Idiopag®

Eltrombopag Olamine INN

Presentation
Idiopag® tablet 25 mg and Idiopag® tablet 50 mg for oral administration.

Composition
Idiopag® tablet 25 mg: Each film coated tablet contains Eltrombopag Olamine INN equivalent to Eltrombopag 25 mg.
Idiopag® tablet 50 mg: Each film coated tablet contains Eltrombopag Olamine INN equivalent to Eltrombopag 50 mg.

Description
Idiopag® tablets contain eltrombopag olamine, a small molecule thrombopoietin (TPO) receptor agonist for oral administration. Eltrombopag interacts with the transmembrane domain of the TPO receptor (also known as cMpl) leading to increased platelet production

Indications
Eltrombopag Olamine is a thrombopoietin receptor agonist indicated for the treatment of:

- Thrombocytopenia in adult and pediatric patients (1 year and older) with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Eltrombopag should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.
- Thrombocytopenia in patients with Chronic Hepatitis C to allow the initiation and maintenance of interferon-based therapy. Eltrombopag should be used only in patients with Chronic Hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy.
- Patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

Dosage and administration
Take on an empty stomach (1 hour before or 2 hours after a meal).
Chronic ITP: Initiate Eltrombopag at 50 mg once daily for most adult and pediatric patients aged 6 years and older and at 25 mg once daily for pediatric patients aged 1 to 5 years. Dose reductions are needed for patients with hepatic impairment. Adjust to maintain platelet count greater than or equal to 50 x 10^9/L. Do not exceed 75 mg per day.
Chronic Hepatitis C-associated Thrombocytopenia: Initiate Eltrombopag at 25 mg once daily for all patients. Adjust to achieve target platelet count required to initiate antiviral therapy. Do not exceed a daily dose of 100 mg.
Severe Aplastic Anemia: Initiate Eltrombopag at 50 mg once daily for most patients. Reduce initial dose in patients with hepatic impairment or patients of East Asian ancestry. Adjust to maintain platelet count greater than 50 x 10^9/L. Do not exceed 150 mg per day

Contraindications
None

Warnings and precautions
Hepatotoxicity: Monitor liver function before and during therapy.
Thrombotic/Thromboembolic Complications: Portal vein thrombosis has been reported in patients with chronic liver disease receiving Eltrombopag. Monitor platelet counts regularly.

Adverse reactions
In adult patients with ITP, the most common adverse reactions were: nausea, diarrhea, upper respiratory tract infection, vomiting, increased ALT, myalgia, and urinary tract infection. In pediatric patients age 1 year and older with ITP, the most common adverse reactions were: upper respiratory tract infection and nasopharyngitis. In patients with Chronic Hepatitis C-associated thrombocytopenia, the most common adverse reactions were: anemia, pyrexia, fatigue, headache, nausea, diarrhea, decreased appetite, influenza-like illness, asthenia, insomnia, cough, pruritus, chills, myalgia, alopecia, and peripheral edema. In patients with severe aplastic anemia, the most common adverse reactions were: nausea, fatigue, cough, diarrhea, and headache.

Use in specific populations
Pregnancy: Pregnancy category C. Based on animal data, Eltrombopag Olamine may cause fetal harm.
Nursing Mothers: A decision should be made to discontinue Eltrombopag Olamine or nursing, taking into account the importance of Eltrombopag Olamine to the mother.

Drug interactions
Polyvalent cations significantly reduce the absorption of Eltrombopag Olamine. Take Eltrombopag at least 2 hours before or 4 hours after any medications or products containing polyvalent cations such as antacids, calcium-rich foods, and mineral supplements.

Over dose
In the event of overdose, platelet counts may increase excessively and result in thrombotic/thromboembolic complications. In case of an overdose, consideration should be given to oral administration of a metal cation-containing preparation, such as calcium, aluminium, or magnesium preparations to chelate Eltrombopag Olamine and thus limit absorption. Platelet counts should be closely monitored. Treatment with Eltrombopag Olamine should be reinitiated in accordance with dosing and administration recommendations.

Storage Condition
Store at temperature not exceeding 30 ^{0}C in a dry place. Protect from light and moisture.

Commercial Packaging
Idiopag® 25 mg: Each commercial box contains 1x7's tablets in Alu-Alu blister pack.
Idiopag® 50 mg: Each commercial box contains 1x7's tablets in Alu-Alu blister pack.

Medicine: Keep out of reach of children

Healthcare

Manufactured by
Healthcare Pharmaceuticals Ltd.
Rajendrapur, Gazipur, Bangladesh

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