MEDICATION GUIDE

PROMACTA® (pro-MAC-ta)
(eltrombopag)
Tablets

Read this Medication Guide before you start taking PROMACTA and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about PROMACTA?

PROMACTA can cause serious side effects, including:

- **Liver problems.** PROMACTA may damage your liver and cause serious illness and death. You must have blood tests to check your liver before you start taking PROMACTA and during treatment with PROMACTA. Your healthcare provider will order these blood tests. In some cases PROMACTA treatment may need to be stopped. Tell your healthcare 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 pain
- **Bone marrow changes (increased reticulin and possible bone marrow fibrosis).** Long-term use of PROMACTA may cause changes in your bone marrow. These changes may lead to abnormal blood cells or your body making less blood cells. The mild form of these bone marrow changes is called "increased reticulin" which may progress to a more severe form called "fibrosis". The mild form may cause no problems while the severe form may cause life-threatening blood problems. Signs of bone marrow changes may show up as abnormal results in your blood tests. Your healthcare provider will decide if abnormal blood test results mean that you should have bone marrow tests or if you should stop taking PROMACTA.
- **Recurrence of low blood platelet count (thrombocytopenia) and risk of bleeding shortly after stopping PROMACTA.** When you stop taking PROMACTA, your blood platelet count may return to a similar low platelet count as before you started taking PROMACTA. These effects are

most likely to happen within 4 weeks after you stop taking PROMACTA. The recurrence of low platelet counts may increase your risk of bleeding, especially if you take a blood thinner or other medicines that affect platelets. Your healthcare provider will check your blood platelet counts for at least 4 weeks after you stop taking PROMACTA. Call your healthcare provider right away to report any bruising or bleeding.

- **High platelet counts and higher chance for blood clots.** Your chance of getting a blood clot is increased if your platelet count is too high during treatment with PROMACTA. Your chance 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 complications 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.
  Patients with chronic liver disease may be at risk for a type of blood clot in the stomach area. Stomach area pain may be a symptom of this type of blood clot.
- **Worsening of blood cancers.** PROMACTA is not for use in patients with blood cancer or a precancerous condition called myelodysplastic syndrome (MDS). If you have one of these conditions, PROMACTA may worsen your cancer or condition and may cause you to die sooner.
- **New or worsened cataracts (a clouding of the lens in the eye).** New or worsened cataracts have happened 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.

When you are being treated with PROMACTA, your healthcare provider will closely monitor your dose of PROMACTA and blood tests, including platelet counts and liver tests.

PROMACTA is available only through a program called "PROMACTA *CARES*". To receive PROMACTA, you must talk to your healthcare provider, understand the benefits and risks of PROMACTA and agree to enroll into PROMACTA *CARES*.

- During therapy with PROMACTA, your healthcare provider may change your dose of PROMACTA, depending upon the change in your blood

platelet count. You must have blood platelet count tests done before, during and after your therapy with PROMACTA.

See "What are the possible side effects of PROMACTA?" for other side effects of PROMACTA.

What is PROMACTA?

PROMACTA is a prescription medicine used to treat low blood platelet counts in adults with chronic immune (idiopathic) thrombocytopenic purpura (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 keep your platelet count about 50,000 per microliter in order to lower your risk for bleeding. PROMACTA is not used to make your platelet count normal.

PROMACTA is only:

- prescribed by healthcare providers who are enrolled in PROMACTA *CARES*.
- given to people who are enrolled in PROMACTA *CARES*.

It is not known if PROMACTA works or if it is safe in people under the age of 18 years.

PROMACTA is for treatment of certain people with low platelet counts caused by chronic ITP, not low platelet counts caused by other conditions or diseases.

What should I tell my healthcare provider before taking PROMACTA?

Before you take PROMACTA, tell your healthcare provider if you:

- have liver or kidney problems
- have or had a blood clot
- have a history of cataracts
- have had surgery to remove your spleen (splenectomy)
- have a bone marrow problem, including a blood cancer or Myelodysplastic Syndrome (MDS)
- have bleeding problems
- are Asian and you are of Chinese, Japanese, Taiwanese, or Korean ancestry, you may need a lower dose of PROMACTA.
- have any other medical conditions

- are pregnant, think you may be pregnant, or plan to get pregnant. It is not known if PROMACTA will harm an unborn baby.
  Pregnancy Registry: There is a registry for women who become pregnant during treatment with PROMACTA. If you become pregnant, consider this registry. The purpose of the registry is to collect safety information about the health of you and your baby. Contact the registry as soon as you become aware of the pregnancy, or ask your healthcare provider to contact the registry for you. You and your healthcare provider can get information and enroll in the registry by calling 1-888-825-5249.
- are breast-feeding or plan to breast-feed. It is not known if PROMACTA passes into your breast milk. You and your healthcare provider should decide whether you will take PROMACTA or breast-feed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal products. PROMACTA may affect the way certain medicines work. Certain other medicines may affect the way PROMACTA works.

Especially tell your healthcare 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 either 4 hours before or 4 hours after taking these products:
- antacids used to treat stomach ulcers or heartburn.
- multivitamins or products that contain iron, calcium, aluminum, magnesium, selenium, and zinc which may be found in mineral supplements.

Ask your healthcare 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 healthcare provider and pharmacist when you get a new medicine.

How should I take PROMACTA?

To receive PROMACTA, you must first talk with your healthcare provider and understand the benefits and risks of PROMACTA. You must agree to and follow all of the instructions in PROMACTA *CARES*.

- Before you can begin to receive PROMACTA, your healthcare provider will:
  - explain PROMACTA *CARES* to you.
  - answer all of your questions about PROMACTA and PROMACTA *CARES*.
  - make sure you read this PROMACTA Medication Guide.
  - have you sign the PROMACTA *CARES* Patient Enrollment Form.
- Take PROMACTA exactly as your healthcare provider tells you. Do not stop using 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.
- Take PROMACTA on an empty stomach, either 1 hour before or 2 hours after eating food.
- Take PROMACTA at least 4 hours before or 4 hours after eating dairy products and calcium fortified juices.
- If you miss a dose of PROMACTA, wait and take your next scheduled dose. Do not take more than one dose of PROMACTA in one day.
- If you take too much PROMACTA, you may have a higher chance of serious side effects. Call your healthcare provider right away.
- Your healthcare provider will check your platelet count every week and change your dose of PROMACTA as needed. This will happen every week until your healthcare provider decides that your dose of PROMACTA can stay the same. After that, you will need to have blood tests every month. When you stop taking PROMACTA, you will need to have blood tests for at least 4 weeks to check if your platelet count drops too low.
- Tell your healthcare provider about any bruising or bleeding that happens while you take and after you stop taking 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.

See **"What is the most important information I should know about PROMACTA?".**

The most common side effects of PROMACTA are:

- nausea
- diarrhea
- upper respiratory tract infection; symptoms may include runny nose, stuffy nose, and sneezing

- vomiting
- muscle aches
- urinary tract infections; symptoms may include frequent or urgent need to urinate, low fever in some patients, pain or burning with urination
- pain or swelling (inflammation) in your throat or mouth (oropharyngeal pain and pharyngitis)
- abnormal liver function tests
- abnormal skin sensations such as tingling, itching, or burning
- back pain
- 'flu' symptoms (influenza); symptoms may include fever, headache, tiredness, cough, sore throat, and body aches
- rash

These are not all the possible side effects of PROMACTA. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. 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?

- Store at room temperature between 59°F and 86°F (15°C and 30°C).
- **Keep PROMACTA and all medicines out of the reach of children.**

General information about the safe and effective use of PROMACTA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PROMACTA for a condition for which it was not prescribed. Do not give PROMACTA to other people even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about PROMACTA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about PROMACTA that is written for healthcare professionals.

For more information, go to www.PROMACTA.com or call toll-free 1-888-825-5249.

What are the ingredients in PROMACTA?

Active Ingredient: eltrombopag olamine.

Inactive Ingredients:

- Tablet Core: Magnesium stearate, mannitol, microcrystalline cellulose, povidone, and sodium starch glycolate.
- Coating: Hypromellose, polyethylene glycol 400, titanium dioxide, and FD&C Yellow No. 6 aluminum lake (25 mg tablet), FD&C Blue No. 2 aluminum lake (50 mg tablet), or Iron Oxide Red and Iron Oxide Black (75 mg tablet).

PROMACTA is a registered trademark of GlaxoSmithKline.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

GlaxoSmithKline
Research Triangle Park, NC 27709

Revised: Month YEAR

PRM:XMG