

Composition : Olapag-25 : Each film coated tablet contains Eltrombopag Olamine INN 31.90 mg eqv. to 25 mg Eltrombopag.

Olapag-50 : Each film coated tablet contains Eltrombopag Olamine INN 63.80 mg eqv. to 50 mg Eltrombopag.

Pharmacology : Eltrombopag is an orally bioavailable, small-molecule TPO-receptor agonist that interacts with the transmembrane domain of the human TPO-receptor and initiates signaling cascades that induce proliferation and differentiation from bone marrow progenitor cells.

Indication : Eltrombopag is 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, immunoglobulin, or splenectomy. Eltrombopag is indicated for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Eltrombopag is indicated for the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

Dosage & Administration : Take orally on an empty stomach (1 hours before or 2 hours after a meal).

Chronic ITP : Adult and Pediatric Patients 6 Years and Older with ITP: Initiate Eltrombopag at a dose of 50 mg once daily. For Pediatric Patients with ITP Aged 1 to 5 Years: Initiate Eltrombopag at a dose of 25 mg once daily. Adjust to maintain platelet count greater than or equal to $50 \times 10^9/L$. Do not exceed 75mg per day.

Chronic Hepatitis C-Associated Thrombocytopenia : Initiate Eltrombopag at a dose of 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. Adjust to maintain platelet count greater than $50 \times 10^9/L$. Do not exceed 150 mg per day. Or, as directed by the registered physician.

Contraindications : It is contraindicated in patients with hypersensitivity to Olapag or any component of this product.

**Olapag
Tablet**



Precautions : Hepatotoxicity: Monitor liver function before and during therapy. Thromboembolic complications: Portal vein thrombosis has been reported in patients with chronic liver disease receiving Eltrombopag. So platelet count should be measured carefully.

Side effects : The most common adverse reactions were nausea, diarrhoea, upper respiratory tract infection, vomiting, urinary tract infection, increased ALT, myalgia, oropharyngeal pain, increased AST, pharyngitis, back pain, influenza, paresthesia, rash etc.

Use in Pregnancy and Lactation : Pregnancy : Pregnancy category C. **Nursing mother** : It is not known whether Eltrombopag is excreted in human milk. A decision should be made whether to discontinue nursing or to discontinue Eltrombopag taking into account the importance of Eltrombopag to the mother.

Use in Child : The safety and efficacy of Eltrombopag in pediatric patients younger than 1 year with ITP and thrombocytopenia associated with chronic hepatitis C & severe aplastic anemia have not been established.

Drug Interactions : Eltrombopag interacts with polyvalent cation containing antacids. Caution should be taken when administered with OATP1B1 substrate and BCRP substrate (Rosuvastatin), Protease inhibitors (Lopinavir) Etc.

Overdose : In case of an overdose, consider oral administration of a metal cation containing preparation such as Calcium, Aluminium or Magnesium preparations to chelate Eltrombopag and thus limit absorption. Closely monitor platelet counts.

Storage : Store below 30° C in a dry place.

Packing : Olapag-25 : Each box contains 10's tablets in blister pack.

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