Mulpleta (lusutrombopag)
Introduction

- **Brand name**: Mulpleta
- **Generic name**: Lusutrombopag
- **Pharmacological class**: Thrombopoietin receptor agonist
- **Strength and Formulation**: 3mg; tabs
- **Manufacturer**: Shionogi, Inc
- **How supplied**: Tabs—7
- **Legal Classification**: Rx
Indication

- **Thrombocytopenia** in adults with chronic liver disease who are scheduled to undergo a procedure
Dosage & Administration

- Start treatment 8–14 days prior to a procedure
- Should undergo procedure within 2–8 days after last dose
- Take with or without food
- 3mg once daily for 7 days
Considerations for Special Populations

- **Pregnancy:** May cause fetal harm
- **Nursing mothers:** Not recommended during and for ≥28 days after last dose
- **Pediatric:** Not established
- **Elderly:** Insufficient number studied
Warnings/Precautions

- Obtain **platelet count** prior to treatment and not more than 2 days prior to procedure.
- Increased **thrombotic risk** with known risk factors (e.g., Factor V Leiden, Prothrombin 20210A, Antithrombin deficiency, Protein C or S deficiency).
Warnings/Precautions

- Ongoing or prior thrombosis or absence of hepatopetal blood flow: use only if potential benefit justifies risk
- Do not use to normalize platelet counts
Adverse Reactions

- Headache
- Portal vein thrombosis
Lusutrombopag is an orally bioavailable, small molecule TPO receptor agonist that interacts with the transmembrane domain of human TPO receptors expressed on megakaryocytes to induce the proliferation and differentiation of megakaryocytic progenitor cells from hematopoietic stem cells and megakaryocyte maturation.
Mulpleta was evaluated in 2 randomized, double-blind, placebo-controlled trials (L-PLUS 1 and L-PLUS 2) for the treatment of thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure.

- Patients were randomized to receive Mulpleta 3mg or placebo once daily for up to 7 days.
Clinical Studies

- Primary efficacy outcomes:
  - **L-PLUS 1**: proportion of patients who require no platelet transfusion prior to the primary invasive procedure
  - **L-PLUS 2**: proportion of patients who require no platelet transfusion prior to the primary invasive procedure and no rescue therapy for bleeding from randomization through 7 days after invasive procedure
Responders were defined as patients who had a platelet count of $\geq 50 \times 10^9/L$ with an increase of $\geq 20 \times 10^9/L$ from baseline.

L-PLUS 1:
- 78% of Mulpleta patients did not require platelet transfusion prior to invasive procedure vs 13% of placebo patients ($P < .0001$)
- 76% of Mulpleta patients were responders vs 6% of placebo patients ($P < .0001$)
Clinical Studies

- **L-PLUS 2:**
  - 65% of Mulpleta patients did not require platelet transfusion prior to invasive procedure or rescue therapy for bleeding from randomization through day 7 after invasive procedure vs 29% of placebo patients ($P < .0001$)
  - 65% of Mulpleta patients were responders vs 13% of placebo patients ($P < .0001$)
Clinical Studies

- The median duration of platelet count increase to at least $\geq 50 \times 10^9$/L:
  - **L-PLUS 1**: 22 days in Mulpleta patients without platelet transfusion vs 1.8 days in placebo-treated patients with platelet transfusions
  - **L-PLUS 2**: 19 days in Mulpleta patients vs 0 days in placebo-treated patients

- For more clinical trial data, see full labeling
New Product Monograph

- For more information view the product monograph available at:
  https://www.empr.com/mulpleta/drug/34871/