

What You Need to Know

**A Patient's Guide to
REVOLADE™ (eltrombopag)**

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: _____

Liver unit address: _____

Liver unit telephone: _____

Hospital number: _____

Please see the Important Safety Information starting on page 31. Please see accompanying SmPC.

Your Practical Guide

Contents

- 4** Supporting you with eltrombopag
- 6** About your condition
- 7** About eltrombopag
- 8** Tell your doctor if you...
- 10** Things to know when taking eltrombopag
- 12** When should you take eltrombopag?
- 22** What to expect from eltrombopag
- 24** What to do if you experience side effects
- 28** FAQs

Supporting you with eltrombopag

Your doctor has decided that you need eltrombopag as part of your treatment for hepatitis C. This booklet will answer many of your questions about eltrombopag, including how it works, how you should take it, and what you need to be aware of.

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.

Please see the Important Safety Information starting on page 31. Please see accompanying SmPC.

About your condition

What is hepatitis C?

Hepatitis C is a disease caused by a virus that travels in the blood and infects the liver. For many people, the virus leads to a long-term infection that requires treatment. Symptoms can vary, and some people will not experience noticeable symptoms for many years; however, hepatitis C is a progressive condition that can lead to serious liver disease, so it is important to start treatment as soon as possible.

What is thrombocytopenia?

Thrombocytopenia is a medical term that means the blood does not contain enough platelets, which are important for blood clotting. Many patients with hepatitis C infections have this condition, which may mean they are unable to take some of the medicines they need to treat their hepatitis C, such as interferon.

Why is it important?

An antiviral medicine called interferon is often involved in the treatment for hepatitis C, but it can cause a drop in the number of platelets in the blood. When a patient's platelet count drops too low, they may not be able to take interferon safely. It is important to correct this so that treatment with interferon can start or continue.

About eltrombopag

Your doctor has decided that you need eltrombopag in addition to your other treatment. Eltrombopag is used to treat thrombocytopenia that affects some people with hepatitis C infections.

How eltrombopag 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. Boosting your platelets could give you a better chance of starting and completing the antiviral treatment used for hepatitis C.

Please see the Important Safety Information starting on page 31.
Please see accompanying SmPC.

Tell your doctor if you...

- Have liver problems
- Are at risk of having a blood clot in your veins or arteries (e.g. if you smoke, are elderly, overweight, take any contraceptive pill or hormone replacement therapy, have been bedridden for a long time, have cancer, have advanced chronic liver disease, or have had recent surgery/trauma), or a member of your family has had a blood clot
- Have had cataracts (the lens of the eye getting cloudy)
- Are pregnant, think you may be pregnant or plan to get pregnant
- Are breast feeding or planning to breast feed
- Have a blood condition, including a blood cancer such as myelodysplastic syndrome (MDS)

Please see the Important Safety Information starting on page 31.
Please see accompanying SmPC.

Tell your doctor if you...

- Are taking or plan 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, used to lower cholesterol
 - Chemotherapy medicines, such as methotrexate or topotecan
 - Medicines used to treat HIV such as lopinavir or ritonavir
 - Medicines to prevent blood clots, such as anticoagulants or antiplatelet therapy
 - Corticosteroids such as danazol, and/or azathioprine
 - 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

You should not take eltrombopag if you are allergic (hypersensitive) to eltrombopag or any of the other ingredients of eltrombopag. Check with your doctor if you think this might apply to you.

Things to know when taking eltrombopag

Eltrombopag is available in three tablet strengths:



25 mg



50 mg



75 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.

Please see the Important Safety Information starting on page 31. Please see accompanying SmPC.

When should you 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 within 4 hours of 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 avoid certain foods, drinks or medicines 4 hours before and after taking eltrombopag

Please see the Important Safety Information starting on page 31.
Please see accompanying SmPC.

Follow the 4-HOUR RULE to ensure you get the best results from eltrombopag

AVOID certain foods, drinks or medicines

For 4 hours before...



...and 4 hours after

Incorporating eltrombopag into your 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

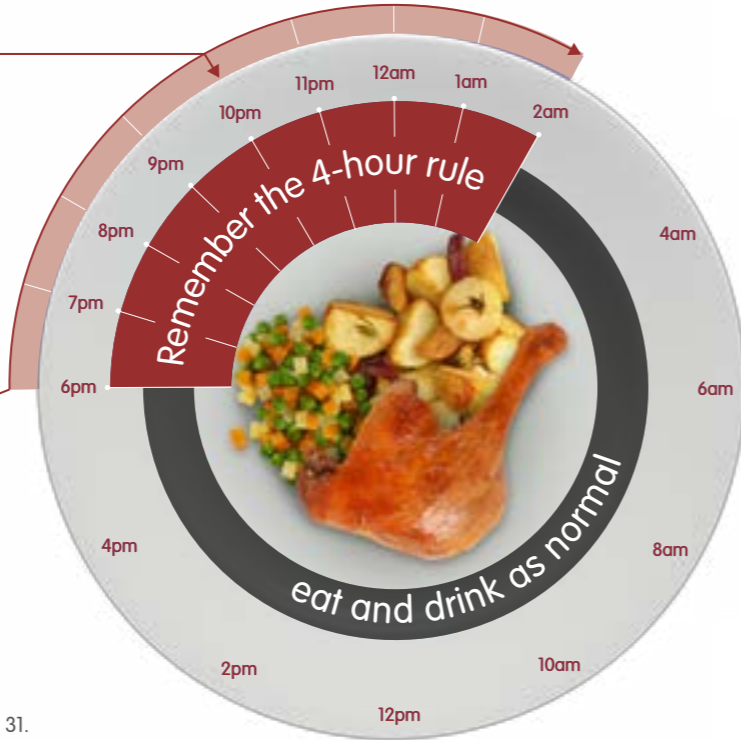
- Taking it in the evening before you go to bed
- Taking it in the morning as soon as you wake up

Please see the Important Safety Information starting on page 31.
Please see accompanying SmPC.

**SPEAK TO YOUR DOCTOR
about finding a time that is right
for you to take eltrombopag**

Revolade (eltrombopag) should be taken once a day around the same time.
Here are some suggestions for planning your meals around eltrombopag.

Taking eltrombopag before you 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, 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

Please see the Important Safety Information starting on page 31.
Please see accompanying SmPC.

REMEMBER...

For four hours before and after you take eltrombopag, you should avoid:

- 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



Cheese



Energy bar



Milkshake



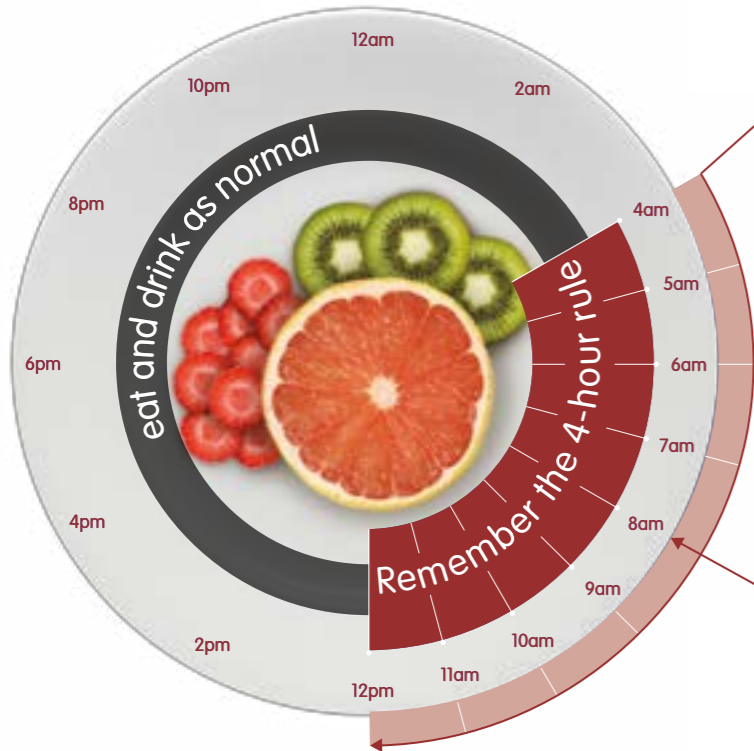
Ice cream

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.

Revolade (eltrombopag) should be taken once a day around the same time. Here are some suggestions for planning your meals around eltrombopag.

Taking eltrombopag as soon as you wake up



Things you could eat before noon are:

- Porridge oats
- Unfortified soy milk
- Fruit
- Small portion of nuts or raisins
- Black coffee/tea
- Unfortified fruit juice

REMEMBER...

For four hours before and after you take eltrombopag, you should avoid:

- 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



Milk



Yoghurt



Fortified cereals



Fortified juices

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.

Please see the Important Safety Information starting on page 31. Please see accompanying SmPC.

Other things TO CONSIDER

The minerals that interact with eltrombopag are also found in some medicines. As with calcium-rich foods, make sure you do not take these medicines 4 hours before or after taking eltrombopag:

- 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, avoid taking it 4 hours before and 4 hours after taking your dose of eltrombopag.

- Ask your doctor to suggest a type of antacid that is less likely to affect how well eltrombopag works.



Please see the Important Safety Information starting on page 31.
Please see accompanying SmPC.

Tell your doctor if you are taking any other medicines, including:

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

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 think you are 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 may help you manage your thrombocytopenia and allow you to start or safely complete your treatment for hepatitis C.

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.

Checking your body's reponse

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.

Please see the Important Safety Information starting on page 31. Please see accompanying SmPC.

What to do if you 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. Discuss any side effects and how to manage them with your doctor.

Being prepared will help you manage any side effects if they do occur. Below are some ideas to help you manage some of 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 follow the 4-hour rule if you adjust your diet

Please see the Important Safety Information starting on page 31. Please see accompanying SmPC.

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

Patients with chronic liver disease taking eltrombopag and interferon are at increased risk for potentially fatal adverse reactions, including hepatic decompensation. For additional information, talk to your doctor.

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

Some people 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.

Please note that this is not a complete list of side effects that may occur with with eltrombopag. For more information on possible side effects, talk to your doctor.

Please see the Important Safety Information starting on page 31. Please see accompanying SmPC.

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 usual 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, and make a note in your treatment tracker. Talk to your doctor if you are in doubt, and follow their recommendation to avoid calcium and dairy products for 4 hours before and 4 hours after taking your eltrombopag.

It's important to remember to avoid 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 hard to manage?

If your side effects are difficult to manage, talk to your doctor; 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.

Some tips on how to deal with select side effects are on Page 25 of this booklet.

? 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 do 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, you will need to have blood tests each week for at least 4 weeks after you took your last dose to monitor your condition.

Please see the Important Safety Information starting on page 31. Please see accompanying SmPC.

Notes:

Please see the Important Safety Information starting on page 31. Please see accompanying SmPC.

REVOLADE®

Important note: Before prescribing, consult full prescribing information.

Presentation: Film-coated tablets containing eltrombopag olamine equivalent to 25 mg, or 50 mg of eltrombopag free acid.

Indications: Eltrombopag is indicated for the treatment of previously treated patients with chronic idiopathic thrombocytopenic purpura (ITP) to increase platelet counts and reduce or prevent bleeding.

Dosage and administration: Dosing regimens must be individualized based on the patient's platelet counts. Dose regimen: Starting dose between 25 to 50 mg once daily. Monitoring and individual dose adjustment. Maintenance doses with maximum daily doses between 75 to 150 mg depending on patient population and indication.

Special populations: Elderly: No clinically significant differences in safety. Renal impairment: Caution and close monitoring recommended. Hepatic impairment: Caution and close monitoring, starting dose 25 mg once daily.

Contraindications: None.

Warnings and precautions: Hepatic monitoring. Hepatic decompensation

Close monitoring for signs and symptoms of hepatic decompensation. Thrombotic/thromboembolic complications: Use with caution in patients with known risk factors for thromboembolism. Monitoring of platelet counts and potentially dose reduction or discontinuation. Increased risk for bleeding after discontinuation of treatment. Monitoring weekly for 4 weeks following discontinuation. Risk for malignancies and progression of malignancies. Patient with cataracts: Routine monitoring.

Women of child-bearing potential, pregnancy: Should be used during pregnancy only if the expected benefit justifies the potential risk to the fetus.

Breast-feeding: Not recommended unless the expected benefit justifies the potential risk to the infant.

Adverse drug reactions (by highest reporting frequency):

ITP study population: Very common ($\geq 10\%$): Nausea, diarrhea. Common (1 to 10%): Pharyngitis, urinary tract infection, dry mouth, vomiting, increased aspartate aminotransferase, increased alanine aminotransferase, alopecia, rash, back pain, musculoskeletal chest pain, musculoskeletal pain, myalgia.

ITP pediatric study population (1 to 17 years

of age) – Additional ADRs: Very common ($\geq 10\%$): Nasopharyngitis, upper respiratory tract infection. Common (1 to 10%): Rhinitis, abdominal pain, toothache, cough, oropharyngeal pain, rhinorrhea, pyrexia.

Adverse reaction from spontaneous reports: Rare (0.01 to 0.1%): Thrombotic microangiopathy with acute renal failure.

For a complete list of ADRs, consult full prescribing information.

Novartis Page 3 BSS v1.1 16-Dec-2015
Revolade

Interactions: Rosuvastatin: Dose reduction and monitoring. Other OATP1B1 and BCRP substrates to be used with caution. Cyclosporine (BCRP inhibitor): monitoring weekly for 2 to 3 weeks, eltrombopag dose may need to be increased: Polyvalent cations (chelation): staggered administration. Food interactions. Lopinavir/ritonavir: Caution and monitoring of platelet count weekly for 2 to 3 weeks.

You can report any problem or adverse events through:

Novartis Consulting AG.

Saudi Arabia: P.O. Box 16032, Riyadh 11464, Tel: +966114658882

DS&E

Phone: +996112658100

Fax: +966112658107

Email: adverse.events@novartis.com

National pharmacovigilance and drug safety center

Toll free phone: 8002490000

Fax: +966112057662

E-mail: npc.drug@sfd.gov.sa

Or by online: <https://ade.sfd.gov.sa>

