

New Drug Approvals

First-Time Generic Approvals

Dofetilide Capsules 125 mcg, 250 mcg and 500 mcg

Approved: June 6, 2016 - Mayne Pharma

Generic for: **Tikosyn**

Dofetilide is a heart rhythm medicine, also called an antiarrhythmic. It is used to help keep the heart beating normally in people with certain heart rhythm disorders of the atrium (the upper chambers of the heart that allow blood to flow into the heart). Dofetilide is used in people with atrial fibrillation or atrial flutter.

Fosaprepitant Dimeglumine Injection 150 mg

(base)/vial

Approved: June 9, 2016 - Fresenius Kabi USA

Generic for: **Emend for Injection**

Fosaprepitant blocks the actions of chemicals in the body that trigger nausea and vomiting. It is used together with other medications to prevent nausea and vomiting that may be caused by chemotherapy. Fosaprepitant will only prevent nausea and vomiting. It will not treat nausea or vomiting that you already have.

Dasatinib Tablets 20 mg, 50 mg, 70 mg and 100 mg

Approved: June 10, 2016 - Apotex, Inc.

Generic for: **Sprycel**

Dasatinib is a cancer medicine that slows the growth and spread of cancer cells in the body. It is used to treat chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL) when other cancer treatments have not been effective.

Levoleucovorin for Injection 50 mg/vial

Approved: June 16, 2016 - Eurohealth International Sarl

Generic for: **Fusilev**

Levoleucovorin is used to treat or prevent toxic effects of methotrexate in people who have received methotrexate to treat bone cancer. It is also used to treat or prevent toxic effects of methotrexate in people whose bodies do not eliminate methotrexate properly after the drug is metabolized. Levoleucovorin may also

be used to treat toxic effects of an accidental methotrexate overdose.

Levoleucovorin is also used in combination chemotherapy with fluorouracil to treat colorectal cancer that has spread to other parts of the body. Levoleucovorin treats only the symptoms of colorectal cancer but does not treat the cancer itself. It should not be used to treat anemia that is caused by a lack of vitamin B₁₂.

Fenofibrate Tablets USP, 40 mg and 120 mg

Approved: June 23, 2016 - Mylan Pharmaceuticals Inc.

Generic for: **Fenoglide**

Fenofibrate helps reduce cholesterol and triglycerides (fatty acids) in the blood. High levels of these types of fat in the blood are associated with an increased risk of atherosclerosis (clogged arteries).

Reference: Drugs.com

New Indications & Dosage Forms for Existing Drugs

Teflaro (ceftaroline fosamil) Injection

Date of Approval: October 29, 2010

Teflaro (ceftaroline fosamil) is a cephalosporin antibacterial indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP).

Patient Population Altered: May 27, 2016

Allergan Receives FDA Approval of Teflaro (ceftaroline fosamil) for pediatric patients

Invokamet (canagliflozin and metformin) Tablets

Date of Approval: August 8, 2014

Invokamet (canagliflozin/metformin) is a selective sodium glucose co-transporter 2 (SGLT2) inhibitor and biguanide combination for the treatment of type 2 diabetes.

Labeling revision approved: May 20, 2016

FDA expands indication of invokamet (canagliflozin/metformin HCl) to include first-line treatment of type 2 diabetes

Opdivo (nivolumab) Injection

Date of Approval: December 22, 2014

Opdivo (nivolumab) is a programmed death receptor-1 (PD-1) blocking antibody for the treatment of advanced melanoma, advanced non-small cell lung cancer, advanced renal cell carcinoma and classical Hodgkin lymphoma.

New Indication Approved: May 17, 2016

Opdivo (nivolumab) FDA Approved for the treatment of Hodgkin lymphoma.

Lenvima (lenvatinib) Capsules

Date of Approval: February 13, 2015

Lenvima (lenvatinib) is an oral multiple receptor tyrosine kinase (RTK) inhibitor for the treatment of progressive radioiodine-refractory differentiated thyroid cancer and advanced renal cell carcinoma.

New Indication Approved: May 13, 2016

FDA Approves Lenvima (lenvatinib) for the treatment of patients with advanced renal cell carcinoma.

Vibati (telavancin) Injection

Date of Approval: September 11, 2009

Vibativ (telavancin) is a bactericidal, once-daily injectable antibiotic for the treatment of complicated skin and skin structure infections (cSSSI), and hospital-acquired and ventilator-associated bacterial pneumonia.

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Labeling Revision Approved: May 6, 2016

Theravance Biopharma announces fda approval of expanded label for Vibativ (telavancin)

Fycompa (perampanel) Tablets and Oral Suspension

Date of Approval: October 22, 2012

Fycompa (perampanel) is a non-competitive AMPA glutamate receptor antagonist indicated as adjunctive therapy for the treatment of partial-onset seizures and primary generalized tonic-clonic (PGTC) seizures in patients with epilepsy.

New Dosage Form Approved: May 2, 2016

Eisai announces FDA approval of Fycompa (perampanel) oral suspension

Trintellix (vortioxetine) Tablets

Date of Approval: September 30, 2013

Trintellix (vortioxetine) is a multimodal antidepressant for the treatment of major depressive disorder (MDD).

Labeling Revision Approved: May 2, 2016

Brintellix (vortioxetine) renamed trintellix (vortioxetine) in the US to avoid name confusion.

Reference: Drugs.com