**Take PROMACTA® (eltrombopag) every day.**

**Tip:** If you want a simpler schedule, try taking PROMACTA® at the same time every day. It may be easiest for you to take it at bedtime or first thing in the morning.

Do not crush PROMACTA tablets.

**Do not take PROMACTA with food.**

Take PROMACTA on an empty stomach, either 1 hour before or 2 hours after eating food.

Calcium interferes with the way PROMACTA works. Consuming more than 50 mg of calcium counteracts its efficacy. Many foods, some antacids, and nutritional supplements contain more than 50 mg of calcium per serving (see below).*

Take PROMACTA at least 2 hours before or 4 hours after eating dairy products and calcium-fortified juices.

*A slice of American cheese has 150 mg of calcium.

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**There are a few ways I can fit PROMACTA into my day.**

Here is a helpful guide for taking PROMACTA on a schedule that works best for you.

**Are you a morning person?**

You can take PROMACTA 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.

**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 any high-calcium food or supplements 4 hours before bed, and no regular meals 2 hours before bed.

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Examples of calcium-rich foods containing >50 mg of calcium include: dairy products (yogurt, cheese, milk, ice cream); calcium-fortified foods (orange juice, dry cereal, bread); leafy greens vegetables (collard greens, spinach).

Please see Important Safety Information for PROMACTA on next pages.

Please click here for full Prescribing Information, including Boxed WARNING, and Medication Guide.
I'M LEARNING TO WORK AROUND THE CALCIUM IN MY DIET.

Eating calcium-rich foods too close to taking PROMACTA® (eltrombopag) can keep the medication from working best. These items (not all are foods) may have more than 50 mg of calcium:

- Dairy products
  - milk (including almond and rice milk)
  - frozen and unfrozen yogurt
  - buttermilk
  - cheese
  - pudding
  - 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; vitamins; or supplements containing iron, calcium, aluminum, magnesium, selenium, or zinc

Talk with your doctor before taking any over-the-counter medications, herbs, or supplements.

Approved Uses and Important Safety Information for PROMACTA® (eltrombopag) Tablets

**Approved Uses for PROMACTA® (eltrombopag) Tablets**

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 a prescription medicine used to treat low blood platelet counts in people with chronic hepatitis C virus (HCV) infection before and during treatment with interferon. PROMACTA should only be used in people with chronic HCV whose low blood platelet counts keep them from starting or continuing interferon-based therapy. It is not known if PROMACTA is safe and effective when used with other antiviral medicines that are approved to treat chronic HCV.

PROMACTA is a prescription medicine used to treat people with severe aplastic anemia (SAA) in combination with standard immunosuppressive therapy as the first treatment for adults and children 2 years of age and older. PROMACTA is also used to treat your SAA when other medicines have not worked well enough.

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 HCV, or 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 when used with other antiviral medicines that are approved to treat chronic HCV.

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) Tablets**

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 (HCV) 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 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 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)

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.

Continued on page 3.

Please see additional Important Safety Information for PROMACTA on page 3.

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

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
• 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 plan to become pregnant while taking PROMACTA
• 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
• 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 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)

The most common side effects when PROMACTA is used in combination with other medicines to treat chronic HCV are:

• low red blood cell count (anemia)
• fever
• tiredness
• headache
• nausea
• diarrhea
• decreased appetite
• flu-like symptoms including fever, headache, tiredness, cough, sore throat, and body aches

The most common side effects associated with PROMACTA when used in combination with standard immunosuppressive therapy to treat severe aplastic anemia (SAA) reported more frequently than in patients with SAA when other medicines to treat SAA have not worked well enough are:

• abnormal liver function tests
• rash
• skin discoloration including darkening of skin patches (hyperpigmentation)

The most common side effects when PROMACTA is used to treat SAA when other medicines to treat SAA have not worked well enough:

• nausea
• feeling tired
• cough
• diarrhea
• headache

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.

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Please see additional Important Safety Information for PROMACTA on page 2.

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