Brand Name:

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Generic Name:

Fingolimod

Therapeutic Area:

Central Nervous System/ MS

Dosage Form:

0.5 mg capsule

Therapeutic Indications:

Fingolimod is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

Mechanism of Action:

Fingolimod is a sphingosine 1-phosphate receptor modulator that may involve reduction of lymphocyte migration into the central nervous system.

Method of Administration:

The recommended dose of Fingolimod is 0.5 mg orally once daily. Fingolimod doses higher than 0.5 mg are associated with a greater incidence of adverse reactions without additional benefit. Fingolimod can be taken with or without food.

Contraindications:

Recent (within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure, History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker, Baseline QTc interval ≥500 ms, Treatment with Class Ia or Class III anti-arrhythmic drugs.

Interactions:

• Ketoconazole: Monitor patients closely, as Fingolimod exposure is increased by 70% during concomitant use with systemic ketoconazole, and risk of adverse reactions is greater.

• Vaccines: Avoid live attenuated vaccines during, and for 2 months after stopping Fingolimod treatment, due to risk of infection.

Pregnancy and Lactation:

Pregnancy Category C

Fingolimod is excreted in the milk of treated rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse

reactions in nursing infants from Fingolimod, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Warning and Precaution:

• Decrease in heart rate and/or atrioventricular conduction after first dose of Fingolimod: Monitor patients

• Infections: Fingolimod may increase the risk of infections. A recent CBC should be available before initiating treatment with Fingolimod. Monitor for signs and symptoms of infection during treatment and for two months after discontinuation. Do not start Fingolimod treatment in patients with active acute or chronic infections

• Macular edema: Can occur with or without visual symptoms. An ophthalmologic evaluation should be performed before starting Fingolimod and at 3-4 months after treatment initiation. Monitor visual acuity at baseline and during routine evaluations of patients. Patients with diabetes mellitus or a history of uveitis are at increased risk and should have regular ophthalmologic evaluations.

• Decrease in pulmonary function tests with Fingolimod: Obtain spirometry and diffusion lung capacity for carbon monoxide (DLCO) when clinically indicated.

• Hepatic effects: Fingolimod may increase liver transaminases. Recent liver enzyme results should be available before starting Fingolimod. Assess liver enzymes if hepatic injury is suspected. Discontinue Fingolimod if significant liver injury occurs

• Fetal risk: Women of childbearing potential should use effective contraception during and for 2 months after stopping Fingolimod.

Adverse Reactions:

Most common adverse reactions (incidence ≥10% and > placebo): Headache, influenza, diarrhea, back pain, liver transaminase elevations and cough.

Storage:

Store below 30 and protect from light and moisture.