

Mulpleta (lusutrombopag)

Mulpleta[®]
(lusutrombopag) 3mg tablets

NEW PRODUCT SLIDESHOW

MPR

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 (eg, 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

Mechanism of Action

- 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

Clinical Studies

- 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

Clinical Studies

- **Responders** were defined as patients who had a platelet count of $\geq 50 \times 10^9/\text{L}$ with an increase of $\geq 20 \times 10^9/\text{L}$ 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/>