

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