

Etragut™

Etrasimod Tablet

Presentation

Etragut™ Tablet: Each film coated tablet contains Etrasimod Arginine INN equivalent to Etrasimod 2 mg.

Description

Etrasimod works by selectively binding to sphingosine-1-phosphate (S1P) receptors (mainly S1P1, S1P4, S1P5) on the surface of lymphocytes. This action prevents the lymphocytes from migrating out of lymph nodes, and into the bloodstream and other tissues. By trapping T and B cells in the lymph nodes, etrasimod reduces their overall circulation and, consequently, limiting their ability to reach tissues and thereby reducing inflammation, particularly in conditions like ulcerative colitis.

Indication & Uses

Moderately to severely active ulcerative colitis in adults.

Dosage and Administration

2 mg orally once daily, with or without food. If a dose is missed, take the next dose at the scheduled time. Do not double the dose.

Side Effects

Common (≥5%): Headache, Elevated liver enzymes, Dizziness

Other reported: Bradycardia, Hypertension, Nausea, Arthralgia, Urinary tract infection, Herpes viral infections, Hypercholesterolemia, Macular Edema, Cutaneous Malignancies, Posterior Reversible Encephalopathy Syndrome, Decreased lung function, Unintended Additive Immune System Effects

Warnings and Precautions

Infections: It can increase the risk of infections.

Heart rhythm problems: May slow your heart rate, especially when first starting.

Liver problems: Can raise liver enzymes. Report yellowing of eyes or skin, dark urine, or unexplained nausea. Blood tests may be needed.

Eye problems: Can cause macular edema (swelling at the back of the eye), especially if you have diabetes or past eye disease. Report vision changes.

Breathing problems: May cause shortness of breath or reduced lung function.

High blood pressure: It may raise blood pressure. Monitoring is recommended.

Skin cancers: Slightly increased risk of skin cancer. Use sun protection and report unusual skin changes.

Vaccinations: Avoid live vaccines during treatment and for 4 weeks after stopping.

Contraindications

- Recent (within 6 months) myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure, or Class III/IV heart failure.
- History or presence of Mobitz type II second-degree or third-degree AV block, sick sinus syndrome, or sino-atrial block without a functioning pacemaker.
- Known hypersensitivity to the active substance or to any of the excipients.
- Patients with severe hepatic impairment.

Drug Interactions

Avoid concomitant use with moderate/strong CYP2C9 and CYP3A4 inhibitors or inducers (e.g., fluconazole, rifampin), certain anti-arrhythmic drugs (e.g., metoprolol, atenolol, propranolol, Diltiazem, Verapamil), QT-prolonging drugs (e.g., quinidine, procainamide, amiodarone) and strong immunosuppressants.

Pregnancy & Lactation

Not recommended for pregnant women, may cause fetal harm. Use effective contraception during and for 1 week after stopping therapy. Unknown if excreted in human milk; It should be used in breastfeeding women only if the potential benefit justifies the potential risk to the fetus.

Overdosage

No specific antidote. Symptomatic and supportive care should be provided in case of overdose.

Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial Pack

Etragut™ Tablet: Each box contains 2 blister strips of 10 tablets.