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.

(Continued on next page)
What is chronic ITP?
• A condition that has lasted 6 months or longer, in which your body does not have enough blood cell fragments (called platelets) in the blood

What happens when you have chronic ITP?
• Not enough platelets are being created in your blood
• Blood clots do not form properly
• Bruising and/or bleeding is hard to stop
• Your body may be destroying healthy platelets

Important Safety Information for PROMACTA® (eltrombopag)
(continued from front cover)
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

What is the goal of treating chronic ITP?
• Increasing your platelet counts to target levels while helping to preserve your lifestyle
PROMACTA MAY HELP YOU

TAKE CHARGE OF YOUR TREATMENT GOALS

When you have ITP, your body sometimes destroys your platelets and doesn’t produce enough new ones. With PROMACTA® (eltrombopag), your body can get back on track by improving platelet production.

What is PROMACTA?
• A once-daily tablet that can help with your chronic ITP by raising platelet counts and maintaining them at safe and stable levels
• The only ITP treatment that has proven to be safe and effective for more than 6 years

How does PROMACTA work?
PROMACTA is a thrombopoietin (TPO) receptor agonist that binds to the same receptors as TPO
• TPO is a protein, primarily produced in the liver, that stimulates platelet production
When PROMACTA binds to a TPO receptor, it sends a signal to your body to make more platelets and release them into the bloodstream.

Important Safety Information for PROMACTA® (eltrombopag) (continued)
Tell your health care provider right away if you have any of these signs and symptoms of liver problems: (continued)
• unusual tiredness
• right upper stomach area (abdomen) pain
• confusion
• swelling of the stomach area (abdomen)
ONCE-DAILY PROMACTA HELPS  
INCREASE AND MAINTAIN YOUR PLATELET COUNTS

In clinical studies of people with chronic ITP...

PROMACTA® (eltrombopag) increased platelet counts to within target range* as early as 8 days after starting treatment.

*Target range is defined as platelet counts of 50,000/mcL to 400,000/mcL during the 6-month period in which patients received PROMACTA or placebo.

PROMACTA was proven safe in hundreds of patients ranging from ages 1 to 86.

More than 10 years’ experience Extensively studied. Consistently proven.

PROMACTA has also been proven to work for children over the age of 1 year with low platelet counts due to chronic ITP.

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

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.

Helpful reminders for staying on track with PROMACTA

• Be aware of how your body is reacting to this new medication
• Contact your doctor if your chronic ITP symptoms are not improving
• Tell your doctor about any bruising or bleeding that happens while taking PROMACTA or after treatment has stopped

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.
THERE ARE A FEW WAYS YOU CAN FIT PROMACTA INTO YOUR DAY

Are you a morning person?
You can take PROMACTA® (eltrombopag) on an empty stomach, right when you wake up. Just wait 1 hour to have a regular meal after taking PROMACTA, and avoid calcium in food and supplements for 2 hours.

Important Safety Information for PROMACTA® (eltrombopag) (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.

More of a night owl?
Another option would be to take PROMACTA right before you go to bed. Just make sure you haven’t had high-calcium food or supplements* 4 hours before bed, or regular meals 2 hours before bed.

* Examples of foods that have more than 50 mg of calcium: Dairy products (yogurt, cheese, milk, ice cream), calcium-fortified foods (orange juice, dry cereal, bread), leafy green vegetables (collard greens, spinach). Check the labels of any food or supplement to be sure.
**PROMACTA® OFFERS BEST-IN-CLASS SUPPORT TO PATIENTS ON PROMACTA® FROM DAY 1 AND THROUGHOUT THEIR JOURNEY**

**Personalized Patient Navigator Support 4U**
- Call to speak with a trained professional about chronic ITP and PROMACTA® ( eltrombopag )

**Co-pay Assistance 4U**
- Pay $25 per month out of pocket*
- Easy sign-up, no additional fees
- Available to most patients with commercial insurance
- Covers up to $15,000 per calendar year

**Meal Planners & Dietary Guides 4U**
- Tools to help you navigate the flexibility of once-daily PROMACTA. Download your personal support materials at www.PROMACTA-4U.com

**PROMACTA®4U Patient Support Line**
- Call to get additional information regarding PROMACTA, including responses to frequently asked questions

**PROMACTA®4U** is brought to you by the Novartis Oncology Patient Support Program. To find out if you are eligible for the Universal Co-pay Program, call 1-877-577-7756 or visit www.Copay.NovartisOncology.com.

*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 the program without notice. For full Terms and Conditions, visit www.Copay.NovartisOncology.com or call 1-877-577-7756.

**Important Safety Information for PROMACTA® ( eltrombopag ) (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.

**Patient Assistance Now Oncology (PANO)**
Our Patient Assistance Now Oncology (PANO) program was created to assist you with accessing your Novartis medicine(s)—from insurance verification to financial assistance—all through a knowledgeable and supportive call center.

To learn more, call 1-800-282-7630 or visit www.Patient.NovartisOncology.com

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**Important Safety Information for PROMACTA® ( eltrombopag ) (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.
Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 14 to 17.

Important Safety Information for PROMACTA® (eltrombopag) (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.

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)
• are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean). 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. 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

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 4 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.

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)

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 full Prescribing Information for PROMACTA, including Boxed WARNING, and Medication Guide.
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 with or without ribavirin
• 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 pre-cancerous conditions called myelodysplastic syndrome (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 severe aplastic anemia (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 healthcare provider tells you to stop taking 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 healthcare provider will do blood tests to check your liver function before you start taking PROMACTA and during your treatment. Your healthcare provider will also monitor your liver function if you have changes in your liver function blood tests.
Tell your healthcare provider right away if you have any of these signs and symptoms of liver problems:
– yellow 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 healthcare provider about all of your medical conditions, including if you:
• have liver problems
• have a precancerous condition called MDS or a blood cancer
• have had surgery that changed the way your liver works
• 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.
• are pregnant or plan to become pregnant.
It is not known if PROMACTA will harm your baby when used during pregnancy.
It is not known if PROMACTA will harm your baby if PROMACTA is used by your healthcare 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 you stop taking PROMACTA. Tell your healthcare provider about breath methods that may be right for you during this time.
– breastfeeding or plan to breastfeed.
You should not breastfeed during your treatment with PROMACTA. Talk to your healthcare provider about breast-feeding methods that may be right for you during this time.

Ask your healthcare provider if you are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean). You may need a lower dose of PROMACTA.

If you have liver problems
• Tell your healthcare provider if you have changes in your liver function blood tests.
• Tell your healthcare provider if you have symptoms of liver problems.
• Ask your healthcare provider if you are pregnant or plan to become pregnant.
• Tell your healthcare provider if you are breastfeeding or plan to breastfeed.

How should I take PROMACTA?
Take PROMACTA exactly as your healthcare provider tells you to take it. Your healthcare provider will prescribe the dose of PROMACTA tablets or PROMACTA for oral suspension that is right for you.

If your healthcare provider prescribes PROMACTA tablets, take PROMACTA tablets whole.
Do not split, chew, or crush PROMACTA tablets, and do not mix with food or liquid.
If your healthcare provider prescribes PROMACTA for oral suspension, see the “Instructions for Use” that comes with each dose of PROMACTA for oral suspension, see the “Instructions for Use” that comes with each dose of PROMACTA for oral suspension.

Use a single-use oral dosing syringe to prepare each dose of PROMACTA for oral suspension.
Do not re-use the oral dosing syringe.
Do not stop taking PROMACTA without talking with your healthcare provider first. Do not change your dose or schedule for taking PROMACTA unless your healthcare provider tells you to change it.
Talk to your healthcare provider on an empty stomach, either 1 hour before or 2 hours after eating food.
Talk to your healthcare provider at least 2 hours before or 4 hours after eating dairy products and calcium-fortified juices.
Summary of Important Information (continued)

- If you miss a dose of PROMACTA® (eltrombopag), 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 healthcare provider right away.
- Your healthcare provider will check your platelet count during your treatment with PROMACTA and change your dose of PROMACTA as needed.
- Tell your healthcare provider about any bruising or bleeding that happens while you take and after you stop taking PROMACTA.
- If you have SAA, your healthcare 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 syndrome (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. Your risk of getting a blood cancer is increased if your platelet count is too high during treatment with PROMACTA. Your risk of getting a blood cancer 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 healthcare provider will check your blood platelet counts and change your dose or stop PROMACTA if your platelet counts get too high. Tell your healthcare 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 healthcare 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 healthcare provider will check your eyes before and during your treatment with PROMACTA. Tell your healthcare 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
- constipation
- headache
- diarrhea
- Laboratory tests may show abnormal changes to the cells in your bone marrow. Tell your healthcare 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 healthcare 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 68ºF to 77ºF (20ºC to 25ºC).
- Keep PROMACTA in the bottle given to you.

For oral suspension:
- Store PROMACTA for oral suspension at room temperature between 68ºF to 77ºF (20ºC to 25ºC).
- After mixing, PROMACTA should be taken right away but may be stored for no more than 30 minutes between 68ºF to 77ºF (20ºC to 25ºC). 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 healthcare provider or pharmacist.

The FDA-approved product labeling can be found at www.PROMACTA.com or 1-888-669-6682.
PROMACTA® (eltrombopag) helps you take charge by:

• Providing once-daily dosing so it can be taken at home, work, or on the go! (see pages 8 and 9)
• Offering dedicated and ongoing programs to ensure you have access to medication and the support to remain on therapy (see pages 10 and 11)

DON’T LET ITP TREATMENT HOLD YOU BACK

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 14 to 17.