When ITP becomes persistent or chronic despite initial treatment in adult and pediatric patients aged ≥1 year[1,*]

PROMACTA DOSING AND ADMINISTRATION GUIDE

Indication and Important Safety Information

Indication for PROMACTA® (eltrombopag)

PROMACTA is indicated for the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. PROMACTA should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.

Limitations of Use

PROMACTA is not indicated for the treatment of patients with myelodysplastic syndromes (MDS).

Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.

Important Safety Information for PROMACTA® (eltrombopag)

WARNING: RISK FOR HEPATIC DECOMPENSATION IN PATIENTS WITH CHRONIC HEPATITIS C
In patients with chronic hepatitis C, PROMACTA in combination with interferon and ribavirin may increase the risk of hepatic decompensation.

RISK OF HEPATOTOXICITY
PROMACTA may increase the risk of severe and potentially life-threatening hepatotoxicity. Monitor hepatic function and discontinue dosing as recommended.

ITP, immune thrombocytopenia.
*Persistent ITP: 3 to 12 months since diagnosis; chronic ITP: >12 months since diagnosis.[2]

Next

Please see additional Important Safety Information for PROMACTA here and throughout. Click here for full Prescribing Information, including Boxed WARNING, and Medication Guide.

PROMACTA® (eltrombopag)
12.5mg, 25mg, 50mg, 75mg tablets
12.5mg, 25mg oral suspension

IT'S TIME TO BE PROMACTIVE

Patient portrayal.

OFFER CONVENIENT ONCE-DAILY ORAL DOSING WITH PROMACTA, THE #1 PRESCRIBED TPO-RA[1,3,*]

At home, at work, or on the go: One tablet, once a day. No weekly injections.[1,4]

PROMACTA can be taken without food or with food low in calcium (≤50 mg)[1]

- PROMACTA should be taken at least 2 hours before or 4 hours after medications such as antacids and mineral supplements or foods high in calcium[1]
- PROMACTA can be taken any time of day, at the same time each day[1]
- No need for weekly office visits for injections, and with PROMACTA tablets, there is less unused medication to discard[1,4]

Dosing flexibility, even for patients who have difficulty swallowing a pill[1]

MULTIPLE TABLET STRENGTHS — **ORAL SUSPENSION OPTIONS**

12.5 mg | **25 mg** | **50 mg** | **75 mg** | **12.5 mg** | **25 mg**

Tablets shown at actual size. 1 cm =

R3M, rolling 3 months; TPO-RA, thrombopoietin receptor agonist; TRx, total prescription.
*Source: IQVIA market sizing TRx monthly equivalents, R3M, March 2021 through August 2022.[3]

Important Safety Information for PROMACTA® (eltrombopag) (continued)

Hepatotoxicity

PROMACTA may increase the risk of severe and potentially life-threatening hepatotoxicity.

Treatment of ITP, chronic hepatitis C, and refractory severe aplastic anemia

- Measure serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), and bilirubin prior to initiation of PROMACTA, every 2 weeks during the dose-adjustment phase, and monthly following establishment of a stable dose
- PROMACTA inhibits UGT1A1 and OATP1B1, which may lead to indirect hyperbilirubinemia. If bilirubin is elevated, perform fractionation
- Evaluate abnormal serum liver tests with repeat testing within 3 to 5 days. If the abnormalities are confirmed, monitor serum liver tests weekly until resolved or stabilized

Prev

PROMACTA offers simplified titration to help maintain response over time[1]

Starting dose for adults:

Initiate at **50** mg/day[1,a]

If after at least 2 weeks platelet count is **<50,000/mcL**

Titrate up to **75** mg/day[b]

Most patients start and stay on a 50-mg dose[1,5]

[a] For patients of Asian ancestry, initiate at 25 mg/day. For patients with mild, moderate, or severe hepatic impairment, initiate at a reduced dose of 25 mg once daily; for patients of Asian ancestry with hepatic impairment, consider initiating at a reduced dose of 12.5 mg once daily.[1]
[b] Do not exceed a dose of 75 mg daily. For patients taking 25 mg once daily, increase dose by 25 mg; for patients taking 12.5 mg once daily, increase the dose to 25 mg daily before increasing the dose amount by 25 mg.[1]

If platelet counts are:

≥200,000/mcL to ≤400,000/mcL at any time
Decrease daily dose by 25 mg[c]

>400,000/mcL
Pause PROMACTA[d]

>400,000/mcL after 2 weeks of PROMACTA at lowest dose
Discontinue PROMACTA

[c] Wait 2 weeks to assess the effects of this and any subsequent dose adjustments. For patients taking 25 mg once daily, decrease the dose to 12.5 mg once daily.[1]
[d] Increase the frequency of platelet monitoring to twice weekly. Once the platelet count is <150,000/mcL, reinitiate therapy at a daily dose reduced by 25 mg. For patients taking 25 mg once daily, reinitiate therapy at a daily dose of 12.5 mg.[1]

- Monitor clinical hematology and liver tests regularly throughout therapy[1]
- If platelet counts do not increase to a level sufficient to avoid clinically important bleeding after 4 weeks at 75 mg, discontinue therapy[1]

Next

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12.5mg, 25mg oral suspension

IT'S TIME TO BE PROMACTIVE

Patient portrayal.

OFFER A TREATMENT THAT FITS YOUR PATIENT'S SCHEDULE[1]

Convenient once-daily oral dosing: At home, at school, or on the go[1]

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Two oral formulations: Dosing flexibility, even for patients who have difficulty swallowing a pill[1]

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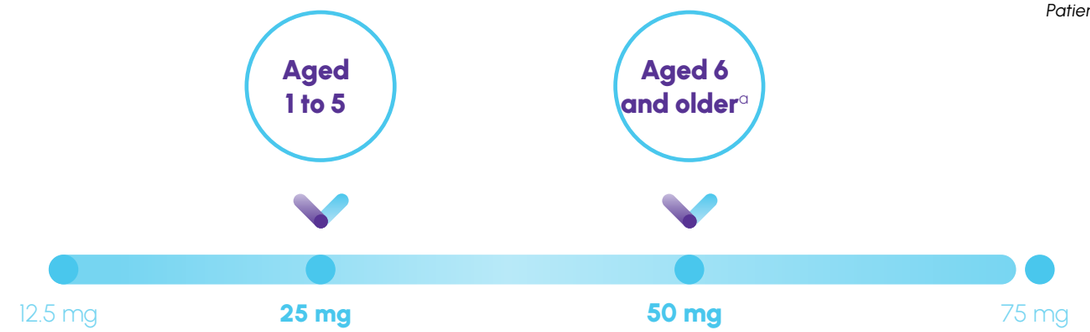
ORAL SUSPENSION OPTIONS

12.5 mg **25 mg**

Recommended starting dose for pediatric patients with persistent or chronic ITP[1]



[a]Except in patients who are of East-/Southeast-Asian ancestry or who have mild to severe hepatic impairment (Child-Pugh class A, B, C).[1]

- For patients aged 6 years and older who are of Asian ancestry or who have mild to severe hepatic impairment, initiate PROMACTA at a reduced dose of 25 mg once daily
- For patients aged 6 years and older who are of Asian ancestry with hepatic impairment, consider initiating at a reduced dose of 12.5 mg once daily

PROMACTA has **a maximum dosage of 75 mg per day** for pediatric patients

NDC: 0078-0972-61

NDC: 0078-0967-61

PROMACTA for oral suspension kits

- Available to order in boxes of 12.5-mg and 25-mg packets
- Request a Demonstration Kit through your local representative

Important Safety Information for PROMACTA® (eltrombopag) (continued)

Hepatotoxicity (continued)

- Discontinue PROMACTA if ALT levels increase to ≥3 times the upper limit of normal in patients with normal liver function or ≥3 times baseline in patients with pretreatment elevations in transaminases and are progressively increasing; or persistent for ≥4 weeks; or accompanied by increased direct bilirubin; or accompanied by clinical symptoms of liver injury or evidence for hepatic decompensation
- If the potential benefit for reinitiating treatment with PROMACTA outweighs the risk for hepatotoxicity, then consider cautiously reintroducing PROMACTA and measure serum liver tests weekly during the dose-adjustment phase. Hepatotoxicity may reoccur if PROMACTA is reinitiated. If liver test abnormalities persist, worsen, or recur, then permanently discontinue PROMACTA

Prev

Next

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NDC, National Drug Code.

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Thrombotic/Thromboembolic Complications

- Thrombotic/thromboembolic complications may result from increases in platelet counts with PROMACTA
- Reported thrombotic/thromboembolic complications included both venous and arterial events, and were observed at low and at normal platelet counts
- Portal vein thrombosis has been reported in patients with chronic liver disease receiving PROMACTA
- To minimize the risk for thrombotic/thromboembolic complications, do not use PROMACTA in an attempt to normalize platelet counts. Follow the dose-adjustment guidelines to achieve and maintain target platelet counts

Increased Risk of Death and Progression of Myelodysplastic Syndromes (MDS) to Acute Myeloid Leukemia (AML)

- In a clinical trial of patients with intermediate- to high-risk MDS and thrombocytopenia receiving PROMACTA, an increased number of progressions from MDS to AML and deaths have been observed compared to placebo
- PROMACTA is not indicated for the treatment of patients with MDS

Cataracts

- Development or worsening of cataracts with PROMACTA has been reported with a frequency of 5% to 11% in 6 clinical studies
- Perform a baseline ocular examination prior to initiating PROMACTA. Regularly monitor patients for signs and symptoms of cataracts while on PROMACTA

Laboratory Monitoring

- Monitor serum liver tests
- During therapy with PROMACTA, assess complete blood counts (CBCs) with differentials, including platelet counts, weekly until a stable platelet count has been achieved. Monitor platelet counts monthly thereafter
- Obtain CBCs with differentials, including platelet counts, weekly for at least 4 weeks following discontinuation of PROMACTA
- When switching between the oral suspension and tablet, assess platelet counts weekly for 2 weeks, then follow standard monthly monitoring

Drug/Drug and Drug/Food Interactions

- PROMACTA must be taken at least 2 hours before or 4 hours after any medications or products containing polyvalent cations such as antacids, calcium-rich foods, and mineral supplements
- Take PROMACTA without a meal or with a meal low in calcium (≤50 mg)

Adverse Reactions

Across all indications, the most common adverse reactions (≥20% in any indication) were anemia, nausea, pyrexia, ALT increased, cough, fatigue, headache, and diarrhea.

The most common adverse reactions in 3 placebo-controlled clinical trials in patients with persistent or chronic ITP (≥3% and greater than placebo) for PROMACTA were nausea (9%), diarrhea (9%), upper respiratory tract infection (7%), vomiting (6%), increased ALT (5%), myalgia (5%), urinary tract infection (5%), oropharyngeal pain (4%), increased AST (4%), pharyngitis (4%), back pain (3%), influenza (3%), paresthesia (3%), and rash (3%).

The most common adverse reactions in 2 placebo-controlled clinical trials in patients with persistent or chronic ITP 1 year and older (≥3% and greater than placebo) for PROMACTA were upper respiratory tract infection (17%), nasopharyngitis (12%), cough (9%), diarrhea (9%), pyrexia (9%), abdominal pain (8%), oropharyngeal pain (8%), toothache (6%), ALT increased (6%), rash (5%), AST increased (4%), and rhinorrhea (4%).

References:

1. Promacta. Prescribing information. Novartis Pharmaceuticals Corp.
2. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv.* 2019;3(23):3829-3866.
3. Data on file. IQVIA market sizing TRx monthly equivalents, R3M, March 2021 through August 2022. Novartis Pharmaceuticals Corp; November 2022.
4. Nplate. Prescribing information. Amgen Inc.
5. Data on file. IQVIA APLD December 2018 to May 2019. Novartis Pharmaceuticals Corp; August 2019.

APLD, anonymous patient-level data.

Prev

Next

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Discover more about convenient once-daily dosing[1] with **PROMACTA at promacta-hcp.com**

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Prev

NOVARTIS

PROMACTA® (eltrombopag)
12.5mg, 25mg, 50mg, 75mg tablets
12.5mg, 25mg oral suspension

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080