



12.5mg, 25mg, 50mg, 75mg tablets 12.5mg, 25mg oral suspension

Patient portrayal.





Please see Important Safety Information throughout this brochure and the Summary of Important Information here.











Important Safety Information for PROMACTA® (eltrombopag)

What is the most important information I should know about PROMACTA?

PROMACTA can cause serious side effects, including:

Liver Problems

PROMACTA may increase your risk of liver problems that may be severe and possibly life-threatening. Your health care provider will do blood tests to check your liver function before you start taking PROMACTA and during treatment. Your health care provider may stop your treatment with PROMACTA if you have changes in your liver function blood tests.

Approved Uses and Important Safety Information Approved Uses for PROMACTA® (eltrombopag)

PROMACTA is a prescription medicine used to treat adults and children 1 year and older with low blood platelet counts due to persistent or chronic immune thrombocytopenia (ITP) when other medicines to treat your ITP or surgery to remove the spleen have not worked well enough. PROMACTA is used to try to raise platelet counts in order to lower your risk for bleeding.

PROMACTA is not used to make platelet counts normal.



If you're feeling stuck with ITP, work together with your doctor to find the right treatment for you

What is ITP?

ITP is a condition in which your blood does not have enough platelets. Platelets are blood cells that help stop bleeding and bruising when you get hurt.

Persistent ITP: Lasting 3 to 12 months after diagnosis. Chronic ITP: Lasting >12 months after diagnosis.

How can ITP affect you?

- Your body may be destroying healthy platelets
- Your body doesn't make enough platelets
- · You may experience common symptoms such as bruising, prolonged bleeding from wounds, visible red or purple dots (petechiae), nosebleeds, bleeding gums, blood in urine or stools, unusually heavy menstrual flow, and feeling tired

Approved Uses for PROMACTA® (eltrombopag) (continued)

PROMACTA is for treatment of certain people with low platelet counts caused by persistent or chronic ITP, chronic hepatitis C virus (HCV), or severe aplastic anemia (SAA), not for a precancerous condition called myelodysplastic syndromes (MDS) or low platelet counts caused by other conditions or diseases.

It is not known if PROMACTA is safe and effective in children with chronic HCV or previously treated SAA, in children younger than 1 year with ITP, or children younger than 2 years when used in combination with standard immunosuppressive therapy as the first treatment for SAA.





Taking back control from ITP

starts with setting clear treatment goals with your doctor

Consider talking to your doctor about the following treatment goals: **Establishing a target platelet count** Getting platelets to your target count and maintaining them over time Managing ITP symptoms so you can keep up with the daily activities that are important to you Choosing the treatment that best suits your needs and lifestyle

Important Safety Information for PROMACTA® (eltrombopag) (continued) What is the most important information I should know about PROMACTA? (continued)

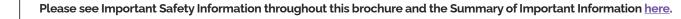
Tell your health care provider right away if you have any of these signs and symptoms of liver problems:

- yellowing of the skin or the whites of the eyes (jaundice)
- unusual darkening of the urine
- unusual tiredness

- right upper stomach area (abdomen) pain
- confusion
- swelling of the stomach area (abdomen)











Patient portraval.

• PROMACTA is a once-daily oral therapy that doesn't suppress your immune system. It works differently than some other medicines for ITP

• PROMACTA may boost your platelet counts and keep them at stable levels. It is not used to make your platelet counts normal. When the body is making more platelets, your ITP symptoms—like bleeding and bruising—may improve as a result

 Your doctor may prescribe PROMACTA when a previous medicine, such as a corticosteroid (steroid), has not worked

Important Safety Information for PROMACTA® (eltrombopag) (continued) What are the possible side effects of PROMACTA?

PROMACTA may cause serious side effects, including:

• Worsening of a precancerous blood condition to a blood cancer called acute myelogenous leukemia (AML). PROMACTA is not for treatment of people with a precancerous condition called myelodysplastic syndromes (MDS). If you have MDS and receive PROMACTA, your MDS condition may worsen and become AML. If MDS worsens to become AML, you may die sooner from AML.

Important Safety Information for PROMACTA® (eltrombopag) (continued) What are the possible side effects of PROMACTA? (continued)

• High platelet counts and higher risk for blood clots. Your risk of getting a blood clot is increased if your platelet count is too high during treatment with PROMACTA. Your risk of getting a blood clot may also be increased during treatment with PROMACTA if you have normal or low platelet counts. You may have severe problems or die from some forms of blood clots, such as clots that travel to the lungs or that cause heart attacks or strokes. Your health care provider will check your blood platelet counts and change your dose or stop PROMACTA if your platelet counts get too high. Tell your health care provider right away if you have signs and symptoms of a blood clot in the leg such as swelling, pain, or tenderness.







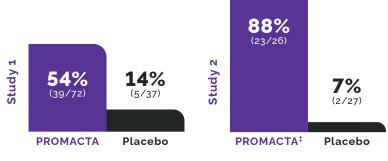
PROMACTA is the #1 prescribed platelet booster, taken by more than 500,000 people worldwide across all approved uses*

PROMACTA WORKED FAST

In 2 separate trials

The majority of patients achieved their target platelet goal (≥50,000/mcL) as early as 2 weeks

Patients who responded after 2 weeks of study treatment



The primary end point in both studies was response rate at Day 43. In Study 1, 59% (43/73) of patients receiving PROMACTA had achieved a response at Day 43 (vs 16% [6/37] for placebo). In Study 2, 70% (19/27) of patients receiving PROMACTA‡ had achieved a response at Day 43 (vs 11% [3/27] for placebo).

To learn more about how PROMACTA may help, visit us.promacta.com

*PROMACTA has been proven to work for children over the age of 1 year with persistent or chronic ITP.

†Source: IQVIA prescription claims data for March 2021 through August 2022. Includes people with chronic immune thrombocytopenia, severe aplastic anemia, and chronic hepatitis C virus.

‡Results for patients receiving 50 mg PROMACTA once daily.

PROMACTA may also help with fatigue, bleeding, and bruising due to reduced platelet counts



In a long-term study, 80% of people on PROMACTA self-reported improvements in measurements of fatigue (291 patients evaluated) and measurements of bleeding or bruising (288 patients evaluated) by Year 1



In the same long-term study, **PROMACTA** showed a 76% reduction in serious bleeding (from 17% to 4%) at Year 1

☆

In a clinical trial of 302 adults,

PROMACTA demonstrated the longest results ever reported in persistent or chronic ITP

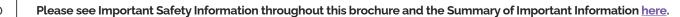
Important Safety Information for PROMACTA® (eltrombopag) (continued)

What are the possible side effects of PROMACTA? (continued)

People with chronic liver disease may be at risk for a type of blood clot in the stomach area. Tell your health care provider right away if you have stomach area pain that may be a symptom of this type of blood clot

• New or worsened cataracts (a clouding of the lens in the eye). New or worsened cataracts have happened in people taking PROMACTA. Your health care provider will check your eyes before and during your treatment with PROMACTA. Tell your health care provider about any changes in your eyesight while taking PROMACTA







PROMACTA has an established safety profile

In clinical trials, the 4 most common side effects of PROMACTA in adults with persistent or chronic ITP were:

NAUSEA 9%





VOMITING 6%

Other common side effects in these clinical trials included:

- urinary tract infection
- pain or swelling (inflammation) in your throat or mouth (oropharyngeal pain and pharyngitis)
- abnormal liver function tests
- · muscle aches

PROMACTA may cause serious side effects, including liver problems, blood clots, and cataracts.

No matter what the treatment, always let your doctor know if the side effects get to be too much. It's important not to stop or change the way you take PROMACTA without talking to your doctor.

*Symptoms may include runny nose, stuffy nose, and sneezing.

Important Safety Information for PROMACTA® (eltrombopag) (continued) What should I tell my health care provider before taking PROMACTA? (continued)

Before you take PROMACTA, tell your health care provider about all of your medical conditions, including if you: (continued)

- are pregnant or plan to become pregnant. It is not known if PROMACTA will harm an unborn baby. Tell your health care provider if you become pregnant or think you may be pregnant during treatment with PROMACTA. If you are a woman who is able to become pregnant, you must use reliable birth control (contraception) while taking PROMACTA and for at least 7 days after you stop taking PROMACTA. Talk to your health care provider about options of effective birth control methods that may be right for you during this
- are breastfeeding or plan to breastfeed. You should not breastfeed during treatment with PROMACTA. Talk to your health care provider about the best way to feed your baby during this time





Important Safety Information for PROMACTA® (eltrombopag) (continued) What should I tell my health care provider before taking PROMACTA?

Before you take PROMACTA, tell your health care provider about all of your medical conditions, including if you:

- have liver problems
- have a precancerous condition called MDS or a blood cancer
- have or have had a blood clot
- have a history of cataracts
- have had surgery to remove your spleen (splenectomy)
- have bleeding problems
- are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean). You may need a lower dose of PROMACTA

Convenient once-daily oral dosing









Tablets and Oral Suspension:

Can't swallow a pill? 12.5 mg and 25 mg are also available in an **oral suspension**



12.5 mg







Tablets displayed in sizes proportional to the following scale: 1 cm = 1

PROMACTA is the only TPO-RA (a type of platelet booster) that offers the flexibility of:

- · Convenient once-daily oral dosing no matter what dose you're on
- Both tablets and oral suspension
- · Click here for information on how to take **PROMACTA**

TPO-RA, thrombopoietin receptor agonist.

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

What should I tell my health care provider before taking PROMACTA? (continued)

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. PROMACTA may affect the way certain medicines work. Certain other medicines may affect the way PROMACTA works.











Get unstuck with PROMACTA... Take **PROMACTA** once a day wherever and whenever it works for you

With PROMACTA, you won't be stuck with weekly doctor visits for the administration of PROMACTA

Important things to know:

PROMACTA can be taken without a meal or



PROMACTA should be taken 2 hours before or 4 hours after taking medications like antacids, mineral supplements, or foods that are high in calcium

Click here to learn more about how you can fit PROMACTA into your lifestyle.

with a meal low in calcium (≤50 mg)

Important Safety Information for PROMACTA® (eltrombopag) (continued) What should I tell my health care provider before taking PROMACTA? (continued)

Especially tell your health care provider if you take:

- · certain medicines used to treat high cholesterol called "statins"
- a blood thinner medicine

Certain medicines may keep PROMACTA from working correctly. Take PROMACTA at least 2 hours before or 4 hours after taking these products:

- · antacids used to treat stomach ulcers or heartburn
- multivitamins, mineral supplements, or products that contain iron, calcium, aluminum, magnesium, selenium, and zinc

Ask your health care provider if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of them and show it to your health care provider and pharmacist when you get a new medicine.



See how far you've come

by tracking your progress with PROMACTA

It's important not to stop or change the way you take PROMACTA without talking to your doctor

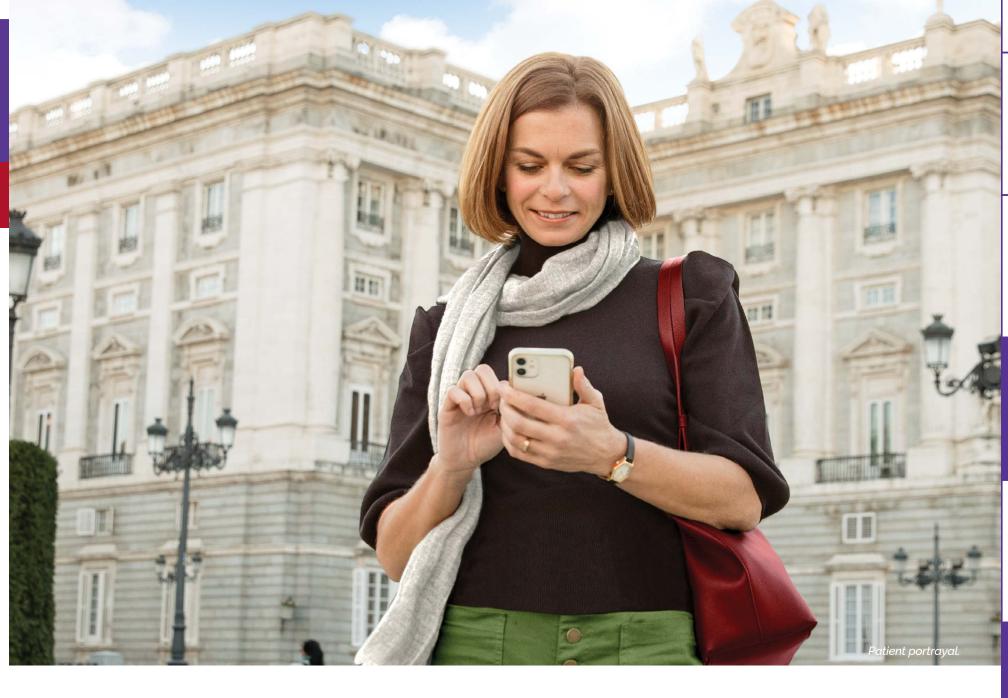
Your doctor will monitor your progress by checking your platelet count

- When you first start taking PROMACTA, your doctor will monitor your platelet counts once a week to help find the appropriate dose.
 Complete blood counts with differentials, including platelet counts, will be obtained monthly thereafter
- Once you and your doctor have found a dose that works for you, platelet count checks may become less frequent

It's important to tell your doctor: How your body is reacting to new medication If your ITP symptoms are not improving If you experience any new or worsening side effects If you experience any bruising or bleeding while taking PROMACTA or after treatment has stopped

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <u>www.fda.gov/medwatch</u>, or call <u>1-800-FDA-1088</u>.

FDA, US Food and Drug Administration.





PROMACTA provides tools and resources

that can help you take an active role

Click here to download helpful materials.



Questions on how to work PROMACTA into your schedule?

The **meal planner** has helpful tips and suggestions on how to fit PROMACTA into your everyday schedule



Want to track how you're doing on PROMACTA?

The <u>platelet tracker</u> is designed to help you monitor your treatment progress



Be part of the conversation at your next doctor visit

The <u>doctor discussion guide</u> can help you get the conversation going about PROMACTA and any questions you may have. Share in decision making with your doctor to ensure that your treatment can meet your needs

COVID-19 Information

Contact your prescribing health care provider if you have any questions or concerns about nonimmunosuppressive PROMACTA when considering whether you should receive any vaccine. Visit <u>us.promacta.com</u> to learn more about PROMACTA

Important Safety Information for PROMACTA® (eltrombopag) (continued) What should I avoid while taking PROMACTA?

Avoid situations and medicines that may increase your risk of bleeding.

The most common side effects of PROMACTA in adults when used to treat persistent or chronic immune thrombocytopenia (ITP) are:

- nausea
- diarrhea
- upper respiratory tract infection (symptoms may include runny nose, stuffy nose, and sneezing)
- vomiting
- urinary tract infection
- pain or swelling (inflammation) in your throat or mouth (oropharyngeal pain and pharyngitis)
- abnormal liver function tests
- muscle aches





Patient portrayal



PROMACTA has the best coverage of all oral ITP treatments for patients who've tried other treatments before*

~99%

of patients have PROMACTA included in their health coverage 70%

of Medicare and commercial patients pay ≤\$10 out of pocket for PROMACTA†

These programs are available to PROMACTA patients regardless of insurance type

Free Trial Program

of treatment

If you have been prescribed PROMACTA, you may be eligible to receive a free 14-day supply by mail to help you begin therapy. You will need to complete a Patient Assistance Now Oncology Service Request Form (PANO SRF) to see if you qualify (for FDA-approved uses/indications only)

You don't have to be stuck by the cost

No matter your coverage, we're here to help

14-Day Sample Program

Get started on Day 1 with a free 14-day supply of PROMACTA

Voucher Program

Novartis provides eligible patients with a temporary supply of PROMACTA. Contact us at 1-800-282-7630 to get more information

	Privately/ Commercially Insured	Medicare/ Medicaid	Uninsured/ Underinsured
14-Day Sample Program	✓	✓	~
Free Trial Program	✓	✓	~
Voucher Program	✓	✓	~
Universal Co-pay Program	✓		
PANO	✓	✓	✓
NPAF	✓	✓	✓

If you have private or commercial insurance...



Universal Co-pay Program

You may be eligible for immediate co-pay savings on your next prescription of PROMACTA

- Eligible patients with private insurance may pay \$0 per month
- · Novartis will pay the remaining co-pay, up to \$15,000 per calendar year

To find out if you are eligible for the Novartis Oncology Universal Co-pay Program today, text SAVINGS to 34039, call 1-877-577-7756, or visit Copay.NovartisOncology.com

Message and data rates may apply.

If you are uninsured or underinsured...

Novartis Patient Assistance Foundation (NPAF)

The Novartis Patient Assistance Foundation, Inc., an independent charitable organization, may provide financial assistance for Novartis Oncology medicine(s) to patients experiencing financial hardship with limited or no prescription coverage. You may be eligible to receive your Novartis medicine(s) for free.

To learn more: Call NPAF at 1-800-277-2254 or visit PAP.Novartis.com.

[†]Based on 30,844 approved claims identified between January 1, 2022, and December 31, 2022, for all relevant payers, including commercial, government, and/or other third-party support. Patients with government insurance are not eligible for the Universal Co-pay Program; any information about these patients' co-pay may be a function of their specific benefit design as applicable to the product.



^{*}Broadest coverage, with highest proportion of preferred-status claims. Based on pharmacy benefit claims for commercial and Medicare management of oral ITP agents.

What is PROMACTA?

PROMACTA is a prescription medicine used to treat adults and children 1 year of age and older with low blood platelet counts due to persistent or chronic immune thrombocytopenia (ITP) when other medicines to treat ITP or surgery to remove the spleen have not worked well enough.

PROMACTA is also used to treat people with:

- low blood platelet counts due to chronic hepatitis C virus (HCV) infection before and during treatment with interferon
- severe aplastic anemia (SAA) in combination with other medicines to treat SAA as the first treatment for adults and children 2 years of age and older
- severe aplastic anemia (SAA) when other medicines to treat SAA have not worked well enough

PROMACTA is used to try to raise platelet counts in order to lower your risk for bleeding.

PROMACTA is not used to make platelet counts normal.

PROMACTA is not for use in people with a precancerous condition called myelodysplastic syndromes (MDS) or in people with low platelet counts caused by certain other medical conditions or diseases.

It is not known if PROMACTA is safe and effective when used with other antiviral medicines to treat chronic hepatitis C. It is not known if PROMACTA is safe and effective in children:

- younger than 1 year with ITP
- with low blood platelet counts due to chronic hepatitis C
- whose SAA has not improved after previous treatments
- younger than 2 years when used in combination with other medicines to treat SAA as the first treatment for SAA

What is the most important information I should know about PROMACTA?

PROMACTA can cause serious side effects, including:

Liver problems:

- If you have chronic hepatitis C virus and take PROMACTA with interferon and ribavirin treatment, PROMACTA may increase your risk of liver problems. If your health care provider tells you to stop your treatment with interferon and ribavirin, you will also need to stop taking PROMACTA
- PROMACTA may increase your risk of liver problems that may be severe and possibly life-threatening. Your health care provider will do blood tests to check your liver function before you start taking PROMACTA and during your treatment Your health care provider may stop your treatment with PROMACTA if you have changes in your liver function blood tests

Tell your health care provider right away if you have any of these signs and symptoms of liver problems:

- yellowing of the skin or the whites of the eyes (jaundice)
- unusual darkening of the urine
- unusual tiredness
- right upper stomach area (abdomen) pain
- confusion
- swelling of the stomach area (abdomen)

Before you take PROMACTA, tell your health care provider about all of your medical conditions, including if you:

- have liver problems
- have a precancerous condition called MDS or a blood cancer
- have or have had a blood clot
- have a history of cataracts
- have had surgery to remove your spleen (splenectomy)
- have bleeding problems
- are of East-/Southeast-Asian ancestry. You may need a lower dose of PROMACTA
- are pregnant or plan to become pregnant. It is not known if PROMACTA will harm an unborn baby. Tell your health care provider if you become pregnant or think you may be pregnant during treatment with PROMACTA
- Females who are able to become pregnant should use effective birth control (contraception) during treatment with PROMACTA and for at least 7 days after stopping treatment with PROMACTA. Talk to your health care provider about birth control methods that may be right for you during this time

- are breastfeeding or plan to breastfeed. You should not breastfeed during your treatment with PROMACTA. Talk to your health care provider about the best way to feed your baby during this time
- Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. PROMACTA may affect the way certain medicines work. Certain other medicines may affect the way PROMACTA works

Especially tell your health care provider if you take:

- certain medicines used to treat high cholesterol, called "statins"
- · a blood thinner medicine

Certain medicines may keep PROMACTA from working correctly. Take PROMACTA at least 2 hours before or 4 hours after taking these products:

- antacid medicine used to treat stomach ulcers or heartburn
- multivitamins or products that contain iron, calcium, aluminum, magnesium, selenium, and zinc which may be found in mineral supplements

Ask your health care provider if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of them and show it to your health care provider and pharmacist when you get a new medicine.

How should I take PROMACTA?

- Take PROMACTA exactly as your health care provider tells you to take it. Your health care provider will prescribe the dose of PROMACTA tablets or PROMACTA for oral suspension that is right for you
- If your health care provider prescribes PROMACTA tablets, take PROMACTA tablets whole. Do not split, chew, or crush PROMACTA tablets and do not mix with food or liquids
- If your health care provider prescribes PROMACTA for oral suspension, see the "Instructions for Use" that comes with your medicine for instructions on how to correctly mix and take a dose of PROMACTA
- Use a new single-use oral dosing syringe to prepare each dose of PROMACTA for oral suspension. Do not reuse the oral dosing syringe

- Do not stop taking PROMACTA without talking with your health care provider first. Do not change your dose or schedule for taking PROMACTA unless your health care provider tells you to change it
- Take PROMACTA without a meal or with a meal low in calcium (50 mg or less) and at least 2 hours before or 4 hours after eating calcium-rich foods, such as dairy products, calcium-fortified juices, and certain fruits and vegetables
- If you miss a dose of PROMACTA, wait and take your next scheduled dose. Do not take more than 1 dose of PROMACTA in 1 day
- If you take too much PROMACTA, you may have a higher risk of serious side effects. Call your health care provider right away
- Your health care provider will check your platelet count during your treatment with PROMACTA and change your dose of PROMACTA as needed
- Tell your health care provider about any bruising or bleeding that happens while you take and after you stop taking PROMACTA
- If you have SAA, your health care provider may do tests to monitor your bone marrow during treatment with PROMACTA

What should I avoid while taking PROMACTA?

Avoid situations and medicines that may increase your risk of bleeding.

What are the possible side effects of PROMACTA? PROMACTA may cause serious side effects, including:

- See "What is the most important information I should know about PROMACTA?"
- Increased risk of worsening of a precancerous blood condition called myelodysplastic syndromes (MDS) to acute myelogenous leukemia (AML). PROMACTA is not for use in people with a precancerous condition called myelodysplastic syndromes (MDS). See "What is PROMACTA?" If you have MDS and receive PROMACTA, you have an increased risk that your MDS condition may worsen and become a blood cancer called AML. If your MDS worsens to become AML, you may have an increased risk of death from AML





About ITP



25

What are the possible side effects of PROMACTA? (continued)

 High platelet counts and higher risk for blood clots. Your risk of getting a blood clot is increased if your platelet count is too high during treatment with PROMACTA. Your risk of getting a blood clot may also be increased during treatment with PROMACTA if you have normal or low platelet counts. You may have severe problems or die from some forms of blood clots, such as clots that travel to the lungs or that cause heart attacks or strokes.

Your health care provider will check your blood platelet counts and change your dose or stop PROMACTA if your platelet counts get too high. Tell your health care provider right away if you have signs and symptoms of a blood clot in the leg, such as swelling, pain, or tenderness in your leg.

People with chronic liver disease may be at risk for a type of blood clot in the stomach area (abdomen). Tell your health care provider right away if you have stomach-area (abdomen) pain, nausea, vomiting, or diarrhea as these may be symptoms of this type of blood clot

New or worsened cataracts (a clouding of the lens in the eye).
 New or worsened cataracts can happen in people taking PROMACTA. Your health care provider will check your eyes before and during your treatment with PROMACTA. Tell your health care provider about any changes in your eyesight while taking PROMACTA

The most common side effects of PROMACTA in adults and children include:

- low red blood cell count (anemia)
- nausea
- fever
- abnormal liver function tests
- cough
- tiredness
- headache
- diarrhea

Laboratory tests may show abnormal changes to the cells in your bone marrow.

Tell your health care provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of PROMACTA. For more information, ask your health care provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store PROMACTA tablets and PROMACTA for oral suspension?

- Tablets:
- Store PROMACTA tablets at room temperature between 68°F to 77°F (20°C to 25°C)
- Keep PROMACTA in the bottle given to you

For oral suspension:

- Store PROMACTA for oral suspension at room temperature between 68°F to 77°F (20°C to 25°C)
- After mixing, PROMACTA should be taken right away but may be stored for no more than 30 minutes between 68°F to 77°F (20°C to 25°C). Throw away (discard) the mixture if not used within 30 minutes

Keep PROMACTA and all medicines out of the reach of children.

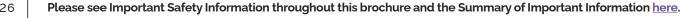
The risk information provided here is not comprehensive. To learn more, talk about PROMACTA with your health care provider or pharmacist. The FDA-approved product labeling can be found at www.PROMACTA.com or 1-888-669-6682.



Aho

Abou PROMA











When other medicines have not worked for you, consider PROMACTA the #1 prescribed platelet booster, taken by more than 500,000 people worldwide across all approved uses*,+

Please see Important Safety Information throughout this brochure and the Summary of Important Information here.





413923



^{*}PROMACTA has been proven to work for children over the age of 1 year with persistent or chronic ITP.

[†]Source: IQVIA prescription claims data for March 2021 through August 2022. Includes people with chronic immune thrombocytopenia, severe aplastic anemia, and chronic hepatitis C virus.