Patient portrayal.

PROMACTA for Oral Suspension

You can take PROMACTA even if you can't swallow a pill

Scan the QR code and watch a helpful step-by-step video!

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.

Please see additional Important Safety Information throughout this brochure.

Please see full Prescribing Information for PROMACTA, including Boxed WARNING, and Medication Guide.

PROMACTA® (eltrombopag)

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

Convenient once-daily oral dosing

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

Important things to know:

1

PROMACTA can be taken without a meal or with a meal low in calcium (≤50 mg)

2

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

Oral Tablets:

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

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

TPO-RA, thrombopoietin receptor agonist.

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)

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

Each PROMACTA for oral suspension kit contains the following:

30 Packets of PROMACTA for oral suspension

1 Reusable mixing bottle with lid and cap. Make sure to save and reuse the bottle as only 1 comes in each kit

30 Single-use 20-mL oral dosing syringes (use a new [single-use] oral dosing syringe to prepare each dose of PROMACTA for oral suspension)

To take PROMACTA for oral suspension, you will need...

From the kit:

- Prescribed number of packets
- One reusable mixing bottle with lid and cap. Note: Due to its small size, the cap may pose a danger of choking to small children
- One single-use, 20-mL oral dosing syringe (use a new [single-use] oral dosing syringe to prepare each dose of PROMACTA for oral suspension)

Not included in the kit:

- One clean glass or cup filled with drinking water
- Scissors to cut packet
- Paper towels or disposable cloth
- Disposable gloves (optional)

For full instructions on preparing PROMACTA for oral suspension, please see inside Medication Guide.

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

How to mix and take PROMACTA for oral suspension

How do I prepare a dose of PROMACTA for oral suspension?

Scan the QR code and watch a helpful step-by-step video!

Using a 12.5-mg or 25-mg packet

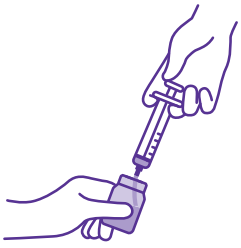
Make sure that the mixing bottle, cap, lid, and oral dosing syringe are dry before use. Remove the lid from the mixing bottle.

- Prepare a clean, flat work surface
- Wash and dry your hands before preparing the medicine

Fill the oral dosing syringe with 20 mL of drinking water from the glass or cup. PROMACTA for oral suspension must be mixed with cool or cold water only. Do not use hot water to prepare the oral suspension.

- Start with the plunger pushed all the way into the syringe
- Place the tip of the oral dosing syringe all the way into the water and pull back on the plunger to the 20-mL mark on the barrel of the syringe

Note: Use a new (single-use) oral dosing syringe to prepare each dose of PROMACTA for oral suspension.



Place the tip of the oral dosing syringe into the open mixing bottle. Empty water into open mixing bottle by slowly pushing the plunger all the way into the oral dosing syringe.

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 additional Important Safety Information throughout this brochure.

Please see full Prescribing Information for PROMACTA, including Boxed WARNING, and Medication Guide.

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

How do I make different dosages?

Take only the prescribed number of packets for 1 dose out of the kit. You may need to use more than 1 packet to prepare the entire dose.

Using the 12.5-mg packets:

- 12.5-mg dose: 1 packet
- 25-mg dose: 2 packets
- 50-mg dose: 4 packets
- 75-mg dose: 6 packets

Using the 25-mg packets:

- 12.5-mg dose: 1 packet (Note: See the next page for instructions on how to take a 12.5-mg dose using a 25-mg packet)
- 25-mg dose: 1 packet
- 50-mg dose: 2 packets
- 75-mg dose: 3 packets

Add the prescribed number of packets to the mixing bottle

- Tap the top of each packet to make sure the contents fall to the bottom
- Cut off the top of the packet with scissors and empty the entire contents of the packet into the mixing bottle
- Make sure not to spill the powder outside the mixing bottle
- Do not exceed 20 mL of water regardless of the dosage used

Screw the lid tightly onto the mixing bottle. Make sure the cap is pushed onto the lid.

Gently and slowly shake the mixing bottle back and forth for at least 20 seconds to mix the water with the powder.

- To prevent the mixture from foaming, do not shake the mixing bottle hard

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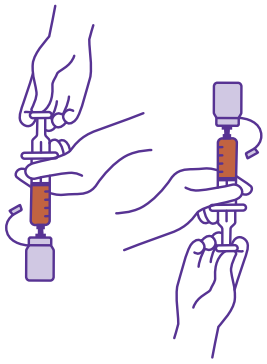
PROMACTA® (eltrombopag)
12.5mg, 25mg, 50mg, 75mg tablets
12.5mg, 25mg oral suspension

How should I take a dose of PROMACTA for oral suspension?

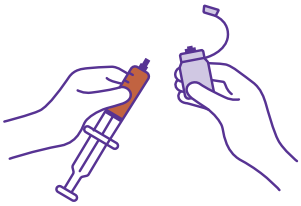


Make sure the plunger is pushed all the way into the oral dosing syringe. Pull cap off the mixing bottle lid and insert the tip of the oral dosing syringe into the hole in the lid.

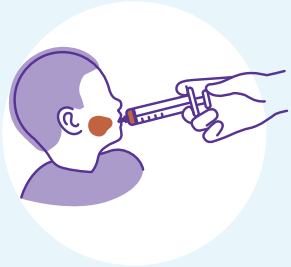
Transfer the mixture into the oral dosing syringe.

The liquid will be dark brown in color.

- Turn the mixing bottle upside down along with the oral dosing syringe
- Pull back the plunger:
  For a 12.5-mg packet
  – until all the medicine is in the oral dosing syringe (12.5-mg, 25-mg, 50-mg, or 75-mg dose)
  For a 25-mg packet
  – to the 10-mL mark on the oral dosing syringe for a 12.5-mg dose only
  OR
  – until all the medicine is in the oral dosing syringe (25-mg, 50-mg, or 75-mg dose)



Return the mixing bottle to the upright position and remove the oral dosing syringe from the mixing bottle.



Giving a dose of PROMACTA for oral suspension to a child

- Place the tip of the oral dosing syringe into the inside of the child's cheek
- Slowly push the plunger all the way down to give the entire dose. Make sure the child has time to swallow the medicine

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 additional Important Safety Information throughout this brochure.

Please see full Prescribing Information for PROMACTA, including Boxed WARNING, and Medication Guide.

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

How should I clean up?

Carefully clean up any spill of the powder or suspension with a damp paper towel or disposable cloth.

- To avoid possibly staining your skin, consider using disposable gloves
- Throw away (discard) used paper towel or disposable cloth and gloves in the trash

Clean the mixing supplies.

- Do not reuse any of the mixture remaining in the mixing bottle
- Throw away (discard) the used oral dosing syringe. Use a new (single-use) oral dosing syringe to prepare each dose of PROMACTA for oral suspension
- Do not throw away the mixing cup
- Throw away (discard) any mixture remaining in the mixing bottle in the trash. Do not pour down the drain
- Rinse the mixing bottle and lid under running water and air dry. The mixing bottle may become stained from the medicine. This is normal
- Wash hands with soap and water

Important reminders:

Store at room temperature between 20˚C and 25˚C (68˚F and 77˚F); excursions permitted between 15˚C and 30˚C (59˚F and 86˚F) [see USP Controlled Room Temperature]. Following reconstitution, the product should be administered immediately but may be stored for a maximum period of 30 minutes between 20˚C and 25˚C (68˚F and 77˚F); excursions permitted between 15˚C and 30˚C (59˚F and 86˚F) [see USP Controlled Room Temperature]. If the medicine is not given within 30 minutes, you will have to mix a new dose. Throw away (discard) the unused mixture into the trash. Do not pour it down the drain. After you have used all 30 packets, throw away all the remaining supplies (mixing bottle, lid with cap, and oral dosing syringe) in the trash.

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

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

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
- 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 throughout this brochure

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Sign up for PROMACTA4U for additional resources and support: www.promacta-patientsupport.com

Follow us on social @Promacta

NOVARTIS

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

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