

## ELTROMBOPAG - ABRIDGED PRESCRIBING INFORMATION

**COMPOSITION:** Each film-coated tablet of LTROMB contains Eltrombopag 50 mg or 25 mg for oral use. Eltrombopag is a thrombopoietin receptor agonist that binds to the human TPO receptor (cMpl), activating signalling cascades that stimulate megakaryocyte proliferation and differentiation to increase platelet production. **INDICATIONS:** LTROMB is indicated for the treatment of thrombocytopenia in adult and pediatric patients ( $\geq 1$  year) with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy; for patients with chronic hepatitis C-associated thrombocytopenia to enable the initiation and maintenance of interferon-based therapy; and in combination with standard immunosuppressive therapy for severe aplastic anemia in patients aged  $\geq 2$  years, including those with refractory disease. **DOSAGE AND ADMINISTRATION:** LTROMB should be taken without food or with a low-calcium meal ( $\leq 50$  mg calcium) and administered at least 2 hours before or 4 hours after any medications or products containing polyvalent cations (e.g., antacids, calcium-rich foods, or mineral supplements). For ITP, initiate with 50 mg once daily for most adult and pediatric patients  $\geq 6$  years and 25 mg once daily for children 1–5 years, adjusting to maintain a platelet count  $\geq 50 \times 10^9/L$  (do not exceed 75 mg/day) with dose reductions recommended for patients with hepatic impairment or of East-/Southeast-Asian ancestry. For chronic hepatitis C-associated thrombocytopenia, initiate at 25 mg once daily and adjust to achieve the platelet count necessary for starting antiviral therapy (do not exceed 100 mg/day). For severe aplastic anemia, first-line therapy involves starting LTROMB at 2.5 mg/kg for pediatric patients 2–5 years, 75 mg for those 6–11 years, or 150 mg for patients  $\geq 12$  years in conjunction with immunosuppressive therapy—with dose reductions for certain Asian populations—while refractory cases should begin at 50 mg once daily (not to exceed 150 mg/day). **CONTRAINDICATIONS:** None. **ADVERSE REACTIONS:** Adverse reactions include hepatic decompensation in chronic hepatitis C patients, hepatotoxicity, an increased risk of death and progression from myelodysplastic syndromes to acute myeloid leukemia, thrombotic or thromboembolic complications, and cataracts. **USE IN SPECIAL POPULATIONS:** Pregnancy: Data are insufficient to assess the risk of major birth defects, miscarriage, or adverse maternal/fetal outcomes. Lactation: No data are available regarding the presence of eltrombopag or its metabolites in human milk or their effects on the breastfed infant or milk production. Pediatric Use: Safety and efficacy have been established for pediatric patients  $\geq 1$  year with ITP and for those  $\geq 2$  years with immunosuppressive therapy—naïve severe aplastic anemia; however, safety and efficacy have not been established in pediatric patients  $< 1$  year with ITP or in those with hepatitis C-associated thrombocytopenia or refractory severe aplastic anemia. **STORAGE:** Store LTROMB protected from light and moisture at temperatures not exceeding 30 °C. **PACKAGING INFORMATION:** LTROMB is supplied as a strip of 7 tablets in a single mono carton. For further information, please contact us.