First-Time Generic Approvals

Tofacitinib

Brand name: Xeljanz, Xeljanz XR

Dosage forms: oral solution (1 mg/mL); oral tablet (10 mg; 5 mg); oral tablet, extended release (11 mg;

22 mg)

Drug class: Antirheumatics

Tofacitinib is used to treat moderate to severe rheumatoid arthritis or active psoriatic arthritis in adults who have tried methotrexate or other medications without successful treatment symptoms. Tofacitinib is sometimes given in combination with methotrexate or other arthritis medicines.

Lopinavir and Ritonavir

Brand name: Kaletra

Dosage forms: oral liquid (400 mg-100 mg/5 mL);

oral tablet (100 mg-25 mg; 200 mg-50 mg)

Drug class: Protease inhibitors

Lopinavir and ritonavir is a combination antiviral medicine used to treat human immunodeficiency virus (HIV), the virus that can cause acquired immunodeficiency syndrome (AIDS). lopinavir and

ritonavir is not a cure for HIV or AIDS.

Etravirine

Brand name: *Intelence*

Dosage forms: Oral tablet (100 mg; 200 mg; 25 mg)

Drug class: NNRTIs

Etravirine is an antiviral medicine that is used with other medicines to treat human immunodeficiency virus (HIV). HIV causes the acquired immunodeficiency syndrome (AIDS). Etravirine is not a cure for HIV or AIDS.

Formoterol (inhalation)

Brand name: Perforomist, Foradil Aerolizer **Dosage forms:** Inhalation Solution (20 mcg/2 mL)

Drug class: Adrenergic bronchodilators

Formoterol inhalation is used to control the symptoms of chronic obstructive pulmonary disease bronchitis (COPD), including chronic and emphysema.

Arformoterol Inhalation

Brand name: Brovana

Dosage forms: Inhalation Solution (15 mcg/2 mL)

Drug class: Adrenergic bronchodilators

Arformoterol inhalation is used to help control the symptoms of chronic obstructive pulmonary disease (COPD), including chronic bronchitis

emphysema.

Enzalutamide

Brand name: Xtandi

Dosage forms: Oral Capsule (40 mg); oral tablet (40

mg; 80 mg)

Drug class: Antiandrogens, Hormones /

antineoplastics

Enzalutamide is a prescription medicine used to treat prostate cancer in men who have received surgery or

hormone therapy to lower testosterone.

Lenalidomide

Brand name: Revlimid

Dosage forms: Oral Capsule (10 mg; 15 mg; 2.5 mg;

20 mg; 25 mg; 5 mg)

Drug class: Miscellaneous antineoplastics, Other

immunosuppressants

Lenalidomide is used to treat multiple myeloma (bone marrow cancer), either in combination with another medicine or after stem cell transplant.

Deoxycholic Acid

Brand name: Kybella

Dosage forms: Subcutaneous Solution (10 mg/mL) Drug class: Miscellaneous uncategorized agents Deoxycholic acid is a manmade form of a substance your body makes that helps to absorb fats. Deoxycholic acid works by destroying fat cells where it is injected into the body.

Macitentan

Brand name: Opsumit

Dosage forms: Oral Tablet (10 mg)

Drug class: Agents for pulmonary hypertension

Macitentan lowers blood pressure in your lungs, helping your heart pump blood more efficiently. Macitentan is used to treat pulmonary arterial hypertension (PAH). It improves your ability to exercise and prevents your condition from getting worse.

Drug class: Miscellaneous genitourinary tract agents Tiopronin is used together with diet, fluids, and other medicines to help prevent kidney stones in adults and children weighing at least 44 pounds (20 kilograms).

www.drugs.com/newdrugs

Tiopronin

Brand name: Thiola, Thiola EC

Dosage forms: oral delayed release tablet (100 mg;

300 mg); oral tablet (100 mg)

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