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Eltrombopag

pronounced as (el trom' boe pag)

IMPORTANT WARNING:

If you have chronic hepatitis C (an ongoing viral infection that may damage the liver) and you take eltrombopag with medications for hepatitis C called interferon (Peginterferon, Pegintron, others) and ribavirin (Copegus, Rebetol, Ribasphere, others), there is an increased risk that you will develop serious liver damage. If you experience any of the following symptoms, call your doctor immediately: yellowing of the skin or eyes, dark urine, excessive tiredness, pain in the upper right part of the stomach, swelling of the stomach area, or confusion.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain laboratory tests before and during your treatment to check your body's response to eltrombopag.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with eltrombopag and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of taking eltrombopag.

Why is this medication prescribed?

Eltrombopag is used to increase the number of platelets (cells that help the blood clot) to decrease the risk of bleeding in adults and children 1 year of age and older who have chronic immune thrombocytopenia (ITP; an ongoing condition that may cause unusual bruising or bleeding due to an abnormally low number of platelets in the blood) and who have not been helped or cannot be treated with other treatments, including medications or surgery to remove the spleen. Eltrombopag is also used to increase the number of platelets in people who have hepatitis C (a viral infection that may damage the liver) so that they can begin and continue treatment with interferon (Peginterferon, Pegintron, others) and ribavirin (Rebetol). Eltrombopag is also used in combination with other medications to treat aplastic

anemia (condition in which the body does not make enough new blood cells) in adults and children 2 years of age and older. It is also used to treat aplastic anemia in adults who have not been helped with other medications. Eltrombopag is used to increase the number of platelets enough to decrease the risk of bleeding in people with ITP or aplastic anemia, or to allow treatment with interferon and ribavirin in people with hepatitis C. However it is not used to increase the number of platelets to a normal level. Eltrombopag should not be used to treat people who have low numbers of platelets due to conditions other than ITP, hepatitis C, or aplastic anemia. Eltrombopag is in a class of medications called thrombopoietin receptor agonists. It works by causing the cells in the bone marrow to produce more platelets.

How should this medicine be used?

Eltrombopag comes as a tablet and as a powder for oral suspension (liquid) to take by mouth. It is usually taken once a day on an empty stomach, at least 1 hour before or 2 hours after eating. Take eltrombopag at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take eltrombopag exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Take eltrombopag at least 2 hours before or 4 hours after you eat or drink foods that contain a lot of calcium, such as dairy products, calcium-fortified juices, cereals, oatmeal, and breads; trout; clams; leafy green vegetables such as spinach and collard greens; and tofu and other soy products. Ask your doctor if you are not sure if a food contains a lot of calcium. You may find it helpful to take eltrombopag close to the beginning or end of your day so that you will be able to eat these foods during most of your waking hours.

Swallow the tablets whole. Do not split, chew, or crush them and mix them into food or liquids.

If you are taking the powder for oral suspension, carefully read the manufacturer's instructions for use that comes with the medication. These instructions describe how to prepare and measure your dose. Mix the powder with cool or cold water before use. Do not mix the powder with hot water. Immediately after preparation, swallow the dose. If it is not taken within 30 minutes or if there is remaining liquid, dispose of the mixture in the trash (do not pour it down the sink).

Do not allow the powder to touch your skin. If you spill the powder on your skin, wash it off immediately with soap and water. Call your doctor if you have a skin reaction or if you have any questions.

Your doctor will probably start you on a low dose of eltrombopag and adjust your dose depending on your response to the medication. At the beginning of your treatment, your doctor will order a blood test to check your platelet level once every week. Your doctor may increase your dose if your platelet level is too low. If your platelet level is too high, your doctor may decrease your dose or may not give you eltrombopag for a time. After your treatment has continued for some time and your doctor has found the dose of eltrombopag that works for you, your platelet level will be checked less often. Your platelet level will also be checked weekly for at least 4 weeks after you stop taking eltrombopag.

If you have chronic ITP, you may receive other medications to treat your condition along with eltrombopag. Your doctor may decrease your dose of these medications if eltrombopag works well for you.

Eltrombopag does not work for everyone. If your platelet level does not increase enough after you have taken eltrombopag for some time, your doctor may tell you to stop taking eltrombopag.

Eltrombopag may help to control your condition but will not cure it. Continue to take eltrombopag even if you feel well. Do not stop taking eltrombopag without talking to your doctor.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking eltrombopag,

- tell your doctor and pharmacist if you are allergic to eltrombopag, any other medications, or any of the ingredients in eltrombopag tablets. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: anticoagulants (blood thinners) such as warfarin (Coumadin, Jantoven); bosentan (Tracleer); cholesterol-lowering medications (statins) such as atorvastatin (Lipitor, in Caduet), fluvastatin (Lescol), pitavastatin (Livalo, Zypitamag), pravastatin (Pravachol), rosuvastatin (Crestor), and simvastatin (Zocor, Flolopid, in Vytorin); ezetimibe (Zetia, in Vytorin); glyburide (Diabeta, Glynase); imatinib (Gleevec); irinotecan (Camptosar, Onivyde); olmesartan (Benicar, in Azor, in Tribenzor); lapatinib (Tykerb); methotrexate (Rasuvo, Trexall, others); mitoxantrone; repaglinide (Prandin); rifampin (Rimactane, Rifadin, in Rifamate, Rifater); sulfasalazine (Azulfidine); topotecan (Hycamtin), and valsartan (Diovan, in Byvalson, in Entresto, in Exforge). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with eltrombopag, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- if you are taking antacids containing calcium, aluminum, or magnesium (Maalox, Mylanta, Tums) or vitamin or mineral supplements containing calcium, iron, zinc or selenium, take eltrombopag 2 hours before or 4 hours after you take them.
- tell your doctor if you are of East Asian (Chinese, Japanese, Taiwanese, or Korean) descent and if you have or have ever had a cataract (clouding of the lens of the eye that may cause vision problems), blood clots, any condition that increases the risk that you will develop a blood clot, bleeding problems, myelodysplastic syndrome (MDS; a blood disorder that can lead to cancer), or liver disease. Also tell your doctor if you have had surgery to remove your spleen.
- tell your doctor if you are pregnant, or plan to become pregnant. You should not become pregnant during your treatment with eltrombopag. Use effective birth control while you are receiving treatment and for 7 days after your last dose. If you become pregnant while taking eltrombopag, call your doctor.
- tell your doctor if you are breastfeeding. You should not breastfeed while you are taking eltrombopag.
- continue to avoid activities that may cause injury and bleeding during your treatment with eltrombopag. Eltrombopag is given to decrease the risk that you will experience severe bleeding, but there is still a risk that bleeding may occur.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one. Do not take more than one dose of eltrombopag in one day.

What side effects can this medication cause?

Eltrombopag may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- back pain
- muscle aches or spasms
- headache
- flu symptoms such as fever, headache, sore throat, cough, tiredness, chills, and body aches
- weakness
- extreme tiredness
- decreased appetite
- pain or swelling in the mouth or throat
- hair loss
- rash
- skin color changes
- skin tingling, itching, or burning
- swelling of the ankles, feet, or lower legs
- toothache (in children)

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately or get emergency medical treatment:

- swelling, pain, tenderness, warmth or redness in one leg
- shortness of breath, coughing up blood, fast heartbeat, fast breathing, pain when breathing deeply
- pain in the chest, arms, back, neck, jaw, or stomach, breaking out in cold sweat, lightheadedness
- slow or difficult speech, sudden weakness or numbness of the face, arm or leg, sudden headache, sudden vision problems, sudden difficulty walking
- stomach pain, nausea, vomiting, diarrhea
- cloudy, blurry vision, or other vision changes

Eltrombopag may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). If your medication came with a desiccant packet (small packet that contains a substance that absorbs moisture to keep the medication dry), leave the packet in the bottle but be careful not to swallow it.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- rash
- slowed heartbeat
- excessive tiredness

What other information should I know?

Your doctor will order an eye exam before and during your treatment with eltrombopag.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary

supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Promacta®

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