

## New Drug Approvals

### **Empagliflozin and Metformin Hydrochloride Tablets 5 mg/500 mg, 5 mg/1000 mg, 12.5 mg/500 mg, and 12.5mg/1000 mg**

Approved: July 7, 2022 - Zydus  
Pharmaceuticals (USA) Inc.  
Treatment for: Type 2 Diabetes  
Generic for: **Synjardy**

### **Brivaracetam Tablets 10 mg, 25 mg, 50 mg, 75 mg and 100 mg**

Approved: June 9, 2022 - Sunshine Lake Pharma  
Co., Ltd.  
Treatment for: Epilepsy  
Generic for: **Briviact**

### **Cabazitaxel Intravenous Solution 60 mg/1.5 mL (40 mg/mL)**

Approved: June 23, 2022 -  
Breckenridge Pharmaceutical, Inc.  
Treatment for: Prostate Cancer  
Generic for: **Jevtana**

### **Abiraterone Acetate Tablets 125 mg**

Approved: June 24, 2022 - Teva  
Pharmaceuticals USA, Inc.  
Treatment for: Prostate Cancer  
Generic for: **Yonsa**

### **Estradiol and Progesterone Capsules 1 mg / 100 mg**

Approved: May 16, 2022 - Amneal Pharmaceuticals  
LLC  
Treatment for: Vasomotor Symptoms Due to  
Menopause  
Generic for: **Bijuva**

### **Iodixanol Injection 55% and 65.2%**

Approved: May 19, 2022 - Jiangsu Hengrui  
Pharmaceuticals Co., Ltd.  
Treatment for: Radiographic Procedures  
Generic for: **Visipaque 270 and Visipaque 320**

### **Lacosamide Oral Solution 10 mg /mL**

Approved: May 19, 2022 - Alkem Laboratories Ltd.  
Treatment for: Seizures  
Generic for: **Vimpat Oral Solution**

### **Pemetrexed Disodium Injection 100 mg (base)/vial and 500 mg (base)/vial**

Approved: May 25, 2022 - Accord Healthcare, Inc.;  
Apotex Corp.; Dr. Reddys Laboratories Inc.; Eugia  
Pharma Specialities Limited; Fresenius Kabi USA,  
LLC; Hospira, Inc.; Jiangsu Hansoh Pharmaceutical  
Group Co., Ltd.; Nang Kuang Pharmaceutical Co.,  
Ltd.; Qilu Pharmaceutical Co., Ltd.; Waverley  
Pharma Inc.; Zydus Pharmaceuticals (USA) Inc.  
Treatment for: Mesothelioma, Non-Small Cell Lung  
Cancer  
Generic for: **Alimta**

### **Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution 0.2% / 0.5% (base)**

Approved: April 4, 2022 - Sandoz Inc.  
Treatment for: Glaucoma  
Generic for: **Combigan**

### **Lacosamide Injection 200 mg/20 mL (10 mg/mL)**

Approved: April 7, 2022 - Indoco Remedies Limited  
Treatment for: Seizures  
Generic for: **Vimpat Injection**

### **Cysteine Hydrochloride Injection 500 mg/10 mL (50 mg/mL)**

Approved: April 8, 2022 - Eton Pharmaceuticals, Inc.  
Treatment for: Total Parenteral Nutrition  
Generic for: **Elcys**

### **Regadenoson Intravenous Solution 0.4 mg/5 mL (0.08 mg/mL)**

Approved: April 11, 2022 - Accord Healthcare, Inc.;  
Apotex Inc.; Hong Kong King-Friend Industrial Co.  
Ltd.; Dr. Reddy's Laboratories Ltd.  
Treatment for: Myocardial Perfusion Imaging  
Generic for: **Lexiscan**

**Bexarotene Topical Gel 1%**

Approved: April 27, 2022 - Amneal Pharmaceuticals LLC  
 Treatment for: Cutaneous T-Cell Lymphoma  
 Generic for: **Targretin Gel**

**Methylphenidate Extended Release Transdermal Film 10 mg, 15 mg, 20 mg and 30 mg**

Approved: March 14, 2022 - Mylan Pharmaceuticals Inc.  
 Treatment for: ADHD  
 Generic for: **Daytrana**

**Budesonide and Formoterol Fumarate Dihydrate Metered Inhalation Aerosol 0.08 mg/0.0045 mg per inhalation and 0.16 mg/0.0045 mg per inhalation**

Approved: March 15, 2022 - Mylan Pharmaceuticals Inc.  
 Treatment for: Asthma; COPD  
 Generic for: **Symbicort**

**Lacosamide Tablets 50 mg, 100 mg, 150 mg and 200 mg**

Approved: March 17, 2022 - Alembic Pharmaceuticals Ltd.; Amneal Pharmaceuticals LLC; Glenmark Pharmaceuticals Inc.; Hetero Labs Limited; Indoco Remedies Limited; MSN Laboratories Private Limited; ScieGen Pharmaceuticals Inc., Sun Pharmaceutical Industries, Inc.  
 Treatment for: Seizures  
 Generic for: **Vimpat**

**Ioflupane I-123 Injection for Intravenous Use 185 MBq (5 mCi) in 2.5 mL**

Approved: March 30, 2022 - Curium US LLC  
 Treatment for: Computed Tomography  
 Generic for: **DaTscan**

**Cyclosporine Ophthalmic Emulsion 0.05%**

Approved: February 2, 2022 - Mylan Pharmaceuticals, Inc.  
 Treatment for: Dry Eye Disease  
 Generic for: **Restasis**

**Information collected and compiled by**

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**Maraviroc Tablets 150 mg and 300 mg**

Approved: February 7, 2022 - Hetero Labs Limited  
 Treatment for: HIV Infection  
 Generic for: **Selzentry**

**Nalmefene Hydrochloride Injection 2 mg base /2 mL**

Approved: February 8, 2022 - Purdue Pharma LP  
 Treatment for: Opioid Overdose  
 Generic for: **Revex**

**Dapagliflozin Tablets 5 mg and 10 mg**

Approved: February 22, 2022 - Zydus Pharmaceuticals USA, Inc.  
 Treatment for: Type 2 Diabetes  
 Generic for: **Farxiga**

**Apomorphine Hydrochloride Injection 30 mg /3 mL (10 mg /mL)**

Approved: February 23, 2022 - Sage Chemicals, Inc.  
 Treatment for: Parkinson's Disease  
 Generic for: **Apokyn**

**Pirfenidone Capsules 267 mg**

Approved: January 3, 2022 - Amneal Pharmaceuticals LLC  
 Treatment for: Idiopathic Pulmonary Fibrosis  
 Generic for: **Esbriet**

**Sofosbuvir Tablets 400 mg**

Approved: January 27, 2022 - Teva Pharmaceuticals USA, Inc.  
 Treatment for: Hepatitis C  
 Generic for: **Sovaldi**

**Brimonidine Tartrate Ophthalmic Solution 0.15%**

Approved: January 31, 2022 - Apotex Inc.  
 Treatment for: Glaucoma  
 Generic for: **Alphagan P**

*Reference: [www.drugs.com](http://www.drugs.com)*