*Breakthrough Therapy* |

# 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 patents, exclusivities, settlement agreements, etc., may delay a biosimilar launch.

| Pipeline Biosimilar | Manufacturer | Reference Biologic | Posible FDA Approval Date | Potential Launch Date |
|---|---|---|---|---|
| Ranibizumab | Samsung Bioepis/ Biogen | Lucentis (ranibizumab) | 9/18/2021 | TBD (Pending FDA Approval) |
| Adalimumab | Cipla/Alvotech | Humira (adalimumab) | Sept. 2021 | Settlement: 06/01/2023 |
| Bevacizumab | Biothera | Avastin (bevacizumab) | 11/27/2021) | TBD (Pending FDA Approval |
| Adalimumab | Coherus | Humira (adalimumab) | Dec. 2021 | Settlement: 07/01/2023 |
| Insulin aspart (Kixelle) | Viatris/Biocon | Novolog (insulin aspart) | 2021 | TBD (Pending FDA Approval) |
| Pegfilgrastim | Fresenius Kabi | Neulasta (pegfilgrastim) | 2021 | TBD (Pending FDA Approval) |
| Bevacizumab | Mylan/Biocon | Avastin (bevacizumab) | 2021 | TBD (Pending FDA Approval) |
| Bevacizumab (Abyntio) | Samsung Bioepis/ Merck | Avastin (bevacizumab) | 2021 | TBD (Pending FDA Approval) |
| Ffilgrastim | Tanvex BioPharma | Neupogen (filgrastim) | 2021 | TBD (Pending FDA Approval) |
| Filgrastim | Adello Biologic | Neupogen (filgrastim) | 2021 | TBD (Pending FDA Approval) |
| Pegfilgrastim | Adello Biologic | Neulasta (pegfilgrastim) | 1/13/2022 | TBD (Pending FDA Approval) |
| Pegfilgrastim (Lupifil-P) | Lupin | Neulasta (pegfilgrastim) | 4/2/2022 | TBD (Pending FDA Approval) |
| Bevacizumab (Almysys) | Amneal | Avastin (bevacizumab) | 4/17/2022 | TBD (Pending FDA Approval) |
| Ranibizumab | Bioeq/Coherus | Lucentis (ranibizumab) | 8/5/2022 | TBD (Pending FDA Approval) |

# New Drug Formulations

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

| Drug Name | Information |
|---|---|
| **Selexipag (Uptravi)** | **Dose:** For Injection: 1800 mcg of Selexipag as a lyophilized powder in a single-dose vial for reconstitution and dilution.<br>**Indication:** for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH.<br>**Comparable:** Teprostinil (Remodulin), Epoprostenol (Flolan)<br>**Guidelines:** https://journal.chestnet.org/article/S0012-3692(19)30002-9/fulltext |
| **Lorazepam (Loreev XR)** | **Dose:** extended-release capsules, 1 mg, 2 mg, and 3 mg<br>**Indication:** for the treatment of anxiety disorders in adults who are receiving stable, evenly divided, three times daily dosing with lorazepam tablets.<br>**Comparable:** Lorazepam (Ativan)<br>**Guidelines:** https://www.psychiatry.org/psychiatrists/practice/clinical-practice-guidelines |
| **Paliperidone palmitate (Invega Hafyera)** | **Dose:** Extended-release injectable suspension: 1,092 mg/3.5 mL or 1,560 mg/5 mL single-dose prefilled syringes.<br>**Indication:** for the treatment of schizophrenia in adults after they have been adequately treated with: • A once-a-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA SUSTENNA) for at least four months or • An every-three-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA TRINZA) for at least one three-month cycle<br>**Comparable:** Invega Sustenna, Invega Trinza<br>**Guidelines:** https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890424841 |
| **Tretinoin and benzoyl peroxide (Twyneo)** | **Dose:** Cream: 0.1% tretinoin/3% benzoyl peroxide<br>**Indication:** is a combination of tretinoin, a retinoid, and benzoyl peroxide indicated for the topical treatment of acne vulgaris in adults and pediatric patients nine years of age and older.<br>**Comparable:** Tretinoin 0.1% cream (Retin-A), Benzoyl peroxide 2.5% gel<br>**Guidelines:** https://www.jaad.org/action/ |

# New Drug Indications

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

| Drug Name | Information |
|---|---|
| **Immune Globulin Intravenous Human (Octagam)** | **Dose:** Solution containing 10% IgG (100 mg/mL)<br>**Indication:** This is an immune globulin intravenous (human) liquid preparation indicated for treating Dermatomyositis (DM) in adults.<br>**Comparable:** Immune Globulins<br>**Guidelines:** https://rarediseases.org/rare-diseases/dermatomyositis/ |
| **Pembrolizumab (Keytruda) and Lenvatinib (Lenvima)** | **Dose:** RCC: 200 mg every three weeks or 400 mg every six weeks with lenvatinib 20 mg orally once daily.<br>**Indication:** In combination with lenvatinib, it is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).<br>**Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/kidney_blocks.pdf |
| **Dalbavancin (Dalvance)** | **Dose:** For Injection: 500 mg of lyophilized powder in a vial for reconstitution.<br>**Indication:** To treat adult and pediatric patients with acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of Grampositive microorganisms to include pediatric patients from birth to less than 18 years of age.<br>**Comparable:** Oritavancin (Kymirsa, Orbactiv), Telavancin (Vibativ)<br>**Guidelines:** https://www.idsociety.org/practice-guideline/practice-guidelines/#/+/0/date_na_dt/desc/ |
| **Exenatide (Bydureon, Bydureon Bcise, Bydureon Pen)** | **Dose:** Extended-release for injectable suspension available as a Single-dose tray containing 2 mg of exenatide in a single-dose vial.<br>**Indication:** Indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged ten years and older with type 2 diabetes mellitus.<br>**Comparable:** Exenatide (Byetta), Liraglutide (Victoza), Dulaglutide (Trulicity)<br>**Guidelines:** https://care.diabetesjournals.org/content/44/Supplement_1/S111 |
| **Duloxetine HCl (Drizalma Sprinkle)** | **Dose:** Delayed-release capsules: 20 mg, 30 mg, 40 mg, and 60 mg<br>**Indication:** For the treatment of Fibromyalgia (FM) in adults.<br>**Comparable:** Duloxetine (Cymbalta)<br>**Guidelines:** https://www.aafp.org/afp/2007/0715/p247.html |
| **Mepolizumab (Nucala)** | **Dose:** For Injection: 100 mg of lyophilized powder in a single-dose vial; Injection: 100 mg/mL, single-dose, prefilled autoinjector or single-dose prefilled syringes.<br>**Indication:** Add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP).<br>**Comparable:** Dupilumab (Dupixent), Omalizumab (Xolair)<br>**Guidelines:** https://www.aaaai.org/Allergist-Resources/Ask-the-Expert/Answers/Old-Ask-the-Experts/biolo |

# New Drug Indications

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

| Drug Name | Information |
|---|---|
| **Tacrolimus (Prograf)** | **Dose:** Capsules: 0.5 mg, 1 mg and 5 mg, Injection: 5 mg/mL; For oral suspension: 0.2 mg, 1 mg unit-dose packets containing granules.<br>**Indication:** For the prophylaxis of organ rejection in adult and pediatric patients receiving allogeneic liver, kidney, heart, or lung transplants, combined with other immunosuppressants.<br>**Comparable:** Cyclosporine (Gengraf), Cyclosporine (Sandimmune) Off label<br>**Guidelines:** https://journal.chestnet.org/article/S0012-3692(15)41985-3/fulltext |
| **Empagliflozin (Jardiance)** | **Dose:** Tablets: 10 mg, 25 mg<br>**Indication:** To reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduce ejection fraction.<br>**Comparable:** Farxiga, Invokana<br>**Guidelines:** https://www.jacc.org/doi/full/10.1016/j.jacc.2020.05.037 |
| **Rivaroxaban (Xarelto)** | **Dose:** Tablets: 2.5 mg, 10 mg, 15 mg, and 20 mg<br>**Indication:** (a) To reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD) (b) To reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD.<br>**Guidelines:** https://journal.chestnet.org/article/S0012-3692(18)32244-X/fulltext#secsectitle0450 |
| **Dostarlimab-gxly (Jemperli)** | **Dose:** Injection: 500 mg/10 mL (50 mg/mL) solution in a single-dose vial.<br>**Indication:** As determined by an FDA-approved test, solid tumors have progressed on or following prior treatment and have no satisfactory alternative treatment options.<br>**Comparable:** Pembrolizumab (Keytruda) |
| **Nivolumab (Opdivo)** | **Dose:** Injection: 40 mg/4 mL, 100 mg/10 mL, and 240 mg/24 mL solution in a single-dose vial.<br>**Indication:** adjuvant treatment of patients with urothelial carcinoma (UC) at high risk of recurrence after undergoing radical resection of UC.<br>**Comparable:** Pembrolizumab (Keytruda)<br>**Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/kidney_blocks.pdf |
| **Ivosidenib (Tibsovo)** | **Dose:** Tablets: 250 mg<br>**Indication:** Locally advanced or metastatic cholangiocarcinoma who have been previously treated.<br>**Comparable:** Pembrolizumab, Nivolumab, Lenvatinib<br>**Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary_blocks.pdf |

# New Drug Indications

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

| Drug Name | Information |
|---|---|
| **Brivaracetam (Briviact)** | **Dose:** (a) Tablets: 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg (b) Oral solution: 10 mg/mL (c) Injection: 50 mg/5 mL single-dose vial<br>**Indication:** for the treatment of partial-onset seizures in patients one month of age and older<br>**Comparable:** Carbamazepine (Tegretol), Phenytoin (Dilantin), Levetiracetam (Keppra)<br>**Guidelines:** https://www.aan.com/Search#stq=partial%20seizures%20treatments%20guidelines&stp=1 |
| **Zanubrutinib (Brukinsa)** | **Dose:** Capsules: 80 mg<br>**Indication:** for the treatment of adult patients with (a) Waldenström's macroglobulinemia (WM). (b) Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen<br>**Comparable:** Ibrutinib +/- rituximab(WM), Umbralisib (Ukoniq) (MZL)<br>**Guidelines:** waldenstroms.pdf (nccn.org) and b-cell.pdf (nccn.org) |
| **Zoster Vaccine Recombinant, Adjuvanted (Shingrix)** | **Dose:** Suspension for Injection supplied as a single-dose vial of lyophilized varicella-zoster virus glycoprotein E (gE) antigen component to be reconstituted with the accompanying vial of AS01B adjuvant suspension component. After reconstitution, a single dose of SHINGRIX is 0.5 mL.<br>**Indication:** A vaccine is indicated to prevent herpes zoster (HZ) (shingles) in adults aged 18 years and older who are or will be at increased risk of HZ due to immunodeficiency or immunosuppression caused by known disease or therapy.<br>**Guidelines:** https://www.cdc.gov/vaccines/vpd/shingles/index.html |
| **Levonorgestrel-releasing intrauterine system (Mirena)** | **Dose:** One sterile intrauterine system consisting of a T-shaped polyethylene frame with a steroid reservoir containing 52 mg levonorgestrel packaged within a sterile inserter.<br>**Indication:** Prevention of pregnancy for up to 7 years.<br>**Comparable:** Liletta, Kyleena<br>**Guidelines:** https://www.acog.org/search?utm_source=redirect&utm_medium=web&utm_campaign=otn#q=contraception&sort=relevancy |

# In Market Brand

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

| Drug Name | Information |
|---|---|
| **Fexinidazole** | **Dose:** Tablets: 600 mg<br>**Indication:** For the treatment of both first-stage (hemolymphatic) and second-stage (meningoencephalitic) human African trypanosomiasis (HAT) due to Trypanosoma brucei gambiense in patients six years of age and older and weighing at least 20 kg.<br>**Guidelines:** WHO interim guidelines for the treatment of gambiense human African trypanosomiasis, 2019 |
| **Odevixibat (Bylvay)** | **Dose:** Oral Pellets: 200 mcg, 600 mcg; Capsules: 400 mcg, 1200 mcg<br>**Indication:** To treat pruritus in patients three months of age and older with progressive familial intrahepatic cholestasis (PFIC).<br>**Guidelines:** https://www.aasld.org/sites/default/files/2019-06/PracticeGuidelines-PBC-November2018.pdf |
| **Insulin glargine-yfgn (Semglee)** | **Dose:** Injection: 100 units/mL (U-100) available as: 10 mL multiple-dose vial and 3 mL single-patient-use prefilled pen.<br>**Indication:** Indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and adults with type 2 diabetes mellitus.<br>***Is interchangeable with LANTUS (insulin glargine)***<br>**Comparables:** Lantus, Basaglar<br>**Guidelines:** https://care.diabetesjournals.org/content/44/Supplement_1/S111 |
| **Anifrolumab-fnia (Saphnelo)** | **Dose:** Injection: 300 mg/2 mL (150 mg/mL) in a single-dose vial.<br>**Indication:** To treat adult patients with moderate to severe systemic lupus erythematosus (SLE) who are receiving standard therapy.<br>**Comparable:** Belimumab (Benlysta)<br>**Guidelines:** https://www.aafp.org/afp/2016/0815/p284.html<br>https://ard.bmj.com/content/78/6/736 |
| **Avalglucosidase alfa-ngpt (Nexviazyme)** | **Dose:** For Injection: 100 mg of avalglucosidase alfa-ngpt as a lyophilized powder in a single-dose vial for reconstitution.<br>**Indication:** For the treatment of patients one year of age and older with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency).<br>**Comparable:** Alglucosidase Alpha (Lumizyme, Myozyme)<br>**Guidelines:** https://rarediseases.org/rare-diseases/pompe-disease/ |

# In Market Brand

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

| Drug Name | Information |
|---|---|
| **Belzutifan (Welireg)** | **Dose:** Tablets: 40 mg<br>**Indication:** For treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery.<br>**Guidelines:** https://rarediseases.org/rare-diseases/von-hippel-lindau-disease/ |
| **Difelikefalin (Korsuva)** | **Dose:** Injection: 65 mcg /1.3 mL (50 mcg/mL) of difelikefalin<br>**Indication:** for treating moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD).<br>**Guidelines:** https://www.bad.org.uk/shared/getfile.ashx?id=5927&itemtype=document |
| **COVID-19 Vaccine, mRNA (Comirnaty)** | **Dose:** Suspension for Injection. After preparation, a single dose is 0.3 mL.<br>**Indication:** Is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.<br>**Comparable:** Moderna Vaccine and J&J Vaccine (emergency use utilization)<br>**Guidelines:** https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html |
| **Lonapegsomatropin-tcgd (Skytrofa)** | **Dose:** For injection: 3 mg, 3.6 mg, 4.3 mg, 5.2 mg, 6.3 mg, 7.6 mg, 9.1 mg, 11 mg and 13.3 mg<br>**Indication:** is a human growth hormone indicated for the treatment of pediatric patients one year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH).<br>**Comparable:** Genotropin, Humatrope, Nutropin AQ<br>**Guidelines:** https://www.karger.com/Article/Pdf/452150 |
| **Pneumococcal 15-valent Conjugate Vaccine (Vaxneuvance)** | **Dose:** Suspension for Injection (0.5 mL dose), supplied as a single-dose prefilled syringe.<br>**Indication:** for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older.<br>**Comparable:** Prevnar 13 (PCV13), Pneumovax 23 (PPSV23), Prevnar 20 (PCV20)<br>**Guidelines:** https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html |

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

## First-Time Generic Approval

| Generic Name | Applicant | Brand Name | Approval Date | Indication |
|---|---|---|---|---|
| Zolmitriptan Nasal Spray USP, 2.5 mg and 5 mg | Padagis Israel Pharmaceuticals Ltd. | Zomig (Zolmitriptan) Nasal Spray USP, 2.5 mg and 5 mg | 9/30/2021 | For the acute treatment of migraine with or without aura in adults and pediatric patients 12 years and older |
| Brimonidine Topical Gel, 0.33% | Padagis Israel Pharmaceuticals Ltd. | Mirvaso (Brimonidine) Topical Gel, 0.33% | 9/23/2021 | For the topical treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years of age or older |
| Ceftaroline Fosamil for Injection, 400 mg, and 600 mg Single-Dose Vials | Apotex Inc. | Teflaro (Ceftaroline Fosamil) for Injection, 400 mg, and 600 mg Single-Dose Vials | 9/21/2021 | For the treatment of acute bacterial skin and skin structure infections in adult and pediatric patients two months of age and older; community-acquired bacterial pneumonia in adult and pediatric patients two months of age and older |
| Vortioxetine Tablets, 5 mg, 10 mg, and 20 mg | Zydus Pharmaceuticals (USA) Inc. | Trintellix (Vortioxetine) Tablets, 5 mg, 10 mg, and 20 mg | 9/17/2021 | Indicated for the treatment of major depressive disorder (MDD) in adults |
| Eliglustat Capsules, 84 mg | Aizant Drug Research Solutions Pvt. Ltd. | Cerdelga (Eliglustat) Capsules, 84 mg | 9/8/2021 | For the long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers, intermediate metabolizers, or poor metabolizers as detected by an FDA-cleared test |
| Paroxetine Oral Suspension, 10 mg (base)/5 mL | Novitium Pharma LLC | Paxil (Paroxetine) Oral Suspension, 10 mg/5 mL | 9/3/2021 | For the treatment of Major Depressive Disorder, Obsessive-Compulsive Disorder, Panic Disorder, Social Anxiety Disorder, Generalized Anxiety Disorder, and Posttraumatic Stress Disorder |

# New Generics

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

| Generic Name | Applicant | Brand Name | Approval Date | Indication |
|---|---|---|---|---|
| Linagliptin Tablets, 5 mg | Sunshine Lake Pharma Co., Ltd. | Tradjenta (Linagliptin) Tablets, 5 mg | 8/31/2021 | Adjunct treatment to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus |
| Linagliptin and Metformin Hydrochloride Tablets, 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1,000 mg | Sunshine Lake Pharma Co., Ltd. | Jentadueto (Linagliptin and Metformin Hydrochloride) Tablets, 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1,000 mg | 8/30/2021 | Adjunct treatment to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus |
| Tofacitinib Extended-Release Tablets, 11 mg, and 22 mg | Zydus Pharmaceuticals (USA) Inc | Xeljanz XR (Tofacitinib) Extended-Release Tablets, 11 mg, and 22 mg | 8/19/2021 | For the treatment of adult patients with moderately to severely active rheumatoid arthritis; active psoriatic arthritis; moderately to severely active ulcerative colitis |
| Sunitinib Malate Capsules, 12.5 mg, 25 mg, 37.5 mg and 50 mg | Sun Pharmaceutical Industries Limited | Sutent (Sunitinib Malate) Capsules, 12.5 mg, 25 mg, 37.5 mg and 50 mg | 8/16/2021 | For the treatment of adult patients with gastrointestinal stromal tumor after disease progression on or intolerance to imatinib mesylate; treatment of adult patients with advanced renal cell carcinoma (RCC); adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy; treatment of progressive, well-differentiated pancreatic neuroendocrine tumors in adult patients with unresectable locally advanced or metastatic disease |

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

## Recall

| Date | Brand Name(s) | Product Description | Product Type | Recall Reason Description | Company Name |
|---|---|---|---|---|---|
| 10/14/2021 | Lupin | Irbesartan and Hydrochlorothiazide Tablets USP, 150mg/12.5 mg and 300mg/12.5 mg | Drugs | API batches above the specification limit for the impurity, N-nitroso irbesartan | Lupin Pharmaceuticals, Inc. |
| 10/12/2021 | Teligent Pharma, Inc. | Lidocaine Hydrochloride Topical Solution USP 4% (40 mg/mL) | Drugs | Super Potent | Teligent Pharma, Inc. |
| 10/01/2021 | Lotrimin® AF and Tinactin® | Over the Counter (OTC) antifungal spray products | Drugs | Presence of benzene | Bayer U.S. LLC |
| 09/26/2021 | Lilly | Glucagon Emergency Kit | Drugs | Loss of potency | Eli Lilly and Company |
| 09/21/2021 | IntegraDose Compounding Services, LLC | Cefazolin | Drugs, Pharmaceutical Quality | Lack of sterility assurance | IntegraDose Compounding Services, LLC |
| 09/16/2021 | CHANTIX | Varenicline tablets | Drugs | N-nitroso-varenicline above acceptable daily intake level | Pfizer |
| 09/13/2021 | Ruzurgi® | Ruzurgi® (amifampridine) 10 mg tablets | Drugs | Exceeds Specification for Total Yeast and Mold Counts | Jacobus Pharmaceutical Company Inc. |
| 09/08/2021 | Azurity | Firvanq | Drugs | Product kit may contain incorrect diluent | Azurity Pharmaceuticals, Inc. |
| 09/07/2021 | Hospira | Aminosyn II, 15%, An Amino Acid Injection, Sulfite | Drugs | Presence of visible particulate matter | ICU Medical, Inc. |

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

| Date | Brand Name(s) | Product Description | Product Type | Recall Reason Description | Company Name |
|---|---|---|---|---|---|
| 09/03/2021 | Teligent | Lidocaine HCl Topical Solution 4% | Drugs | Super potency | Teligent Pharma, Inc. |
| 08/16/2021 | CHANTIX | Smoking cessation treatment | Drugs | N-Nitroso Varenicline content above acceptable daily intake level | Pfizer |

# Safety

| Date | Title |
|---|---|
| 09/01/2021 | FDA requires warnings about the increased risk of serious heart-related events, cancer, blood clots, and death for JAK inhibitors that treat certain chronic inflammatory conditions<br><br>The FDA concluded that there is an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death with arthritis and ulcerative colitis medicines Xeljanz and Xeljanz XR (tofacitinib).<br><br>The FDA required new and updated warnings for two other arthritis medicines in the same drug class as Xeljanz, called Janus kinase (JAK) inhibitors, Olumiant (baricitinib), and Rinvoq (upadacitinib). Olumiant and Rinvoq have not been studied in trials similar to the extensive safety clinical trial with Xeljanz, so the risks have not been adequately evaluated. However, since they share mechanisms of action withXeljanz, FDA considers that these medicines may have similar risks as seen in the Xeljanz safety trial. |

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

## Shortages (New)

| Date | Drug Name (Shortage Reason) |
|---|---|
| 10/15/2021 | Busulfan Injection (Discontinuation) |
| 10/13/20211 | Metronidazole (Flagyl) Tablets (Discontinuation) |
| 10/12/2021 | Fentanyl Citrate (Sublimaze) Injection (Currently in Shortage) |
| 10/12/2021 | Montelukast Sodium Chewable Tablet (Discontinuation) |
| 10/08/2021 | Daptomycin Injection (Discontinuation) |
| 10/08/2021 | Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection (Currently in Shortage) |
| 10/07/2021 | Azacitidine for Injection (Currently in Shortage) |

# Off Market


**References:**

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

- https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
- https://www.ashp.org/Coronavirus
  - ASHP provides free access to its AHFS Clinical Drug Information application, which also includes access to drug shortages information. AHFS Drug Information® - Open Access Effective March 16, 2020
- Username: ahfs@ashp.org
- Password: covid-19

**Sources:**

- https://www.ashp.org/COVID-19 t https://www.ashp.org/COVID-19 t
- https://www.cdc.gov/media/releases/2021/s-07082021.html t
- https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e2.htm t
- https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls t
- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts t
- https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-newtherapeutic-biological-products/novel-drug-approvals-2021 t
- https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/firstgeneric-drug-approvals t https://clinicaltrials.gov
- https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications
- https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-warnings-about-increased-risk-serious-heart-related-events-cancer-blood-clots-and-death
- https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals

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