Tavalisse

(fostamatinib disodium hexahydrate)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Tavalisse
- **Generic name:** Fostamatinib disodium hexahydrate
- **Pharmacological class:** Tyrosine kinase inhibitor
- **Strength and Formulation:** 100mg, 150mg; tabs
- **Manufacturer:** Rigel Pharmaceuticals
- **How supplied:** Tabs—60
- **Legal Classification:** Rx

Indications

- Thrombocytopenia in adults with **chronic immune thrombocytopenia (ITP)** who have had insufficient response to previous treatment

Tavalisse


NDC 71332-001-01
Rx only
Tavalisse™
(fostamatinib) tablets
100 mg
60 Tablets
NDC 71332-002-01
Rx only
Tavalisse™
(fostamatinib) tablets
150 mg
60 Tablets

Dosage & Administration

- **≥18yrs:** Initially 100mg twice daily
- Increase to 150mg twice daily if platelet count not at ≥50x10^9/L after 4 weeks
- Discontinue if insufficient increase in platelet count after 12 weeks
- Dose modifications: see full labeling

Considerations for Special Populations

- **Pregnancy:** Confirm negative status prior to initiation
- **Nursing mothers:** Not recommended (during and for ≥1 month after last dose)
- **Pediatric:** <18yrs: not recommended
- **Elderly:** No overall differences in efficacy compared to younger patients

Warnings/Precautions

- **Monitor** CBCs, including platelets, monthly until stable count (≥50x10^9/L) achieved, then periodically thereafter
- **Monitor** LFTs monthly
- **Discontinue** if AST/ALT >5XULN for ≥2wks or ≥3XULN and total bilirubin >2XULN

Warnings/Precautions

- **Monitor** blood pressure every 2 weeks until stable dose established, then monthly thereafter
- **Interrupt or discontinue** dose if hypertensive crisis (>180/120mmHg) occurs; discontinue if repeat BP >160/100mmHg for >4 weeks
- **Temporarily interrupt** if severe diarrhea (Grade ≥3) occurs; resume at next lower daily dose if improved to Grade 1

Warnings/Precautions

- **Monitor** ANC monthly and for infection
- **Temporarily interrupt** if ANC $<1x10^9/L$ occurs and remains low after 72hrs until resolved; resume at next lower daily dose
- Use lowest effective dose
- Embryo-fetal toxicity
- Use effective contraception during and for ≥1 month after last dose

Interactions

- Concomitant **strong CYP3A4 inducers**: not recommended
- Concomitant **strong CYP3A4 inhibitors** or substrates; monitor for toxicity
- May potentiate concomitant **BCRP** (eg, rosuvastatin) or **P-gp** (eg, digoxin) substrates: monitor for toxicity

Adverse Reactions

- Diarrhea
- Hypertension
- Nausea
- Respiratory infection
- Dizziness
- ALT/AST increase
- Rash
- Abdominal pain
- Fatigue
- Chest pain
- Neutropenia

Mechanism of Action

- Fostamatinib is a tyrosine kinase inhibitor with activity against spleen tyrosine kinase
- The major metabolite, R406, inhibits signal transduction of Fc-activating receptors and B-cell receptor
- R406 reduces antibody-mediated destruction of platelets

Clinical Studies

- Tavalisse was evaluated in 2 identical placebo-controlled efficacy and safety studies **(FIT-1 and FIT-2)** and in an open-label extension study **(FIT-3)**

Clinical Studies

- 150 patients with persistent or chronic ITP who had an insufficient response to previous therapy were enrolled in FIT-1 (n=76) and FIT-2 (n=74)
  - Patients were randomized to Tavalisse 100mg twice daily or placebo for 24 weeks
  - Dose was escalated to 150mg twice daily based on platelet count and tolerability

Clinical Studies

- Efficacy was based on **stable platelet response** (≥50x10^9/L on at least 4 of 6 visits between Weeks 14–24)

Clinical Studies

- **In FIT-1**, 18% of the Tavalisse group achieved stable platelet response vs 0% in the placebo group (*P* =.03)
- **In FIT-2**, 16% of the Tavalisse group achieved stable platelet response vs 4% in the placebo group (*P*-value not significant)

Clinical Studies

- **FIT-3** (n=123) included patients from FIT-1 and FIT-2 who completed 24 weeks of treatment or who did not respond to treatment after 12 weeks
  - **Responders** at the time of rollover were continued at current trial dose and regimen
  - **Non-responders** received Tavalisse 100mg twice daily regardless of prior dose and regimen

Clinical Studies

- **Stable response** was prospectively defined as no 2 visits (≥4 weeks apart) with a platelet count $<50x10^9/L$, within a period of 12 weeks following initial achievement of target platelet count

Clinical Studies

- 50% of patients discontinued from the study early
- The prospective analysis (n=44) showed **23%** of patients achieved the criteria for stable response

- For more clinical trial info, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/tavalisse/drug/34821/