Drug Discovery

FDA Approved Drugs

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FDA approved drugs – January 2015

Vidhya

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1. RYTARY (CARBIDOPA AND LEVODOPA) EXTENDED-RELEASE CAPSULES

Company: Impax Labs; Approved by January 2015

Treatment Area: Parkinson's disease

General Information
Carbidopa is an inhibitor of aromatic amino acid decarboxylation and levodopa is an aromatic amino acid. Carbidopa inhibits the decarboxylation of peripheral levodopa, making more levodopa available for delivery to the brain. Rytary is specifically indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication. It is supplied as a capsule for oral administration. It should be swallowed whole with or without food. A high-fat, high-calorie meal may delay the absorption of levodopa by about 2 hours. The recommended starting dosage is 23.75 mg / 95 mg taken orally three times a day for the first 3 days. On the fourth day of treatment, the dosage may be increased to 36.25 mg / 145 mg taken three times a day. Based upon individual patient clinical response and tolerability, the Rytary dose may be increased up to a maximum recommended dose of 97.5 mg / 390 mg taken three times a day. The dosing frequency may be changed from three times a day to a maximum of five times a day if more frequent dosing is needed and if tolerated. The maximum recommended daily dose of Rytary is 612.5 mg / 2450 mg. Maintain patients on the lowest dosage required to achieve symptomatic control and to minimize adverse reactions.

Mechanism of Action
Rytary is an extended release formulation of carbidopa and levodopa. Carbidopa: When levodopa is administered orally, it is rapidly decarboxylated to dopamine in extracerebral tissues so that only a small portion of a given dose is transported unchanged to the central nervous system. Carbidopa inhibits the decarboxylation of peripheral levodopa, making more levodopa available for delivery to the brain. Levodopa: Levodopa is the metabolic precursor of dopamine, does cross the blood-brain barrier, and presumably is converted to dopamine in the brain. This is thought to be the mechanism whereby levodopa relieves symptoms of Parkinson's disease.

Side Effects
Adverse effects associated with the use of Rytary may include: nausea, dizziness, headache, insomnia, abnormal dreams, dry mouth, dyskinesia, anxiety, constipation, vomiting, orthostatic hypotension.

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2. DUOPA (CARBIDOPA AND LEVODOPA) ENTERAL SUSPENSION

Company: Abbvie; Approved by January 2015

Treatment Area: motor fluctuations in patients with advanced Parkinson's disease

General Information

Duopa is specifically indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease. It is supplied as a solution for enteral infusion. The maximum recommended daily dose is 2000 mg of levodopa (i.e., one cassette per day) administered over 16 hours. Prior to initiating Duopa, convert patients from all forms of levodopa to oral immediate-release carbidopa-levodopa tablets. Administer Duopa into the jejunum through a percutaneous endoscopic gastrostomy with jejunal tube (PEG-J).

Mechanism of Action

Duopa is an enteral suspension of carbidopa and levodopa. Carbidopa: When levodopa is administered orally, it is rapidly decarboxylated to dopamine in extracerebral tissues so that only a small portion of a given dose is transported unchanged to the central nervous system. Carbidopa inhibits the decarboxylation of peripheral levodopa, making more levodopa available for delivery to the brain. Levodopa: Levodopa is the metabolic precursor of dopamine, does cross the blood-brain barrier, and presumably is converted to dopamine in the brain. This is thought to be the mechanism whereby levodopa treats the symptoms of Parkinson's disease.

Side Effects

Adverse effects associated with the use of Duopa may include: complication of device insertion, nausea, depression, peripheral edema, hypertension, upper respiratory tract infection, oropharyngeal pain, incision site erythema

3. BEXSERO (MENINGOCOCCAL GROUP B VACCINE)

Company: Novartis; Approved by January 2015

Treatment Area: invasive meningococcal disease caused by serogroup B

General Information

Bexsero is specifically indicated for active immunization to prevent invasive disease caused by Neisseria meningitidisserogroup B. It is approved for use in individuals 10 through 25 years of age. It is supplied as a solution for intramuscular administration. It should be administer in two doses (0.5 mL each) at least 1 month apart.

Mechanism of Action

Bexsero is a multicomponent Meningococcal Serogroup B vaccine. NHBA, NadA, fHbp, and PorA are proteins found on the surface of meningococci and contribute to the ability of the bacterium to cause disease. Vaccination with Bexsero leads to the production of antibodies directed against NHBA, NadA, fHbp, and PorA P1.4. The susceptibility of serogroup B meningococci to complement-mediated antibodydependent killing following vaccination with Bexsero is dependent on the antigenic similarity of the bacterial and vaccine antigens, as well as the amount of antigen expressed on the surface of the invading meningococci.

Side Effects

Adverse effects associated with the use of Bexsero may include: pain at the injection site, myalgia, erythema, fatigue, headache, induration, nausea, arthralgia.

4. PREZCOBIX (DARUNAVIR AND COBICISTAT)

Company: Janssen; Approved by January 2015

Treatment Area: HIV-1 infection

General Information

Prezcobix is specifically indicated for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in treatment-naïve and treatment-experienced adults with no darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V). It is supplied as a tablet (800 mg of darunavir and 150 mg of cobicistat) for oral administration. The recommended dose is one tablet taken once daily with food.

Mechanism of Action

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Prezcobix is a once-daily, fixed-dose combination tablet containing darunavir, a protease inhibitor, and the pharmacokinetic enhancing or boosting agent cobicistat.

Side Effects
Adverse effects associated with the use of darunavir may include: diarrhea, nausea, rash, headache, abdominal pain, vomiting

5. EVOTAZ (ATAZANAVIR AND COBICISTAT)

Company: Bristol-Myers Squibb; Approved by January 2015

Treatment Area: HIV-1 infection

General Information
Evotaz is specifically indicated for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in adults. It is supplied as a tablet for oral administration. In treatment-naive and -experienced adults, the recommended dosage of Evotaz is one tablet taken once daily orally with food. Administer Evotaz in conjunction with other antiretroviral agents.

Mechanism of Action
Evotaz is a fixed-dose combination of atazanavir and cobicistat. Atazanavir is an HIV-1 protease inhibitor. Cobicistat is a mechanism-based inhibitor of cytochrome P450 (CYP) enzymes of the CYP3A family.

Side Effects
Adverse effects associated with the use of Evotaz may include: jaundice, ocular icterus, nausea.

6. SAVAYSA (EDOXABAN)

Company: Daiichi Sankyo; Approved by January 2015

Treatment Area: deep vein thrombosis, pulmonary embolism and risk of stroke and embolism due to atrial fibrillation

General Information
Savaysa is specifically indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF). It is also indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) following 5 to 10 days of initial therapy with a parenteral anticoagulant. It is supplied as a tablet for oral administration. It can be taken without regard to food. The recommended dose of Savaysa is as follows:

Nonvalvular atrial fibrillation
The recommended dose is 60 mg taken orally once daily Assess creatinine clearance, as calculated using the Cockcroft-Gault equation, before initiating therapy with Savaysa. Do not use Savaysa in patients with CrCL > 95 mL/min due to an increased risk of ischemic stroke compared to warfarin. Reduce Savaysa dose to 30 mg once daily in patients with CrCL 15 to 50 mL/min.

Deep vein thrombosis and pulmonary embolism
The recommended dose of Savaysa is 60 mg taken orally once daily following 5 to 10 days of initial therapy with a parenteral anticoagulant. The recommended dose of Savaysa is 30 mg once daily in patients with CrCL 15 to 50 mL/min, patients who weigh less than or equal to 60 kg, or patients who are taking certain concomitant P-gp inhibitor medications based on clinical study data in this indication.

Mechanism of Action
Savaysa (edoxaban) is a selective inhibitor of FXa. It does not require antithrombin III for antithrombotic activity. It inhibits free FXa, and prothrombinase activity and inhibits thrombin-induced platelet aggregation. Inhibition of FXa in the coagulation cascade reduces thrombin generation and reduces thrombus formation.

Side Effects
Adverse effects associated with the use of Savaysa may include:
NVAF (Nonvalvular atrial fibrillation): bleeding, anemia
DVT and PE (Deep vein thrombosis and pulmonary embolism): bleeding, rash, abnormal liver function tests, anemia

7. COSENTYX (SECUKINUMAB)

Company: Novartis; Approved by January 2015

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Treatment Area: plaque psoriasis

General Information
Cosentyx is specifically indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. It is supplied as a solution for subcutaneous injection. The recommended dose is 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. Each 300 mg dose is given as 2 subcutaneous injections of 150 mg.

Mechanism of Action
Cosentyx (secukinumab) is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. It inhibits the release of proinflammatory cytokines and chemokines.

Side Effects
Adverse effects associated with the use of Cosentyx may include: nasopharyngitis, diarrhea, upper respiratory tract infection

8. NATPARA (PARATHYROID HORMONE)

Company: NPS Pharmaceuticals; Approved by January 2015

Treatment Area: hypocalcemia in patients with hypoparathyroidism

General Information
Natpara is specifically indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism. Because of the potential risk of osteosarcoma, Natpara is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone. It is supplied as a solution for subcutaneous injection. The dose should be individualized based on total serum calcium (albumin-corrected) and 24-hour urinary calcium excretion. The recommended dose is the minimum dose required to prevent both hypocalcemia and hypercalciuria. This dose will generally be the dose that maintains total serum calcium (albumin-corrected) within the lower half of the normal range (i.e., between 8 and 9 mg/dL) without the need for active forms of vitamin D and with calcium supplementation sufficient and individualized to meet the patient's daily requirements. For specific dose adjustments, please see the drug label.

Mechanism of Action
Natpara is a parathyroid hormone. Parathyroid hormone raises serum calcium by increasing renal tubular calcium reabsorption, increasing intestinal calcium absorption (i.e., by converting 25 OH vitamin D to 1,25 OH2 vitamin D) and by increasing bone turnover which releases calcium into the circulation.

Side Effects
Adverse effects associated with the use of Natpara may include: paresthesia, hypocalcemia, headache, hypercalcemia, nausea, hypoaesthesia, diarrhea, vomiting, arthralgia, hypercalciuria, pain in extremity.

9. PRESTALIA (PERINDOPRIL ARGININE AND AMLODIPINE BESYLATE)

Company: Symplmed Pharmaceuticals; Approved by January 2015

Treatment Area: hypertension

General Information
Prestalia is specifically indicated for the treatment of hypertension, to lower blood pressure in patients not adequately controlled with monotherapy and as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. It is supplied as a tablet for oral administration. The recommended starting oral dose of Prestalia is 3.5/2.5 mg once daily. The dose may be adjusted according to blood pressure goals waiting 1 to 2 weeks between titration steps. The maximum recommended dose is 14/10 mg once daily.

Mechanism of Action
Prestalia is a combination of perindopril, an angiotensin converting enzyme (ACE) inhibitor, and amlodipine, a dihydropyridine calcium channel blocker.

Side Effects
Adverse effects associated with the use of Prestalia may include: edema, cough, headache, dizziness.

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