Doptelet (avatrombopag)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Doptelet
- **Generic name:** Avatrombopag
- **Pharmacological class:** Thrombopoietin receptor agonist
- **Strength and Formulation:** 20mg; tabs
- **Manufacturer:** Dova Pharmaceuticals
- **How supplied:** Tabs—10,15
- **Legal Classification:** Rx

Doptelet


Rx Only
NDC 71369-020-10
Doptelet
(avatrombopag) tablets
20 mg
One blister card with 10 tablets
Rx Only
NDC 71369-020-15
Doptelet
(avatrombopag) tablets
20 mg
One blister card with 15 tablets

Indications

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

Dosage & Administration

- Start treatment 10–13 days prior to procedure; undergo procedure within 5–8 days after last dose
- Take with food
- Platelet count <40 x 10^9/L: 60mg once daily for 5 days; 40–<50 x 10^9/L: 40mg once daily for 5 days

Considerations for Special Populations

- **Pediatric:** Not established
- **Pregnancy:** May cause fetal harm
- **Nursing mothers:** Not recommended during and for ≥2 weeks after last dose
- **Elderly:** Insufficient number of subjects studied

Warnings/Precautions

- Obtain **platelet count** prior to treatment and on day of procedure
- Increased **thrombotic risk** with known risk factors (eg, Factor V Leiden, Prothrombin 20210A, Antithrombin deficiency, Protein C or S deficiency)
- **Do not use** to normalize platelet counts

Adverse Reactions

- Pyrexia
- Abdominal pain
- Nausea
- Headache
- Fatigue
- Peripheral edema
- Thrombotic/thromboembolic complications

Mechanism of Action

- **Avatrombopag** is an orally bioavailable, small molecule TPO receptor agonist that stimulates proliferation and differentiation of megakaryocytes form bone marrow progenitor cells resulting in an increased production of platelets
- It does not compete with TPO for binding to the TPO receptor and has an additive effect with TPO on platelet production

Clinical Studies

- Efficacy of Doptelet was evaluated in 2 identically-designed multicenter, randomized, double-blind, placebo-controlled trials (**ADAPT-1 and ADAPT-2**)

Clinical Studies

- **Low** baseline platelet count cohort (<40 x 10^9/L)
  - Doptelet 60mg or placebo once daily for 5 days
- **High** baseline platelet count cohort (≥40 to <50 x10^9/L)
  - Doptelet 40mg or placebo once daily for 5 days

Clinical Studies

- The **major efficacy outcome** was the proportion of patients who did not require a platelet transfusion or any rescue procedure for bleeding after randomization and up to 7 days following an elective procedure (”Responders”)

Clinical Studies

- In **ADAPT-1** (N=231), 66% of low baseline platelet count cohort patients who received Doptelet were responders vs 23% of placebo patients (difference 43%, 95% CI, 27, 58; *P* <.0001)
- 88% of high baseline platelet count cohort patients who received Doptelet were responders vs 38% of placebo patients (difference 50%, 95% CI, 32, 68; *P* <.0001)

Clinical Studies

- In **ADAPT-2** (N=204), 69% of low baseline platelet count cohort patients who received Doptelet were responders vs 35% of placebo patients (difference 34%, 95% CI, 16, 52; *P* =.0006)
- 88% of high baseline platelet count cohort patients who received Doptelet were responders vs 33% of placebo patients (difference 55%, 95% CI, 37, 73; *P* <.0001)

Clinical Studies

- Both trials also showed a higher proportion of patients who achieved the target platelet count ≥ 50 x10^9/L on the day of the procedure (secondary efficacy endpoint) in both Doptelet-treated groups vs placebo

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/doptelet/drug/34836/