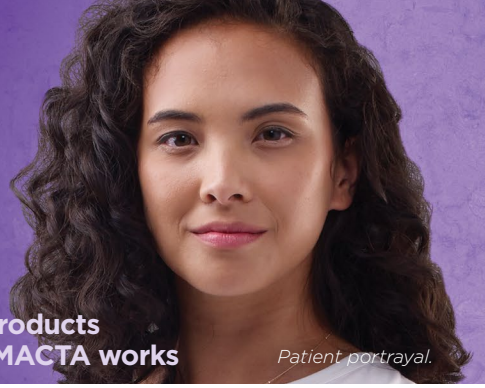
How to take PROMACTA

If you or the person you care for has been prescribed PROMACTA, you should be aware of certain dosing rules that affect the way PROMACTA works



Patient portrayal.

Take PROMACTA every day

If you want a schedule, take once-daily PROMACTA® (eltrombopag) at the same time every day. You may prefer to take it at bedtime or first thing in the morning. Do not split, chew, or crush PROMACTA tablets and do not mix with food or liquids.

Certain foods and products affect the way PROMACTA works

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* or taking products that contain iron, calcium, aluminum, magnesium, selenium, or zinc. Not following these rules can keep PROMACTA from working correctly.

*Examples of calcium-rich foods (those containing more than 50 mg of calcium) include dairy products (yogurt, cheese, milk, ice cream), calcium-fortified foods (orange juice, dry cereal, bread), and certain fruits and vegetables.

Here are a couple of ways you can fit PROMACTA into your day

Are you a morning person?

If you normally have a breakfast that is high in calcium (more than 50 mg), you should take PROMACTA at least 2 hours before you eat. If you forget to take PROMACTA 2 hours before a breakfast that has more than 50 mg of calcium, you must wait at least 4 hours after eating to take your dose.

More of a night owl?

If you plan to have a dinner high in calcium (more than 50 mg), you must take PROMACTA at least 2 hours before that meal. If you prefer to take PROMACTA before bed, you must wait at least 4 hours after you've had a meal that has more than 50 mg of calcium to take your dose.

Important things to remember:

- If you miss a dose of PROMACTA, wait to take your dose at the next scheduled time. **Do not take more than 1 dose of PROMACTA in a 24-hour period**
- If you take too much PROMACTA, you may have a higher risk of serious side effects. Call your health care provider right away

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.

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.

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 additional Important Safety Information for PROMACTA® (eltrombopag) throughout. Please click here for full Prescribing Information, including Boxed WARNING, and Medication Guide.

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

Learning to fit PROMACTA into your day

Consuming certain foods or products too close to taking PROMACTA can keep the medication from working correctly. Some examples include:

Dairy products

- Milk (including almond and rice milk)
- Yogurt and frozen yogurt
- Cheese*
- Ice cream

Calcium-fortified foods

- Some types of oatmeal
- Orange juice
- Dry cereal
- Bread

Some types of seafood

- Clams
- Trout

Leafy green vegetables

- Collard greens
- Spinach

Tofu and other soy products

Antacids, multivitamins, or supplements

These may contain iron, calcium, aluminum, magnesium, selenium, or zinc.

*Just 1 slice of American cheese has 150 mg of calcium.

Check the FoodData Central website for a comprehensive list of foods and supplements!

Find nutritional values for your specific foods and supplements on the FoodData Central website. Visit **https://fdc.nal.usda.gov**.

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
- **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
- **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)
- have bleeding problems
- are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean). You may need a lower dose of PROMACTA

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12.5mg, 25mg oral suspension

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

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:

- 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 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

The most common side effects of PROMACTA in children 1 year and older when used to treat persistent or 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 additional Important Safety Information for PROMACTA® (eltrombopag) throughout. Please click here for full Prescribing Information, including Boxed WARNING, and Medication Guide.

NOVARTIS

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

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080