

— NAVIGATING —

PROMACTA AND FOOD

KNOW WHAT TO PACK
FOR YOUR ITP ADVENTURE

Please see [Important Safety Information](#) throughout and full [Prescribing Information](#), including **Boxed WARNING**, and Medication Guide.

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

A GUIDEBOOK TO TAKING PROMACTA

Before your child heads out on their PROMACTA adventure, you should be aware of certain dosing rules that affect the way PROMACTA works.

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.

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Take PROMACTA every day



Whether your child prefers to take PROMACTA in the morning or evening, it may be helpful to create a schedule to take it at the same time every day.

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 (pears, spinach, collard greens).

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.

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BE ON THE LOOKOUT FOR THESE HIGH-CALCIUM FOODS

These examples may have more than 50 mg of calcium per serving (or in combination with other calcium-rich items). Your child should only take PROMACTA 2 hours before or 4 hours after consuming products like these:

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)

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.

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Dairy products



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

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

Calcium-fortified foods



- Some types of oatmeal
- Orange juice
- Dry cereal
- White bread

Some types of seafood



- Clams
- Trout

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.

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CALCIUM MAY BE HIDING IN SOME UNEXPECTED PLACES

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.

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

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Tip: To check the calcium content of specific foods,
visit <https://fdc.nal.usda.gov>

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
- 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

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SET A SCHEDULE THAT WORKS FOR YOU

You can try either way with your child and see what works.

Morning



Your child may take PROMACTA before school starts. They 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.

Evening



Your child might take PROMACTA after dinner. They 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.

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:

- 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.

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Important things to remember

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

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.

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LOW-CALCIUM FOODS THAT WORK WITH PROMACTA

Keep the calcium down and the tastiness up with these kid-friendly foods.

Breakfast



Scrambled egg (1/4 cup, 36 mg calcium)

Apple slices (6 ounces, 0 mg calcium)

Lunch



PB&J (3 tbsp peanut butter and jelly spread, 0 mg calcium; 2 slices white bread, 20 mg calcium)

Carrot sticks (100 g, 24 mg calcium)

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

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Snack



Soft pretzel
(large pretzel,
33 mg calcium)

Dinner



Roasted chicken
(3 ounces, 10 mg calcium)
Corn on the cob
(1 ear, 5 mg calcium)

Dessert



Ice pop
(0 mg calcium)

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

What should I avoid while taking PROMACTA?

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.

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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.



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Pay attention to the total amount of calcium in the entire meal. Make sure your child avoids consuming more than 50 mg of calcium when taking PROMACTA.

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