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WHEN NAVIGATING
THE JOURNEY AHEAD:

**Be Informed.
Be Involved.**

Patient portrayal.

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 41 to 45.

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



WHAT ELSE IS IMPORTANT TO KNOW ABOUT CHRONIC ITP?

Chronic ITP Facts: [What is it?](#) | [Types of ITP](#) | [Symptoms](#)



Patient portrayal.

ITP, immune thrombocytopenia.

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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 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.

PROMACTA is for treatment of certain people with low platelet counts caused by 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.

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.

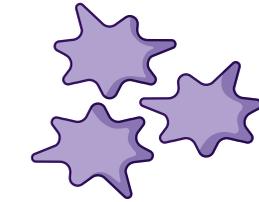
Tell your health care provider right away if you have any of these signs and symptoms of liver problems:

- 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)

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 41 to 45.

What is chronic ITP?

Chronic ITP is a rare blood disorder. Children who have chronic ITP do not have enough platelets in their blood—which can lead to bleeding and bruising.



Is it acute or chronic ITP?

There are many important differences between acute and chronic ITP.

Acute ITP

Lasts **less than 6 months**

With treatment, it **may go away** on its own within a few weeks or months and not return

More common in children **ages 10 and younger**

Chronic ITP

Lasts **6 months or longer**

Often requires **further treatment**

More common if ITP is **diagnosed after the age of 10**

You and your child’s doctor should discuss a treatment approach that fits your family’s lifestyle

ITP, immune thrombocytopenia.



Actively monitor your child's chronic ITP symptoms

Keeping track of your child's symptoms is something beneficial you can do every day! While your child may not have symptoms every day, you should continually keep a record of:

- Each type of symptom
- How often they occur
- Whether they are mild or severe

Symptoms can range from mild to severe, and you should take different steps consistent with the guidance from your child's doctor depending on how severe they become.

ITP, immune thrombocytopenia.

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.

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 41 to 45.



Patient portrayal.

Chronic ITP symptoms



MILD:
Keep an eye on them

- Occasional nosebleeds that can be stopped by applying pressure
- Blood blisters in the mouth
- Small bruises
- A few petechiae (tiny red or purple dots on the skin)



MODERATE:
Let your child's doctor know

- Nosebleeds lasting longer than 15 minutes
- Bleeding from the gums, lips, mouth, esophagus, or intestines
- Blood in the urine, stool, or vomit
- Large, new bruises (bigger than about 2 inches)
- Lots of new petechiae



SEVERE:
See the doctor right away

- Continuous bleeding from the gums, lips, mouth, or throat
- Suspected internal bleeding (brain, lung, muscles, joints, other)
- Many large, new bruises or petechiae

For more information about what to do when your child experiences bleeding, consult your child's doctor and visit <https://www.us.promacta.com/itp-in-children/about-the-disease/signs-symptoms/>



HOW CAN YOU HELP YOUR CHILD WITH CHRONIC ITP?

Chronic ITP: [Health care team](#) | [Disease terms](#) | [Treatment options](#)

ITP, immune thrombocytopenia.

Patient portrayal.



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Who can you talk to for support?

Pediatrician

- Your child's main doctor for any health issue



Medical staff

- Nurses and physician assistants can help you and your child along the chronic ITP journey



Social worker or therapist

- Chronic ITP can take a toll on your child and the family. These specialists give family members the opportunity to discuss their feelings and to find a way to keep living a normal life



ITP, immune thrombocytopenia.

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.

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

[Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 41 to 45.](#)

What terms should you know?

While you work closely with your child's health care team, it may be helpful to learn some of the terms you may be hearing or reading about.

Autoimmune condition

A condition in which the immune system attacks healthy parts of the body

Bone marrow

Tissue inside some bones that makes red blood cells, white blood cells, and platelets

Fatigue

Feeling extremely tired without a clear or direct cause

Immune system

A system that protects the body from disease

Immunosuppressant

A drug that limits the activity of the immune system

Infusion/intravenous

Medicine given in a doctor's office through a needle or tube inserted into a vein

Oncologist

A doctor who treats cancer. The oncologist can help rule out other diseases and administer a treatment

Petechiae

Pinpoint red or purple dots that appear on the skin as a result of bleeding

Platelet

A fragment of a blood cell that helps blood to clot

Spleen

An organ that helps the body fight infection

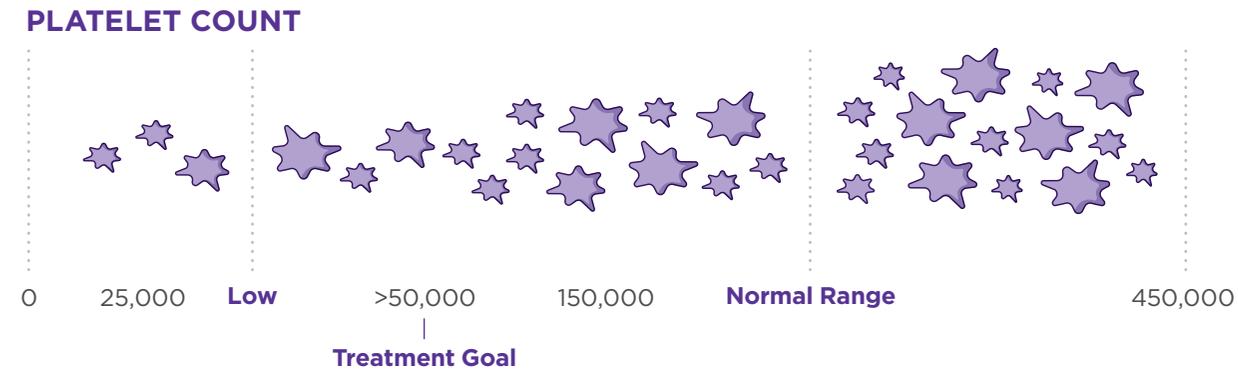
Thrombopoietin (TPO)

A protein produced primarily in the liver that controls how many platelets are made



Choosing your child's treatment

Your child may start with treatment for acute ITP. Their platelet count will be consistently monitored to see if therapy is working. If your child's platelet levels do not improve enough, your child's doctor may begin therapy for chronic ITP. **It's important to know that it's common for acute ITP to become chronic ITP.**

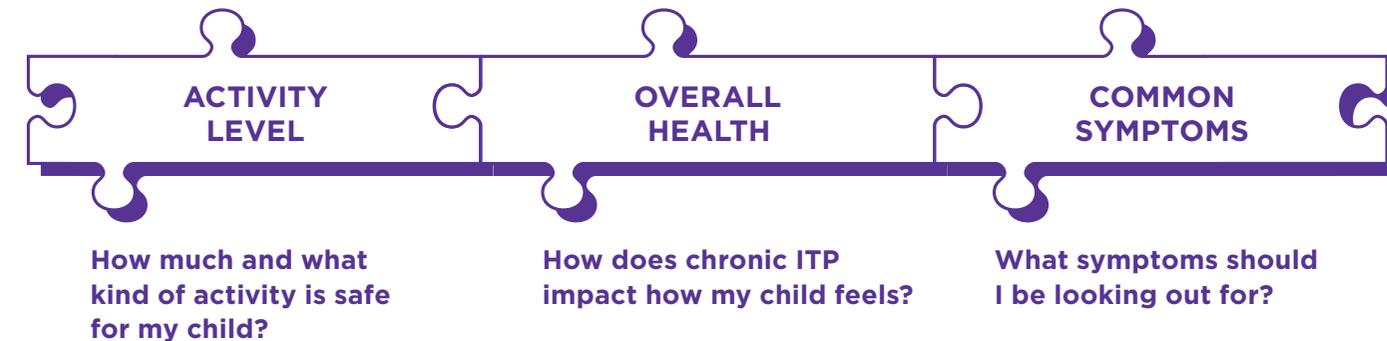


ITP, immune thrombocytopenia.

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 41 to 45.

Understand your child's treatment options

Treatment can be tailored to your child's needs. In fact, when it comes to choosing the right treatment for your child, there is more to it than just raising their platelet count. When speaking with your child's doctor, consider the following topics and potential questions:



For more questions that you may find helpful to ask your child's doctor, visit www.PROMACTA.com

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

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

- **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



Understand professional treatment guidelines



Many health care professionals follow the guidelines of the American Society of Hematology (ASH), the society for doctors who treat blood diseases. Here is an overview of the recommendations you can use when discussing treatment with your child's doctor.

ACUTE ITP

Corticosteroids (steroids)

Most ITP patients start with a round of steroids to stop the body from destroying platelets and quickly raise platelet counts. Unfortunately, steroids can also have side effects, such as insomnia, weight gain, and mood changes. That's 1 of the reasons why ASH recommends the use of steroids for no more than 6 weeks.

Intravenous immunoglobulin (IVIg)

IVIg is also an option to raise platelet counts quickly. IVIg is an infusion given with a needle and requires sitting still for some time while the medicine goes into the veins.

CHRONIC ITP

TPO-RAs (thrombopoietin receptor agonists)

Instead of trying to stop the body from destroying platelets, TPO-RAs are platelet boosters that encourage the body to make more. ASH recommends the use of TPO-RAs before other chronic ITP treatments (see **Monoclonal antibodies** and **Splenectomy**). Currently, there are 2 approved for use in pediatric patients:

- Nplate® (romiplostim) is an injection that requires a weekly doctor's visit to receive treatment
- PROMACTA® (eltrombopag) is a once-daily tablet that can be taken wherever and whenever it works for you and your child. It is also available as an oral suspension for children who have difficulty swallowing a pill

Monoclonal antibodies

Rituxan® (rituximab) is a monoclonal antibody that suppresses a specific target in the immune system. While part of the ASH guidelines, it is not an FDA-approved treatment for chronic ITP.

Splenectomy

A splenectomy is surgery to remove the spleen. While doctors would not normally remove a healthy organ, taking it out can help some people with chronic ITP. However, there is no test to show whether or not a splenectomy will work, and there is always a risk with any surgical procedure.

RESCUE THERAPY

Sometimes, treatment doesn't work or it works for a while and then platelets drop again. If platelet levels get too low, your child may receive a different or additional treatment until they feel better again. Your child's doctor may try to get their platelet count back up with:

- Steroids
- IVIg
- Platelet transfusions

➔ Proactively speak with your child's health care team to create a treatment plan

FDA, US Food and Drug Administration; ITP, immune thrombocytopenia.

Nplate is a registered trademark of Amgen Inc. *Rituxan* is a registered trademark of Biogen.

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



[Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 41 to 45.](#)

HOW MAY PROMACTA HELP YOUR CHILD WITH CHRONIC ITP?

PROMACTA® (eltrombopag) and patient preference:

[How it's different](#) | [How it works](#) | [Preferred treatment](#) | [Shared decision making](#)

ITP, immune thrombocytopenia.

Patient portrayal.

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What makes PROMACTA different?

PROMACTA® (eltrombopag) is the #1 platelet booster, prescribed to more than 200,000 people worldwide*

For pediatric patients, it's the only once-daily oral treatment for chronic ITP and it has the following features:

- Can be given as an oral tablet or suspension
- Can be given at home, without the need to visit a doctor's office for an injection
- Fits in with an active lifestyle; can be given wherever you and your child go



ITP, immune thrombocytopenia.

*Source: IQVIA claims data for October 2018 to December 2019. Includes people with chronic immune thrombocytopenia, severe aplastic anemia, and chronic hepatitis C virus.

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 time
- 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

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 41 to 45.

How does PROMACTA work?

PROMACTA was studied in more pediatric patients than any other drug of its kind

In a clinical trial of 67 pediatric chronic ITP patients...

PROMACTA worked fast

62% of patients reached their target platelet level (28 of 45), some as early as Week 1

In a clinical trial of 92 pediatric chronic ITP patients...

PROMACTA kept working

41% of patients maintained a response for at least 6 weeks (26 of 63)

PROMACTA helped in other ways

13% of patients on PROMACTA (6 of 45) needed to take rescue medication to raise their platelet levels compared with 50% of patients on placebo (11 of 22)

53% of patients taking other ITP medications were able to reduce or stop using them after starting PROMACTA (8 of 15)

PROMACTA has been proven to help pediatric chronic ITP patients reach target levels and maintain them for a long time

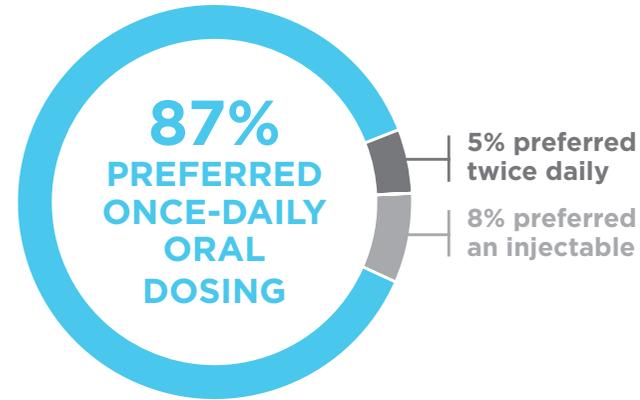


See what others living with ITP prefer

ITP patients prefer once-daily oral dosing

I-WISH was a global survey conducted in 13 countries with 1507 patients and 472 physicians. In the US alone, there were more than 500 patients. The survey asked about patient preference for administration. Here's what they found:

- ➔ Most ITP patients, 87%, said they prefer treatment that could be taken by mouth once a day (over an injectable therapy or a twice-daily oral regimen)



ASH, American Society of Hematology; ITP, immune thrombocytopenia; IVIg, intravenous immunoglobulin; I-WISH, ITP World Impact Survey.

Important Safety Information for PROMACTA® (eltrombopag) (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.

Especially tell your health care provider if you take:

- certain medicines used to treat high cholesterol, called “statins”
- a blood thinner medicine

[Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 41 to 45.](#)

Participate in shared decision making with your child's doctor



For the treatment of chronic ITP, ASH recommends:

- ➔ Patient education and shared decision making between the doctor and patient
- ➔ Making treatment decisions based on patient preference

➔ **Get information on how to talk to your child about treating their condition**

Talk to your child's doctor to see if PROMACTA® (eltrombopag) may be the right treatment option for your child after corticosteroids or IVIg



HOW DOES YOUR CHILD START PROMACTA?

Starting PROMACTA: How to take | When to take

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

Patient portrayal.



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Which dosing administration will work best for you and your child?

PROMACTA® (eltrombopag) is the only second-line chronic ITP treatment of its kind that offers convenient once-daily oral dosing for pediatric patients. Most younger children start PROMACTA on 25 mg once daily. Your child's doctor will work with you to find which strength and formulation work best for your child over the long term.

➔ PROMACTA comes in both an oral tablet and oral suspension:

Oral tablets:
12.5 mg | 25 mg | 50 mg | 75 mg

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



You and your child can choose which way is best to take PROMACTA

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

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.

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 41 to 45.

How should your child take PROMACTA?

HERE ARE 3 IMPORTANT THINGS TO KNOW:

- ➔ PROMACTA can be taken without a meal or it can be taken with a meal low in calcium (≤ 50 mg)
- ➔ PROMACTA should be taken 2 hours before or 4 hours after taking medications like antacids, mineral supplements, or foods that are high in calcium
- ➔ Weekly doctor's visits aren't required for administration of PROMACTA



Patient portrayal.

Get the Pediatric Oral Suspension Brochure at www.PROMACTA-kids.com

ITP, immune thrombocytopenia.



How to fit PROMACTA into your family's lifestyle

Create a schedule

With PROMACTA® (eltrombopag), you don't have to build your child's life around treatment administration. You and your child decide when to take it. Once you find a time that works, you can simply stick to that time, all the time. Here are some ideas to get you started creating a schedule.



Take PROMACTA before school starts...

Your child can take PROMACTA with or without breakfast.* By the time school starts, you can rest assured knowing that your child is covered for the rest of the day even if they have a calcium-rich snack.

OR: Take PROMACTA after dinner...

Your child can take PROMACTA before, during, or after dinner.* This allows you to establish a schedule for taking PROMACTA that works for your family.

*If meals have more than 50 mg of calcium, PROMACTA needs to be taken 2 hours before or 4 hours after eating.

 **Proceed with a schedule that works best for you and your child**

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 41 to 45.

Get the Pediatric Meal Planner Brochure at www.PROMACTA-kids.com

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 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

The most common side effects of PROMACTA in children 1 year and older when used to treat chronic ITP are:

- upper respiratory tract infection (symptoms may include runny nose, stuffy nose, and sneezing)
- pain or swelling (inflammation) in your nose or throat (nasopharyngitis)



HOW MAY PROMACTA HELP THE FIGHT AGAINST SECOND-LINE CHRONIC ITP?

Staying on PROMACTA® (eltrombopag): Getting better | Tracking progress

ITP, immune thrombocytopenia.

Patient portrayal.

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How will you know if PROMACTA is working?

The doctor will continue to check your child's platelet count to monitor if PROMACTA® (eltrombopag) is working and your child is on the appropriate dose.



When your child first starts taking PROMACTA...

Platelet counts will be tracked once a week.



Once you and your child's doctor have found a dose that works...

Platelet count checks will become less frequent.

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

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

Tell your health care provider about any bruising or bleeding that happens while you take or after you stop taking PROMACTA.

Tell your health care provider if you have any side effect that bothers you or does not go away.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 41 to 45.

Keep track of your child's progress

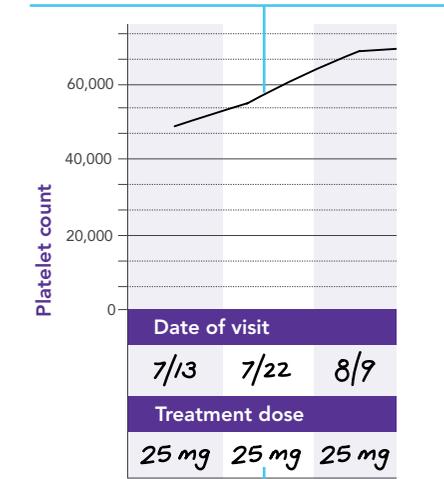
Use the platelet tracker to see how PROMACTA is working.

Your child's platelet count is important, but how they feel is also helpful to keep in mind when keeping track of their progress.

Progress should be tracked while on PROMACTA

Get the Pediatric Platelet Tracker at www.PROMACTA-kids.com

→ Plot your child's platelet count after each blood test.



→ To keep your child involved with their treatment, fill the tracker out together.



WHAT ABOUT THE SAFETY OF PROMACTA?

Staying on PROMACTA: Side effects | Stopping therapy

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12.5mg, 25mg oral suspension



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Consistent safety across multiple trials

What are the most common side effects of PROMACTA® (eltrombopag)?

The most common side effects of PROMACTA in children 1 year and older when used to treat second-line chronic ITP are:

- Upper respiratory tract infection (symptoms may include runny nose, stuffy nose, and sneezing), 17%
- Pain or swelling (inflammation) in their nose or throat (nasopharyngitis), 12%



treated with PROMACTA in clinical trials (8 of 156) had to stop taking therapy due to side effects

No other side effects occurred in more than 9% of children in the 2 main pediatric studies of PROMACTA

ITP, immune thrombocytopenia.

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 41 to 45.

No matter what the treatment, always let your child's doctor know about any side effects

➔ **Provide information about side effects to your child's doctor**

Always speak with your child's doctor if you have questions or if you notice a difference in your child's symptoms

WHAT SUPPORT IS AVAILABLE TO YOU AND YOUR CHILD?

PROMACTA4U: Support line | 1-on-1 support | Patient Navigator | Co-pay assistance | PANO

PANO, Patient Assistance Now Oncology.

Patient portrayal.



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PROMACTA offers guidance and tools to help from the start

Free **Patient Support Line**—just call **1-800-282-7630** and you will be directed to support services.



1-on-1 support specific to questions you may have regarding your child's treatment, financial assistance, private insurance, and Medicare.*



Select **prompt 3** to speak with a **Patient Navigator**, a trained professional **who can provide personalized support**. They can guide you as your child begins treatment with PROMACTA® (eltrombopag) and provide responses to frequently asked questions like:

- ➔ How should your child take PROMACTA?
- ➔ What should your child avoid while taking PROMACTA?
- ➔ How does PROMACTA work?
- ➔ What should your child do if they miss a dose of PROMACTA?
- ➔ What dietary considerations does your child have to follow when taking PROMACTA?



Or visit us at www.PROMACTA-4U.com

For more helpful information about chronic ITP and PROMACTA, as well as tools like meal planners and dietary guides, visit www.PROMACTA-4U.com today!

ITP, immune thrombocytopenia.

*Novartis Pharmaceuticals Corporation does not guarantee success in obtaining reimbursement or financial assistance. Third-party payment for medical products and services is affected by numerous factors, not all of which can be anticipated or resolved.



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Patient portrayal.

Making access to PROMACTA easy

→ **\$0 co-pay:** You may be eligible for immediate co-pay savings on your child's next PROMACTA® (eltrombopag) prescription

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



\$0
co-pay

*Limitations apply. This offer is only available to patients with private insurance. The program is not available for patients who are enrolled in Medicare, Medicaid, or any other federal or state health care program. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full Terms and Conditions, visit Copoly.NovartisOncology.com or call 1-877-577-7756.

→ **Easy sign-up, no additional fees**

→ **Financial assistance may be available** for underinsured or uninsured patients

To find out if your child is eligible for the Universal Co-pay Program, call **1-877-577-7756** or visit **Copoly.NovartisOncology.com**.

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 41 to 45.

Patient Assistance Now Oncology (PANO) offerings

- The Patient Assistance Now Oncology (PANO) program was created to assist with accessing your child's PROMACTA medication—from insurance verification to financial assistance—all through a knowledgeable and supportive call center. You can also visit us at Patient.NovartisOncology.com
- If your child has been prescribed PROMACTA, he/she may be able to receive their first dose FREE up to a 14-day supply shipped directly to your home, which will allow him/her to start their treatment quickly†
- No purchase of PROMACTA or any other product is required

†Program rules may vary by product. This offering is for approved uses/indications only.

➔ **Committed to getting your child access to PROMACTA**

Summary of Important Information for PROMACTA

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 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



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

Summary of Important Information for PROMACTA® (eltrombopag) (continued)

What is PROMACTA? (continued)

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 Asian ancestry (such as Chinese, Japanese, Taiwanese, Korean, or Thai). 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



Summary of Important Information for PROMACTA® (eltrombopag) (continued)

How should I take PROMACTA? (continued)

- 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
- **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

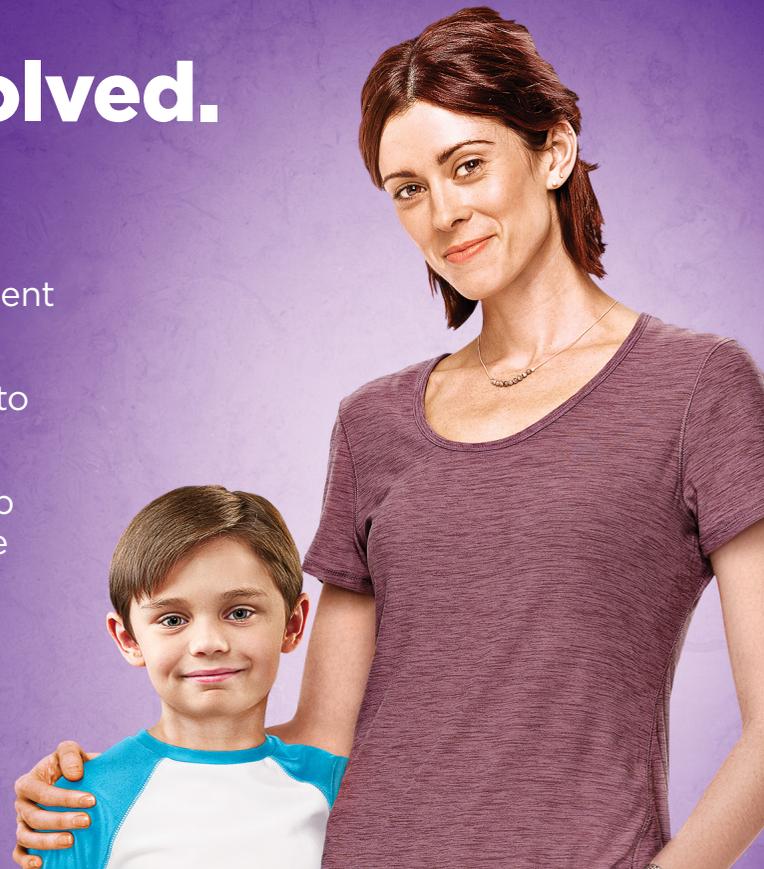
Keep PROMACTA and all medicines out of the reach of children.

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.



Be Informed. Be Involved. Be in Control!

- **Be Informed:** Learn about the different treatment options for your child
 - **Be Involved:** Tell the doctor what's important to you in the choice of treatment for your child
 - **Be in Control:** Work with the doctor every step of the way to make sure you and your child are getting what you want out of treatment
- ➔ **Ask the doctor if prescription PROMACTA® (eltrombopag) is right for your child**



Patient portrayal.

For more information about PROMACTA, go to www.PROMACTA-kids.com

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 41 to 45.



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About
Chronic ITP

Chronic ITP
Care

How
PROMACTA
May Help

Getting
Started

Keep It
Going

PROMACTA
Safety

Patient
Support