Your practical guide to REVOLADE™ (eltrombopag)

Eltrombopag is indicated for chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients aged 1 year and above who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).
About you

Patient information

Name:

Address:

Telephone/mobile:

Date of birth:

Allergies:

Emergency contact:

Your doctor and hospital information

Doctor’s name:

Nurse’s name:

Address:

Telephone number:

Hospital number:
Your practical guide

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Supporting you with eltrombopag

Your doctor has prescribed you (your child) eltrombopag to help treat chronic immune thrombocytopenic purpura (chronic ITP) and has provided you with this practical guide.

Get off to a good start
Taking the time to read these materials will help give you a better understanding of how eltrombopag works, how to take it correctly and any side effects to watch out for, as well as giving you some practical tips to ensure eltrombopag fits as seamlessly into your daily routine as possible. But don’t forget, you should always speak to your doctor or nurse for further advice.

These materials are not meant to replace the information in the patient information leaflet you received with your pack of eltrombopag. Please make sure to read the patient information leaflet for more information on eltrombopag.
Important FACTS about you (your child)

Tell your doctor if you (your child)...

- Have liver problems. You will be monitored closely while you are taking eltrombopag
- Are taking medicines that prevent blood clots, such as anticoagulants or antiplatelet therapy
- Are at risk of having a blood clot in your veins or arteries (e.g. smoke, taking any contraceptive birth control pill, hormone replacement therapy or if you have undergone recent surgery/trauma), member of your family has had a blood clot, or if you have chronic liver disease
- Have cataracts (the lens of the eye getting cloudy)
- Have a bone marrow problem, including a blood cancer such as myelodysplastic syndrome (MDS) or myelofibrosis
- Are pregnant, think you may be pregnant or plan to get pregnant
- Are breast feeding or planning to breast feed
Tell your doctor if you (your child)...

- Are taking or planning to take any other medicine. This includes:
  - Antacids (medicines taken for indigestion, heartburn or stomach ulcers) that contain minerals, such as aluminium, calcium or magnesium
  - Statins, which are used to lower cholesterol
  - Medicines used to treat HIV such as lopinavir or ritonavir
  - Medicines or supplements that contain calcium, aluminium, iron, magnesium, selenium or zinc. This includes some over-the-counter medicines, herbal medicines, mineral and multivitamin supplements and protein shakes
  - Medicines used to treat cancer, such as methotrexate or topotecan
  - Medicines to prevent blood clots, such as anticoagulants or antiplatelet therapy
  - Any other medication for your ITP, such as corticosteroids, danazol or azathioprine

- Are of East Asian ancestry (such as Chinese, Japanese, Taiwanese or Korean), as this may mean you need a lower starting dose of eltrombopag

You (your child) should not receive eltrombopag if you (your child):

- Are allergic (hypersensitive) to the active ingredient in eltrombopag, or any of the other ingredients contained within this product
  - Check with your doctor if you think this might apply to you
What is CHRONIC ITP?

Blood is made up of lots of different types of cells, including platelets. These are tiny cells that help your blood to clot and form a scab in order to limit bleeding, for example when you have a cut or graze.

Platelets are made in the bone marrow and are normally removed naturally by the spleen and liver after about seven days. However, in people with ITP, antibodies attack the platelets and stop them from working properly. These platelets are then removed from the body more quickly than usual.

Antibodies also interact with the cells that make new platelets, meaning less platelets are produced.

When the number of platelets being removed outnumbers the platelets being produced, your platelet count falls, meaning blood isn’t able to clot normally. You may then experience symptoms such as bruising, purpura (a type of speckled rash), nosebleeds, bleeding gums, and not being able to control bleeding if cuts or injuries occur.

If you have (your child has) ITP for over 12 months, this is known as ‘chronic ITP’
What is eltrombopag?

Eltrombopag is indicated for chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients aged 1 year and above who are refractory to other treatments.

How it works

It works in a similar way to your body’s natural hormones (called growth factors) that increase platelet production in the bone marrow. This, in turn, may increase the number of platelets in your blood.

You may have had other therapies in the past that work by slowing down platelet destruction. A TPO-R agonist, like eltrombopag, works differently by helping your body to produce more platelets. This should raise your platelet count and help you to better manage your chronic ITP.
Things to know when taking eltrombopag tablets

In Ireland eltrombopag is available in two tablet strengths:

- 25 mg
- 50 mg

Your eltrombopag tablet may look different than the images above.

Your doctor will tell you what is the right dose for you. Depending on how you respond to treatment, this may change over time.

Your doctor will tell you if you need to change your treatment plan. Do not change the number of eltrombopag tablets you take unless instructed by your doctor.

Taking eltrombopag

You should take eltrombopag:
- In one daily dose
  - If you have to take more than one tablet, take them all at the same time
- By mouth, one at a time, with water

Storing eltrombopag

Your eltrombopag does not need any special storage conditions, but you should keep it out of sight and reach of children.

Do not use eltrombopag after the expiry date on the pack.
Things to know when giving eltrombopag powder for oral suspension

For paediatric patients aged 1 to 5 years, eltrombopag is also available as a 25 mg sachet of powder for oral suspension.

Giving eltrombopag

- Do not open the foil sachets until ready for use.
- Ektrombopag powder must be mixed with water only.
- When preparing eltrombopag oral suspension, use the reusable mixing bottle and reusable oral syringe included in your eltrombopag kit.

- Fill a cup with water, and with the plunger pushed all the way into the syringe, put the syringe in the cup and pull back on the plunger until the syringe is filled with 20mL of water. Put this into the bottle.
- Pour the powder from the sachet into the bottle, making sure not to spill any outside the bottle.
- Close the lid on the bottle, and gently shake it for 20 seconds. To prevent foaming, do not shake hard.
- Put the syringe into the bottle lid, turn upside-down, and fill the syringe with the medicine.
- Give the medicine by putting the tip of the syringe to the inside of your child’s cheek and pushing the plunger down. Make sure the child has time to swallow.
- To ensure your child receives the full prescribed dose, fill the bottle with another 10mL of clean water and give it to your child.

The dose should be given to your child within 30 minutes of mixing. If the dose cannot be given within 30 minutes, then use a new sachet and make a new mixture.
When should you (your child) take eltrombopag?

You should take eltrombopag once a day. The time of day (or night) is up to you. However, it will be easier to remember if you take it at the same time every day.

**IMPORTANT:** Eltrombopag should not be taken with foods, drinks, or other medicines that contain high concentrations of calcium, iron, magnesium, aluminium, selenium or zinc.

The interaction is not harmful, but it does stop your body from being able to absorb eltrombopag properly, which means it won’t work as well.

That’s why you must take eltrombopag at least 2 hours before or 4 hours after certain foods, drinks or medicines.
Incorporating eltrombopag conveniently into your (child’s) daily routine

It’s worth thinking about when the best time for you to take your eltrombopag would be. This is particularly important as you must not take eltrombopag with certain foods, drinks or medicines that contain high concentrations of calcium, iron, magnesium, aluminium, selenium or zinc.

The following pages give you recommendations for making eltrombopag part of your daily routine

- Taking it in the evening before you go to bed
- Taking it in the morning as soon as you wake up
To ensure you get the best results from eltrombopag...

...take eltrombopag

at least 2 hours before...

...or 4 hours after certain foods, drinks or medicines
Taking eltrombopag before you (your child) go to bed

If you feel that you want to take your eltrombopag earlier than 10pm, here are some foods you could eat for your evening meal:

- Meats such as chicken, lean ham or beef
- White fish e.g., cod or haddock
- Non-leafy vegetables
- Potatoes, brown rice, pasta
- Fruit
- Unfortified (no added minerals) fruit juice
- Black coffee/tea

Remember to eat and drink as normal.
REMEMBER…

Eltrombopag should be taken at least 2 hours before or 4 hours after certain products:

- Foods, drinks or medicines that are high in calcium*
- Mineral supplements or fortified foods, i.e. those with added calcium, iron, magnesium, aluminium, selenium or zinc

You should speak to your doctor if you are unsure about any aspect of taking eltrombopag.

* ‘High in calcium’ means foods, drinks or medicines that contain 50 mg or more of calcium. Ensure you check the packet nutritional information, or if you aren’t sure speak to your doctor.
Taking eltrombopag as soon as you (your child) wake up

Things you could eat for breakfast are:
- Porridge oats
- Unfortified soy milk
- Cold meats such as lean ham
- Fruit
- Small portion of nuts or raisins
- Black coffee/tea
- Unfortified fruit juice

Things you should avoid:
- Elizabeth strawberry
- Lacto-fermented foods
- Tomatoes
- Unpasteurised dairy products

Eat and drink as normal at these times:
- 4pm
- 8am
- 11am
- 12pm
- 2pm
- 4am
- 6am
- 7am
- 9am
- 10am
- 12am
- 2am
REMEMBER…

Eltrombopag should be taken at least 2 hours before or 4 hours after certain products:

- Foods, drinks or medicines that are high in calcium*
- Mineral supplements or fortified foods, i.e. those with added calcium, iron, magnesium, aluminium, selenium or zinc

You should speak to your doctor if you are unsure about any aspect of taking eltrombopag.

* ‘High in calcium’ means foods, drinks or medicines that contain 50 mg or more of calcium. Ensure you check the packet nutritional information, or if you aren’t sure speak to your doctor.
Other things TO CONSIDER

The minerals that interact with eltrombopag are also found in some medicines. As with calcium-rich foods, make sure you take eltrombopag at least 2 hours before or 4 hours after these medicines:

- Certain antacids (medicines taken for indigestion, heartburn or stomach ulcers)
- Medicines and supplements containing calcium, aluminium, iron, magnesium, selenium or zinc. This includes some over the counter medicines, mineral and multivitamin supplements and protein shakes

If you need to take an antacid, be sure to take eltrombopag at least 2 hours before or 4 hours after the antacid.

- Ask your doctor to suggest a type of antacid that is less likely to affect your ITP medicine
Tell your doctor if you are taking any other medicines, including:

- Statins, used to lower cholesterol
- Medicines used to treat HIV such as lopinavir or ritonavir
- Chemotherapy drugs such as topotecan or methotrexate
- Medicines to prevent blood clots, such as anticoagulants or antiplatelet therapy
- Other medicines for ITP, such as corticosteroids, danazol or azathioprine
- The contraceptive pill or hormone replacement therapy
- Herbal preparations and other medicines you may have purchased without a prescription

If you are pregnant or breastfeeding

You should not take eltrombopag if you are pregnant unless your doctor specifically recommends it. The effect of taking eltrombopag during pregnancy isn’t known.

- Tell your doctor if you become pregnant, or are planning on becoming pregnant, while taking eltrombopag
- Use a reliable method of contraception while you are taking eltrombopag

You should not breast-feed while taking eltrombopag. Tell your doctor if you are breastfeeding or planning to breast-feed.

Your doctor might recommend checks for cataracts

In animal studies, cataracts (a clouding of the lens of the eye) were observed with the use of eltrombopag. The clinical relevance of this finding is unknown and in human trials, no increased risk of cataracts has been found so far. Your doctor may recommend that you are checked for cataracts as part of routine eye tests.
What to expect from eltrombopag

When taken correctly, eltrombopag should help you (your child) manage your chronic ITP and reduce its effects on your body, such as bleeding.

In the first weeks
With daily treatments like eltrombopag, it can take a little time for the medicine to start working. Typically, it can take up to 2 weeks for your body to respond to eltrombopag, so don’t get worried if you don’t notice any change straightaway.

When you first start your treatment with eltrombopag, your doctor will need to take blood tests from you each week to check your blood cells and platelet count. Your liver function will also be tested before and during treatment with eltrombopag. Based on your initial response to the treatment, your doctor might recommend changing tablet strength.

Once your doctor thinks that your tablet strength can stay the same, you will only need to have a blood test once per month. Your doctor will continue to monitor your response to treatment to decide if you need to continue taking eltrombopag.
What to do if you (your child) experience SIDE EFFECTS

As with all medicines, you may experience some side effects with eltrombopag and you should tell your doctor, nurse or pharmacist when they arise. Your doctor will also closely monitor you for side effects during treatment with eltrombopag.

Do not stop taking your medication without first consulting your doctor.
Being prepared will help you manage any side effects if they do occur. Below are some ideas to help you manage the more common side effects that you might get with eltrombopag:

**If you get a headache:**
- Drink plenty of water
- Limit caffeine intake
- Avoid bright lights, loud noise, strong odours

**If you feel nauseous:**
- Change your eating habits:
  - Eat before you feel hungry
  - Eat small meals throughout the day
  - Sip liquids throughout the day
  - Avoid foods that are greasy, very sweet or spicy

**If you have diarrhoea:**
- Try making changes to the way you eat:
  - Drink plenty of water
  - Eat low-fat, high-protein foods such as lean meat, instead of fried, fatty or spicy foods
  - Avoid milk and milk products, including ice cream
  - Eat cooked vegetables instead of raw, and remove skins from fruits
  - Avoid herbal preparations as some may cause diarrhoea

Remember to take eltrombopag at least 2 hours before or 4 hours after certain foods, drinks and medicines.

If you have any questions about the side effects that you are experiencing or how to manage them, please speak with your doctor.
Other side effects that may occur with eltrombopag

High platelet counts
If your platelet count becomes too high, your doctor may adjust your tablet strength, or ask you to stop taking eltrombopag.

Liver problems
You should contact your doctor immediately if you develop signs or symptoms of liver problems such as:
- Drowsiness
- Hyperventilation
- Shaking hands
- Yellowing of the skin or whites of the eyes (jaundice)
- Swollen abdomen or ankles
- Very dark-coloured urine
Bleeding (after you stop treatment)
In 8% of clinical study patients, after stopping eltrombopag, platelet levels dropped below what they were before starting eltrombopag. Tell your doctor if you have any bleeding or bruising in the 4 weeks after you have stopped taking eltrombopag.

Risk of blood clots
Eltrombopag may increase your risk of developing a blood clot. You are more at risk if you: smoke, are elderly, take any contraceptive pill or hormone replacement therapy, have had recent surgery/trauma, are overweight (obese), have been bedridden for a long time, have a certain genetic predisposition that may run in the family or have chronic liver disease. You should contact your doctor immediately if you have any symptoms of a blood clot, such as:
• Swelling, pain or tenderness in one leg
• Sudden shortness of breath, especially if you also have sharp chest pain, and/or rapid breathing
• Abdominal pain, enlarged (swollen) abdomen, or blood in your stool

Problems with bone marrow
People with ITP may have problems with their bone marrow (the tissue inside your bones) and medicines, including eltrombopag, could make this problem worse. Your doctor may carry out tests to check your bone marrow during treatment with eltrombopag.

Worsening of blood cancers
Before you started eltrombopag, your doctor will have carried out tests to ensure that you have ITP and not another condition such as Myelodysplastic Syndrome (MDS). If you have MDS and receive eltrombopag, your MDS condition may worsen. For more advice, talk to your doctor.
Frequently asked QUESTIONS

This section covers some of the common questions asked about eltrombopag. If you have a question that isn’t answered in this section, please speak to your doctor.

I’ve forgotten to take my dose of eltrombopag, what should I do?
Take your next dose at the usual time, and tell your doctor. Do not take a double dose to make up for any forgotten doses.

I have taken too much eltrombopag, what should I do?
Contact your doctor, nurse or pharmacist immediately. If you can, show them the pack that the medication comes in, or the leaflet that comes with it. Your doctor should monitor you for any signs of side effects and make sure that you are given any appropriate treatment immediately.

What do I do if I vomit after taking eltrombopag?
Wait until the next day and take your dose at the usual time. If you are often sick from taking eltrombopag, talk to your doctor about it.
I have eaten dairy products and taken my dose of eltrombopag, what should I do?
It is likely that your dose hasn’t been properly absorbed into your body. Take your next dose at the usual time. Talk to your doctor if you are in doubt, and follow their recommendation to take eltrombopag at least 2 hours before or 4 hours after calcium and dairy products.

It’s also important to remember to take eltrombopag at least 2 hours before or 4 hours after food, drinks or medicines that contain a high concentration of iron, magnesium, aluminium, selenium or zinc, as well as calcium.

What happens if I find the side effects too hard to manage?
Please talk to your doctor if your side effects become too much; they may be able to give you some advice on how to better manage them. Do not stop taking eltrombopag without talking to your doctor.

What if I become pregnant?
If you become pregnant, tell your doctor immediately. They will be able to advise you on the best course of action.

What should I do if I have any extra or expired eltrombopag tablets?
Do not use any eltrombopag after the expiry date printed on the carton and blister pack. If you have extra or expired eltrombopag, you should ask your pharmacist how to dispose of it. It should not be flushed or thrown in the bin with household waste.

When will I stop taking eltrombopag?
Do not stop taking eltrombopag without first talking to your doctor. If you and your doctor decide that you should stop taking eltrombopag, your doctor will check your platelet counts for at least 4 weeks after you took your last dose to monitor your condition.
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpра.ie; E-medsafety@hpра.ie. By reporting side effects you can help provide more information on the safety of this medicine. Adverse events should also be reported to Novartis Ireland by calling 01-2080612 or by email to drugsafety.dublin@novartis.com. If you use email please write “reporting of adverse event” in the mail heading.