Generic Name:
Lusutrombopag
Trade Name:
Mulpleta
Company:
Shionogi
Notes:

FDA approved lusutrombopag, a once-daily, orally administered, small molecule thrombopoietin receptor agonist, for treatment of thrombocytopenia in adults with chronic liver disease who are scheduled to undergo a medical or dental procedure.

Approval was based on two randomized, double-blind, placebo-controlled trials involving 312 patients with chronic liver disease and severe thrombocytopenia who were undergoing an invasive procedure and had a platelet count of less than 50 x 109/L. Patients were randomized 1:1 to receive 3 mg of lusutrombopag or placebo once daily for up to 7 days.

In one trial, 78% of patients (38/49) receiving lusutrombopag required no platelet transfusion prior to the primary invasive procedure, compared with 13% (6/48) who received placebo. In the second trial, 65% (70/108) of patients who received lusutrombopag required no platelet transfusion prior to the primary invasive procedure or rescue therapy for bleeding from randomization through 7 days after the procedure, compared with 29% (31/107) receiving placebo.

The most common adverse reaction (?3% of patients) was headache.

The recommended lusutrombopag dosage is 3 mg orally once daily with or without food for 7 days.

Medication Monitor Categories:
New Drug Approvals