MEDICATION GUIDE

Eltrombopag

(el-TROM-boe-pag)

Tablets

What is the most important information I should know about eltrombopag tablets?

Eltrombopag tablets can cause serious side effects, including:

Liver problems:

- If you have chronic hepatitis C virus and take eltrombopag tablets with interferon and ribavirin treatment, eltrombopag tablets may increase your risk of liver problems. If your healthcare provider tells you to stop your treatment with interferon and ribavirin, you will also need to stop taking eltrombopag tablets.
- Eltrombopag tablets may increase your risk of liver problems that may be severe and possibly life threatening. Your healthcare provider will do blood tests to check your liver function before you start taking eltrombopag tablets and during your treatment. Your healthcare provider may stop your treatment with eltrombopag tablets if you have changes in your liver function blood tests.

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 (abdomen) pain
- confusion
- swelling of the stomach area (abdomen)

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

What are eltrombopag tablets?

Eltrombopag tablet is a prescription medicine used to treat adults and children 1 year of age and older with low blood platelet counts due to persistent or chronic immune thrombocytopenia (ITP), when other medicines to treat ITP or surgery to remove the spleen have not worked well enough.

Eltrombopag tablet are also used to treat people with:

- low blood platelet counts due to chronic hepatitis C virus (HCV) infection before and during treatment with interferon.
- severe aplastic anemia (SAA) when other medicines to treat SAA have not worked well enough.

Eltrombopag tablets are used to try to raise platelet counts in order to lower your risk for bleeding.

Eltrombopag tablets are not used to make platelet counts normal.

Eltrombopag tablets are not for use in people with a pre-cancerous condition called myelodysplastic syndrome (MDS), or in people with low platelet counts caused by certain other medical conditions or diseases.

It is not known if eltrombopag tablets are safe and effective when used with other antiviral medicines to treat chronic hepatitis C.

It is not known if eltrombopag tablets are safe and effective in children:

- younger than 1 year with ITP
- with low blood platelet counts due to chronic hepatitis C
- whose severe aplastic anemia (SAA) has not improved after previous treatments
- younger than 2 years when used in combination with other medicines to treat SAA as the first treatment for SAA

Before you take eltrombopag tablets, tell your healthcare provider about all your medical conditions, including if you:

- have liver problems
- have a precancerous condition called MDS or a blood cancer
- have or had a blood clot
- have a history of cataracts
- have had surgery to remove your spleen (splenectomy)
- have bleeding problems
- are of East-/Southeast-Asian ancestry. You may need a lower dose of eltrombopag tablets
- are pregnant or plan to become pregnant. It is not known if eltrombopag tablets will harm an unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with eltrombopag tablets.
  - Females who are able to become pregnant, should use effective birth control (contraception) during treatment with eltrombopag tablets and for at least 7 days after stopping treatment with eltrombopag tablets. Talk to your healthcare provider about birth control methods that may be right for you during this time.
- are breastfeeding or plan to breastfeed. You should not breastfeed during your treatment with eltrombopag tablets. Talk to your healthcare provider about the best way to feed your baby during this time.
- **Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Eltrombopag tablets may affect the way certain medicines work. Certain other medicines may affect the way eltrombopag tablets 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 eltrombopag tablets from working correctly. Take eltrombopag tablets at least 2 hours before or 4 hours after taking these products:

- antacid medicine 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 eltrombopag tablets?

- Take eltrombopag tablets exactly as your healthcare provider tells you to take them. Your healthcare provider will prescribe the dose of eltrombopag tablets that is right for you.
- If your healthcare provider prescribes eltrombopag tablets, take eltrombopag tablets whole.

Do not split, chew, or crush eltrombopag tablets and do not mix with food or liquids.

- **Do not** stop taking eltrombopag tablets without talking with your healthcare provider first. Do not change your dose or schedule for taking eltrombopag tablets unless your healthcare provider tells you to change them.
- Take eltrombopag tablets 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, such as dairy products, calcium-fortified juices, and certain fruits and vegetables.
- If you miss a dose of eltrombopag, wait and take your next scheduled dose. Do not take more than 1 dose of eltrombopag tablets in 1 day.

Artwork information			
Customer	Camber	Market	USA
Dimensions (mm)	200 x 350 mm	Non Printing Colors	Die cut
Pharma Code No.	NA		
Printing Colours (01)	Black		

Others: Pharma code position and Orientation are tentative, will be changed based on folding size.

- If you take too much eltrombopag tablets, you may have a higher risk of serious side effects. Call your healthcare provider right away.
- Your healthcare provider will check your platelet count during your treatment with eltrombopag tablets and change your dose of eltrombopag tablets as needed.
- Tell your healthcare provider about any bruising or bleeding that happens while you take and after you stop taking eltrombopag tablets.
- If you have SAA, your healthcare provider may do tests to monitor your bone marrow during treatment with eltrombopag tablets.

What should I avoid while taking eltrombopag tablets?

Avoid situations and medicines that may increase your risk of bleeding.

What are the possible side effects of eltrombopag tablets?

Eltrombopag tablets may cause serious side effects, including:

- See **"What is the most important information I should know about eltrombopag tablets?"'**
- **Increased risk of worsening of a precancerous blood condition called myelodysplastic syndrome (MDS) to acute myelogenous leukemia (AML).** Eltrombopag tablets are not for use in people with a precancerous condition called myelodysplastic syndromes (MDS). See "**What are eltrombopag tablets**?" If you have MDS and receive eltrombopag tablets, you have an increased risk that your MDS condition may worsen and become a blood cancer called AML. If your MDS worsens to become AML, you may have an increased risk of death 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 eltrombopag tablets. Your risk of getting a blood clot may also be increased during treatment with eltrombopag tablets 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 healthcare provider will check your blood platelet counts, and change your dose or stop eltrombopag tablets 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.
  People with chronic liver disease may be at risk for a type of blood clot in the stomach area (abdomen). Tell your healthcare provider right away if you have stomach-area (abdomen) pain, nausea, vomiting, or diarrhea as these may be symptoms of this type of blood clot.
- **New or worsened cataracts (a clouding of the lens in the eye).** New or worsened cataracts can happen in people taking eltrombopag tablets. Your healthcare provider will check your eyes before and during your treatment with eltrombopag tablets. Tell your healthcare provider about any changes in your eyesight while taking eltrombopag tablets.

The most common side effects of eltrombopag tablets in adults and children include:

- low red blood cell count (anemia)
- nausea
- fever
- abnormal liver function tests
- cough
- tiredness
- headache
- diarrhea

Laboratory tests may show abnormal changes to the cells in your bone marrow.

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

- Store eltrombopag tablets at room temperature between 68° to 77°F (20° to 25°C).
- Keep eltrombopag tablets in the bottle given to you.

Keep eltrombopag tablets and all medicines out of the reach of children.

General information about the safe and effective use of eltrombopag tablets

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

You can ask your healthcare provider or pharmacist for information about eltrombopag tablets that is written for health professionals.

What are the ingredients in eltrombopag tablets?

Active ingredient: eltrombopag olamine.

Inactive ingredients:

- **Tablet Core:** magnesium stearate, mannitol, microcrystalline cellulose, povidone and sodium starch glycolate.
- **Coating:** FD&C Blue #2/Indigo carmine aluminum lake (for 25 mg), FD & C Yellow # 6/Sunset Yellow FCF Aluminum lake (for 25 mg), hypromellose, iron oxide yellow (for 75 mg), polyethylene glycol, polysorbate 80 (for 12.5 mg and 75 mg) and titanium dioxide.

Additional pediatric use information is approved for Novartis Pharmaceuticals Corporation's PROMACTA® (eltrombopag) tablets. However, due to Novartis Pharmaceuticals Corporation's marketing exclusivity rights, this drug product is not labeled with that information.

Medication Guide available at http://camberpharma.com/medication-guides

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

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