

What you need to know

A patient's guide to

REVOLADE™
(eltrombopag olamine)



REVOLADE is used to treat a blood disorder known as thrombocytopenia. Thrombocytopenia is a medical term that means the blood does not contain enough platelets, which are important for blood clotting.



How does REVOLADE work?

REVOLADE works by helping the body to produce platelets.

It works in a similar way to a hormone produced naturally by the body that stimulates platelet production in the bone marrow and so increases the number of platelets in your blood.

What are platelets?

Platelets are small, irregularly-shaped blood cells that are produced in the **bone marrow**. They have an important role in forming clots to stop bleeding, and patients with a low platelet count (thrombocytopenia) are at increased risk of serious bleeds. If your platelet counts are low you may be at risk of increased bleeding, and may have symptoms such as bruising, nosebleeds, and small flat round red spots on the skin.



Before you take REVOLADE

You must 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, or have had recent surgery/trauma), or a member of your family has had a blood clot
- Have a history of alcohol consumption
- 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 bone marrow problem, including a blood cancer such as myelodysplastic syndrome (MDS)
- Are taking 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
- 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
- Are of East Asian ancestry (such as Chinese, Japanese, Taiwanese or Korean), as this may mean you need a lower starting dose of REVOLADE

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

How to take REVOLADE

To get the best results when taking REVOLADE, it is important that you take the correct dose, every day, at the same time. Your doctor will tell you what dose is right for you, and this may change during your treatment depending on how you respond to therapy.

REVOLADE is taken:

- In **one daily dose**; your doctor may tell you to take more than one tablet but you should take them all at the same time
- By mouth, one at a time, with water
- Preferably at the **same time every day**

Things to remember when taking REVOLADE

Meals

REVOLADE interacts with minerals found in some foods, in particular dairy products. This interaction is harmless, but it affects how much REVOLADE is absorbed by your body, so it is important to follow the instructions in this booklet.

Other medications

The minerals that interact with REVOLADE are also found in some medications. It is important that you do not take these medications for **4 hours** before or after taking REVOLADE. They include:

- Antacids (medicines taken for indigestion, heartburn or stomach ulcers) containing minerals such as aluminium, calcium and magnesium
- Medicines and supplements that contain 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, your doctor may suggest taking a type of antacid which is less likely to affect your REVOLADE medication.

Tell your doctor if you are taking, have taken recently, or start to take any other medications. These include:

- 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 medicines and other medicines you may have purchased without a prescription

Things to remember when taking REVOLADE

How to store REVOLADE

Your REVOLADE does not need any special storage conditions, but you should keep it out of sight and reach of children. Do not use REVOLADE after the expiry date on the pack.

If you are pregnant or breastfeeding

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

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

You should not breast-feed while taking REVOLADE.

- Tell your doctor if you are breast-feeding or planning to breast-feed

Keep REVOLADE and all other medicines away from children

Planning your meals

Some foods, drinks and medications, especially those containing minerals such as calcium, aluminium and magnesium, can stop your body absorbing REVOLADE properly. For this reason you need to plan carefully when you take your medication and what you eat and drink for **4 hours** before and after taking it. Many patients find it easier to follow a morning OR an evening plan for taking REVOLADE. You can work with your doctor or nurse to find a treatment plan that works for you. You should bear in mind any requirements of other medicines you are taking and discuss these with your doctor or nurse.

For 4 hours before you take Revolade



No dairy products, antacids or mineral supplements



...and 4 hours after

Food low in calcium can be consumed



Planning your meals

Foods to avoid

Foods to avoid for **4 hours** before or after taking REVOLADE are:

- Dairy foods, such as butter, cheese, yoghurt and ice cream
- Milk, milkshakes or drinks made with milk, yoghurt or cream. **This includes milk in tea or coffee**
- Calcium-rich, or fortified foods and drinks, such as some types of juices, cereals and energy bars
- Foods which contain calcium-rich edible bones (e.g. sardines, salmon)
- Antacids that are based on minerals such as aluminium, calcium and magnesium
- Medicines and supplements that contain calcium, aluminium, iron, magnesium, selenium or zinc. This includes some over-the-counter medicines, mineral and multivitamin supplements and protein shakes

Foods you can eat with REVOLADE

You can take REVOLADE with food low in calcium (less than 50 mg). Food and drinks that are low in calcium include:

- Many fruits such as strawberries, kiwi, and pineapple
- Nuts and raisins
- Meat such as chicken, lean ham, and beef
- Most vegetables
- Unfortified non-dairy milk substitutes
- Unfortified fruit juices
- Cereals like oatmeal
- Brown sugar

Useful substitutes

This table shows you some low-calcium alternatives that you can take with REVOLADE. You should always check the nutritional label to make sure products are not fortified with calcium and contain less than 50 mg of calcium per serving.

Instead of:	Try:
Milk	Unfortified soya milk Unfortified rice milk
Butter	Vegetable oil margarine
Cheese	Unfortified vegan cheese
Antacids	H2 blocker, proton pump inhibitor

Following these guidelines will make your treatment more effective

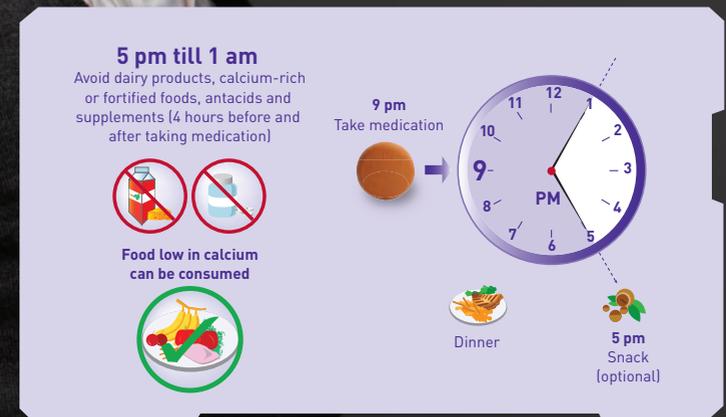
Taking REVOLADE in the morning...

You may find it easiest to take your medication in the morning when you get up. Although you will need to avoid dairy products, calcium-rich or fortified foods, antacids and mineral supplements for your breakfast (including milk added to tea or coffee), a morning plan will allow you to have a normal lunch and evening meal.



... or taking REVOLADE in the evening

Alternatively, you may find it easiest to take your medication in the evening before you go to bed. Although you will need to avoid dairy products, calcium-rich or fortified foods, antacids and supplements (including milk added to tea or coffee) for your evening meal, an evening plan will allow you to have a normal breakfast in the morning.



While you are taking REVOLADE

While you are taking REVOLADE, your doctor may want to run extra tests.

These include:

Eye checks

REVOLADE may increase your risk of getting a cataract. Because of this, your doctor might recommend that you are checked for cataracts as part of routine eye tests.

Blood tests

Before you start taking REVOLADE your doctor will carry out blood tests to check your blood cells, including your platelet count. These tests will be done again while you are taking REVOLADE, and for up to 4 weeks after you have stopped taking it. Your doctor will advise you on how often you will need blood tests. Your doctor may also carry out some additional blood tests to check your liver and bone marrow are working properly.



Possible side effects

This section covers some of the more common side effects you may experience while taking REVOLADE, and how to manage them. More information is given in the leaflet inside your medication packet.

Very common side effects

- Headache
- Nausea (feeling sick)
- Diarrhoea

Common side effects

- Infections of the urinary system

Other side effects

- Bleeding (after you stop treatment)
- High platelet counts
- Risk of blood clots
- Liver problems
- Bone marrow problems

Side effects are common but contact your doctor if they become serious.



Do not stop taking REVOLADE without speaking to your doctor.

How to manage side effects

This table gives some ideas to help you manage some of the more common side effects of REVOLADE. Remember to avoid eating calcium-rich foods for **4 hours before and after** taking REVOLADE.

If you have:	Try to:
Headache	<ul style="list-style-type: none"> • Drink plenty of water • Limit caffeine intake (e.g. coffee, tea and soft drinks) • Avoid drinking alcohol • Avoid bright lights, loud noise, strong odours • Ask your doctor about medications used for headache • Try to go to sleep and wake up at the same time each day • Try to eat all meals at roughly the same time each day
Nausea (Feeling sick)	<ul style="list-style-type: none"> • Eat before you feel hungry • Eat small meals throughout the day • Eat foods at room temperature • Avoid foods that are greasy, very sweet or spicy • Sip liquids all day long • Go into another room to eat if cooking odours make you feel sick
Diarrhoea	<ul style="list-style-type: none"> • Drink 8 to 10 glasses a day of water, sports drinks, or other clear liquids • Avoid fried, fatty or spicy food • Avoid milk and milk products, including ice cream • Eat cooked vegetables instead of raw, and remove skins from fruits • Avoid herbal supplements as some may cause diarrhoea

Other side effects

Bleeding (after you stop treatment)

Tell your doctor if you have any bleeding or bruising in the 4 weeks after you have stopped taking REVOLADE.

High platelet counts

If your platelet count becomes too high, your doctor may adjust your dose, or ask you to stop taking REVOLADE.

Risk of blood clots

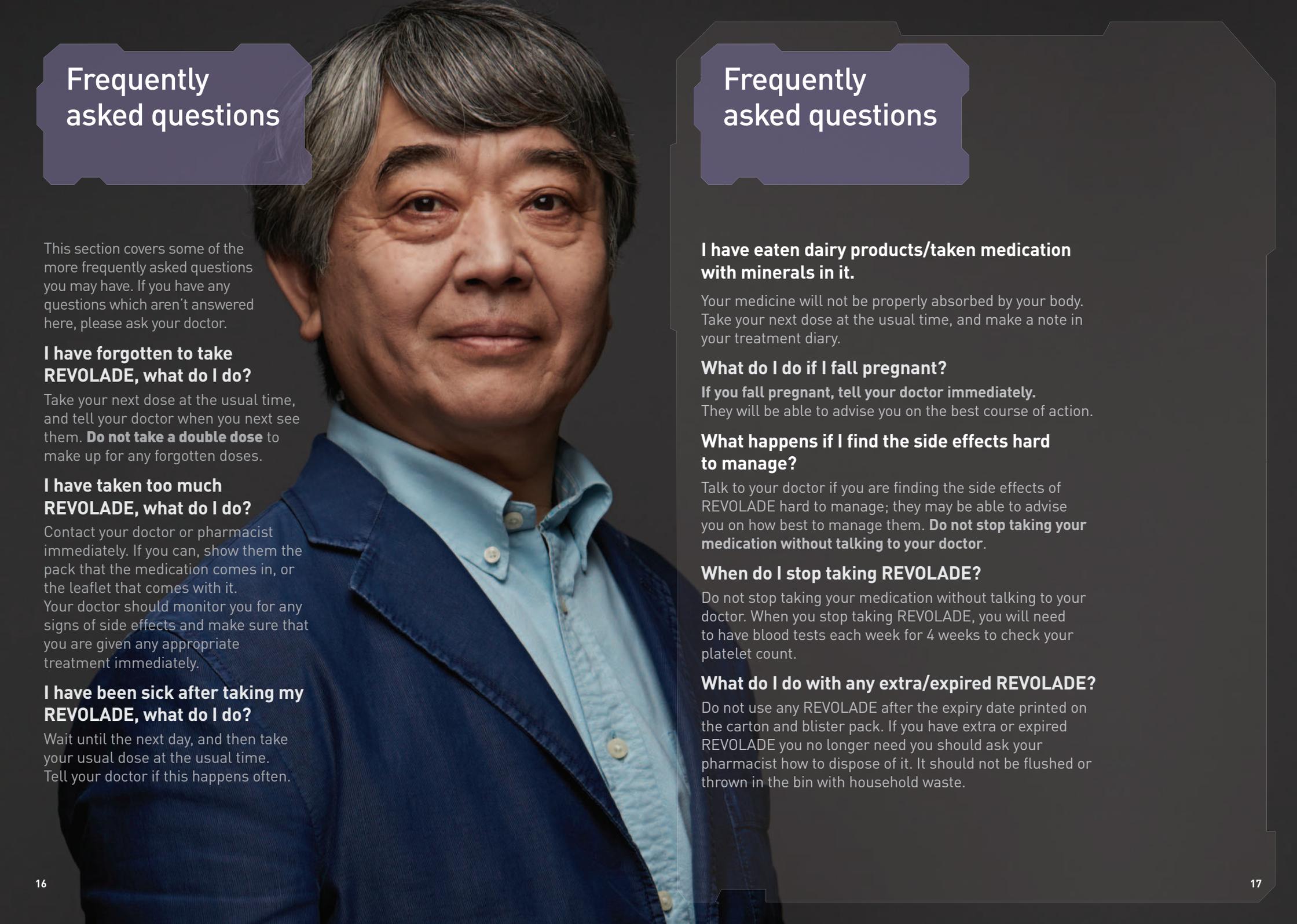
REVOLADE may increase your risk of developing a blood clot. You are more at risk if you: smoke, are elderly, take any contraceptive pill, hormone replacement therapy or have had recent surgery/trauma. You should contact your doctor immediately if you have any symptoms of a blood clot, such as:

- 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

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)
- White spots on your nails
- Swollen abdomen or ankles
- Any unusual bleeding or bruising
- Very dark coloured urine



Frequently asked questions

This section covers some of the more frequently asked questions you may have. If you have any questions which aren't answered here, please ask your doctor.

I have forgotten to take REVOLADE, what do I do?

Take your next dose at the usual time, and tell your doctor when you next see them. **Do not take a double dose** to make up for any forgotten doses.

I have taken too much REVOLADE, what do I do?

Contact your doctor 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.

I have been sick after taking my REVOLADE, what do I do?

Wait until the next day, and then take your usual dose at the usual time. Tell your doctor if this happens often.

Frequently asked questions

I have eaten dairy products/taken medication with minerals in it.

Your medicine will not be properly absorbed by your body. Take your next dose at the usual time, and make a note in your treatment diary.

What do I do if I fall pregnant?

If you fall pregnant, tell your doctor immediately. They will be able to advise you on the best course of action.

What happens if I find the side effects hard to manage?

Talk to your doctor if you are finding the side effects of REVOLADE hard to manage; they may be able to advise you on how best to manage them. **Do not stop taking your medication without talking to your doctor.**

When do I stop taking REVOLADE?

Do not stop taking your medication without talking to your doctor. When you stop taking REVOLADE, you will need to have blood tests each week for 4 weeks to check your platelet count.

What do I do with any extra/expired REVOLADE?

Do not use any REVOLADE after the expiry date printed on the carton and blister pack. If you have extra or expired REVOLADE you no longer need you should ask your pharmacist how to dispose of it. It should not be flushed or thrown in the bin with household waste.



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If you experience any side effects with GSK products, please report the case to GSK (Malta) Limited, 1, De la Cruz Avenue, Qormi QRM 2458, Malta [Tel: +356 21238131]. If you have questions about a specific medical condition, please consult a healthcare professional.