

<div>MEDICATION GUIDE</div> <div>Eltrombopag (el trom' boe pag)</div> <div>for oral suspension</div>			
<div>What is the most important information I should know about eltrombopag for oral suspension?</div> <div>Eltrombopag for oral suspension can cause serious side effects, including:</div> <div>Liver problems:</div> <div><div><div><div><div></div></div><div>If you have chronic hepatitis C virus and take eltrombopag for oral suspension with interferon and ribavirin treatment, eltrombopag for oral suspension 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 for oral suspension.</div></div><div><div><div></div></div><div>Eltrombopag for oral suspension 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 for oral suspension and during your treatment. Your healthcare provider may stop your treatment with eltrombopag for oral suspension if you have changes in your liver function blood tests.</div></div></div><div>Tell your healthcare provider right away if you have any of these signs and symptoms of liver problems:</div><div><div><div><div></div><div>yellowing of the skin or the whites of the eyes (jaundice)</div></div><div><div></div><div>right upper stomach area (abdomen) pain</div></div></div><div><div><div></div><div>unusual darkening of the urine</div></div><div><div></div><div>confusion</div></div></div><div><div><div></div><div>unusual tiredness</div></div><div><div></div><div>swelling of the stomach area (abdomen)</div></div></div></div><div>See "What are the possible side effects of eltrombopag for oral suspension?" for other side effects of eltrombopag for oral suspension.</div></div>			
<div>What is eltrombopag for oral suspension?</div> <div>Eltrombopag for oral suspension 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.</div> <div>Eltrombopag for oral suspension is also used to treat people with:</div> <div><div><div><div></div></div><div>low blood platelet counts due to chronic hepatitis C virus (HCV) infection before and during treatment with interferon.</div></div><div><div><div></div></div><div>severe aplastic anemia (SAA) when other medicines to treat SAA have not worked well enough.</div></div></div> <div>Eltrombopag for oral suspension is used to try to raise platelet counts in order to lower your risk for bleeding.</div> <div>Eltrombopag for oral suspension is not used to make platelet counts normal.</div> <div>Eltrombopag for oral suspension is 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.</div> <div>It is not known if eltrombopag for oral suspension is safe and effective when used with other antiviral medicines to treat chronic hepatitis C.</div> <div>It is not known if eltrombopag for oral suspension is safe and effective in children:</div> <div><div><div></div><div>younger than 1 year with ITP</div></div><div><div></div><div>with low blood platelet counts due to chronic hepatitis C</div></div><div><div></div><div>whose severe aplastic anemia (SAA) has not improved after previous treatments.</div></div></div>			
<div>Before you take eltrombopag for oral suspension, tell your healthcare provider about all of your medical conditions, including if you:</div> <div><div><div><div></div></div><div>have liver problems</div></div><div><div><div></div></div><div>have a precancerous condition called MDS or a blood cancer</div></div><div><div><div></div></div><div>have or had a blood clot</div></div><div><div><div></div></div><div>have a history of cataracts</div></div><div><div><div></div></div><div>have had surgery to remove your spleen (splenectomy)</div></div><div><div><div></div></div><div>have bleeding problems</div></div><div><div><div></div></div><div>are of East-/Southeast-Asian ancestry. You may need a lower dose of eltrombopag for oral suspension.</div></div><div><div><div></div></div><div>are pregnant or plan to become pregnant. It is not known if eltrombopag for oral suspension will harm an unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with eltrombopag for oral suspension.</div></div><div><div><div></div><div>Females who are able to become pregnant, should use effective birth control (contraception) during treatment with eltrombopag for oral suspension and for at least 7 days after stopping treatment with eltrombopag for oral suspension. Talk to your healthcare provider about birth control methods that may be right for you during this time.</div></div></div><div><div><div></div></div><div>are breastfeeding or plan to breastfeed. You should not breastfeed during your treatment with eltrombopag for oral suspension. Talk to your healthcare provider about the best way to feed your baby during this time.</div></div></div> <div><div><div><div></div></div><div>Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Eltrombopag for oral suspension may affect the way certain medicines work. Certain other medicines may affect the way eltrombopag for oral suspension works.</div></div></div> <div>Especially tell your healthcare provider if you take:</div> <div><div><div></div><div>certain medicines used to treat high cholesterol, called "statins"</div></div><div><div></div><div>a blood thinner medicine</div></div></div> <div>Certain medicines may keep eltrombopag for oral suspension from working correctly. Take eltrombopag for oral suspension at least 2 hours before or 4 hours after taking these products:</div> <div><div><div></div><div>antacid medicine used to treat stomach ulcers or heartburn</div></div><div><div></div><div>multivitamins or products that contain iron, calcium, aluminum, magnesium, selenium, and zinc which may be found in mineral supplements</div></div></div> <div>Ask your healthcare provider if you are not sure if your medicine is one that is listed above.</div> <div>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.</div>			
<div>How should I take eltrombopag for oral suspension?</div> <div><div><div><div></div></div><div>Take eltrombopag for oral suspension exactly as your healthcare provider tells you to take it. Your healthcare provider will prescribe the dose of eltrombopag for oral suspension that is right for you.</div></div><div><div><div></div></div><div>If your healthcare provider prescribes eltrombopag for oral suspension, see the "<b>Instructions for Use</b>" that comes with your medicine for instructions on how to correctly mix and take a dose of eltrombopag for oral suspension.</div></div><div><div><div></div></div><div>Use a new single-use oral dosing syringe to prepare each dose of eltrombopag for oral suspension. <b>Do not re-use the oral dosing syringe.</b></div></div><div><div><div></div></div><div><b>Do not</b> stop taking eltrombopag for oral suspension without talking with your healthcare provider first. Do not change your dose or schedule for taking eltrombopag for oral suspension unless your healthcare provider tells you to change it.</div></div><div><div><div></div></div><div>Take eltrombopag for oral suspension 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.</div></div><div><div><div></div></div><div>If you miss a dose of eltrombopag for oral suspension, wait and take your next scheduled dose. Do not take more than 1 dose of eltrombopag for oral suspension in 1 day.</div></div><div><div><div></div></div><div>If you take too much eltrombopag for oral suspension, you may have a higher risk of serious side effects. Call your healthcare provider right away.</div></div><div><div><div></div></div><div>Your healthcare provider will check your platelet count during your treatment with eltrombopag for oral suspension and change your dose of eltrombopag for oral suspension as needed.</div></div><div><div><div></div></div><div>Tell your healthcare provider about any bruising or bleeding that happens while you take and after you stop taking eltrombopag for oral suspension.</div></div><div><div><div></div></div><div>If you have SAA, your healthcare provider may do tests to monitor your bone marrow during treatment with eltrombopag for oral suspension.</div></div></div>			
<div>What should I avoid while taking eltrombopag for oral suspension?</div> <div>Avoid situations and medicines that may increase your risk of bleeding.</div>			
<div>What are the possible side effects of eltrombopag for oral suspension?</div> <div>Eltrombopag for oral suspension may cause serious side effects, including:</div> <div><div><div><div></div></div><div>See "What is the most important information I should know about eltrombopag for oral suspension?"</div></div><div><div><div><div></div></div><div><b>Increased risk of worsening of a precancerous blood condition called myelodysplastic syndrome (MDS) to acute myelogenous leukemia (AML).</b> Eltrombopag for oral suspension is not for use in people with a precancerous condition called myelodysplastic syndromes (MDS). See "<b>What is eltrombopag for oral suspension?</b>" If you have MDS and receive eltrombopag for oral suspension, 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.</div></div><div><div><div></div></div><div><b>High platelet counts and higher risk for blood clots.</b> Your risk of getting a blood clot is increased if your platelet count is too high during treatment with eltrombopag for oral suspension. Your risk of getting a blood clot may also be increased during treatment with eltrombopag for oral suspension 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 for oral suspension 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.</div></div><div><div><div></div></div><div><b>New or worsened cataracts (a clouding of the lens in the eye).</b> New or worsened cataracts can happen in people taking eltrombopag for oral suspension. Your healthcare provider will check your eyes before and during your treatment with eltrombopag for oral suspension. Tell your healthcare provider about any changes in your eyesight while taking eltrombopag for oral suspension.</div></div></div><div>The most common side effects of eltrombopag for oral suspension in adults and children include:</div><div><div><div><div></div><div>low red blood cell count (anemia)</div></div><div><div></div><div>cough</div></div></div><div><div><div></div><div>nausea</div></div><div><div></div><div>tiredness</div></div></div><div><div><div></div><div>fever</div></div><div><div></div><div>headache</div></div></div><div><div><div></div><div>abnormal liver function tests</div></div><div><div></div><div>diarrhea</div></div></div></div><div>Laboratory tests may show abnormal changes to the cells in your bone marrow.</div><div>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 for oral suspension. For more information, ask your healthcare provider or pharmacist.</div><div>Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</div></div>			
<div>How should I store eltrombopag for oral suspension?</div> <div><div>For oral suspension</div><div><div><div></div></div><div>Store eltrombopag for oral suspension at room temperature between 68°F to 77°F (20°C to 25°C).</div></div><div><div><div></div></div><div>After mixing, eltrombopag for oral suspension should be taken right away but may be stored for no more than 30 minutes between 68°F to 77°F (20°C to 25°C). Throw away (discard) the mixture if not used within 30 minutes.</div></div></div> <div>Keep eltrombopag for oral suspension and all medicines out of the reach of children.</div>			
<div>General information about the safe and effective use of eltrombopag for oral suspension</div> <div>Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use eltrombopag for oral suspension for a condition for which it was not prescribed. Do not give eltrombopag for oral suspension to other people, even if they have the same symptoms that you have. It may harm them.</div> <div>You can ask your healthcare provider or pharmacist for information about eltrombopag for oral suspension that is written for health professionals.</div>			
<div>What are the ingredients in eltrombopag for oral suspension?</div> <div><div>For oral suspension</div><div>Active ingredient: eltrombopag olamine</div><div>Inactive ingredients: mannitol, sucralose, and xanthan gum</div><div>For more information, call 1-866-495-1995.</div><div>Additional pediatric use information is approved for Novartis Pharmaceuticals Corporation's PROMACTA® (eltrombopag) for oral suspension. However, due to Novartis Pharmaceuticals Corporation's marketing exclusivity rights, this drug product is not labeled with that information.</div><div>Medication Guide available at <a href="http://camberpharma.com/medication-guides">http://camberpharma.com/medication-guides</a></div><div><div><div><div><div></div><div>CAMBER</div><div>Pharmaceuticals, Inc.</div></div></div><div>Manufactured for: Camber Pharmaceuticals, Inc. Piscataway, NJ 08854.</div></div><div><div>By: Annora Pharma Pvt. Ltd. Sangareddy - 502313, Telangana, India.</div><div>2103427</div></div></div></div>			
<div>This Medication Guide has been approved by the U.S. Food and Drug Administration.</div> <div>Revised: 09/2024</div>			

Artwork information			
Customer	Camber	Market	USA
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Pharma Code No.	Front-NA & Back-NA		
Printing Colours	Black		
Others:	NA		


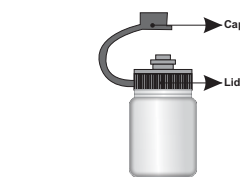
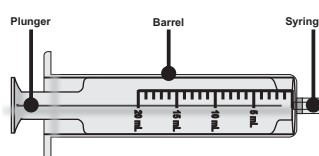
INSTRUCTIONS FOR USE  
Eltrombopag (el trom’ boe pag)  
for oral suspension

Read all the Instructions for Use and follow the steps below to mix and give a dose of eltrombopag for oral suspension.

Important information you need to know before taking eltrombopag for oral suspension:

- **Do not take eltrombopag for oral suspension or give it to someone else until you have been shown how to properly mix and give a dose of eltrombopag for oral suspension.** Your healthcare provider or nurse will show you how to mix and give a dose of eltrombopag for oral suspension properly.
- **Eltrombopag for oral suspension must be mixed with cool or cold water only.** Do not use hot water to prepare the oral suspension.
- Give the dose of suspension right away after mixing with water. **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.
- If eltrombopag for oral suspension comes in contact with your skin, wash the skin right away with soap and water. Call your healthcare provider if you have a skin reaction or if you have any questions. If you spill any powder or liquid, follow the clean-up instructions in **Step 12**.
- Contact your healthcare provider or pharmacist if you have any questions about how to mix or give eltrombopag for oral suspension to your child, or if you damage or lose any of the supplies in your kit.
- **Do not** re-use the oral dosing syringe. Use a new single-use oral dosing syringe to prepare each dose of eltrombopag for oral suspension.
- After you have used all 30 packets, throw all the remaining supplies (mixing bottle, lid with cap, and oral dosing syringe) away in the trash.

Each eltrombopag for oral suspension kit contains the following supplies:

30 packets of eltrombopag for oral suspension	
1 Reusable mixing bottle with lid and cap	
30 Single-use 20-mL oral dosing syringes (Use a new (single-use) oral dosing syringe to prepare each dose of eltrombopag for oral suspension)	

You will need the following to give a dose of eltrombopag for oral suspension.

From the kit:

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

Not included in the kit:

- 1 clean glass or cup filled with drinking water
- scissors to cut packet
- paper towels or disposable cloth
- disposable gloves (optional)

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

Step 1. 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.

**Step 2.** Fill the oral dosing syringe with 20 mL of drinking water from the glass or cup.

- 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 oral dosing syringe.

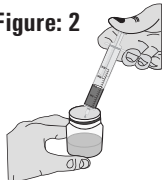
Figure: 1



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

**Step 3.** 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.

Figure: 2



**Step 4.** Take only the prescribed number of packets for one dose out of the kit. You may need to use more than one packet to prepare the entire dose.

12.5 mg packets

Dose	Number of 12.5 mg Packets Needed
12.5 mg dose	1 packet
25 mg dose	2 packets
50 mg dose	4 packets
75 mg dose	6 packets

25 mg packets

Dose	Number of 25 mg Packets Needed
12.5 mg dose	1 packet (Note: See Step 9 for instructions on how to give 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

**Step 5.** 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.

Figure: 3

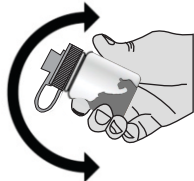


**Step 6.** Screw the lid tightly onto the mixing bottle. Make sure the cap is pushed onto the lid.

**Step 7.** 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.

Figure: 4



How should I give a dose of eltrombopag for oral suspension?

**Step 8.** 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.

**Step 9.** 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:
  - 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)
  - 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).

Figure: 5



**Step 10.** Return the mixing bottle to the upright position and remove the oral dosing syringe from the mixing bottle.

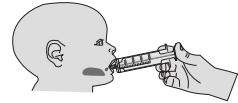
Figure: 6



**Step 11.** Giving a dose of eltrombopag 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.

Figure: 7



How should I clean up?

**Step 12.** 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.

**Step 13.** Clean the mixing supplies.

- **Do not reuse any of the mixture remaining in the mixing bottle.**
- Throw away (discard) any mixture remaining in the mixing bottle in the trash. Do not pour down the drain.
- Throw away (discard) the used oral dosing syringe. Use a new (single-use) oral dosing syringe to prepare each dose of eltrombopag for oral suspension.
- 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.

How should I store eltrombopag for oral suspension?

- Store eltrombopag for oral suspension at room temperature between 68°F to 77°F (20°C to 25°C).
- After mixing, eltrombopag for oral suspension should be taken right away but may be stored for no more than 30 minutes between 68°F to 77°F (20°C to 25°C). Throw away (discard) the mixture if not used within 30 minutes.

**Keep eltrombopag for oral suspension and all medicines out of the reach of children.**



Manufactured for:  
Camber Pharmaceuticals, Inc.  
Piscataway, NJ 08854.

By: Annora Pharma Pvt. Ltd.  
Sangareddy - 502313, Telangana, India.

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