

REVOLADE®

film-coated tablets

Eltrombopag olamine

CONSUMER MEDICINE INFORMATION

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about REVOLADE.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking REVOLADE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

WHAT REVOLADE IS USED FOR

REVOLADE is a medicine that may help to increase the number of platelets, a type of blood cell that helps to reduce or prevent bleeding.

It may be used to treat a bleeding disorder known as idiopathic thrombocytopenic purpura (ITP). ITP is the condition of having a low platelet count (thrombocytopenia). ITP patients may suffer from an increased risk of bleeding.

Symptoms/signs patients with ITP may notice are petechiae (pinpoint sized flat round red spots under the skin), purpura (bruising), nosebleeds, bleeding gums and not being able to

control bleeding if cuts or injuries occur.

REVOLADE also may be used to treat patients with hepatitis C virus (HCV) infections for the treatment of thrombocytopenia.

Many patients with HCV infections have low platelet counts (thrombocytopenia) not only as a result of the disease but also due to some of the medicines that are used to treat the disease. The use of REVOLADE to increase and maintain the platelet count prior to and throughout antiviral treatment of HCV infection gives patients a better opportunity to maintain the optimal the dose and duration of their antiviral therapy.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU TAKE REVOLADE

You must not take REVOLADE:

- if you are allergic (hypersensitive) to eltrombopag olamine or to any other ingredients of REVOLADE (listed at the end of this leaflet).

Check with your doctor if you think this may apply to you.

Tell your doctor if you:

- have liver problems. You may need a lower dose of REVOLADE
- have kidney problems
- have risk factors for thrombosis (formation of a clot inside a blood vessel, obstructing the flow of blood), or you know that thrombosis occurs frequently in your family
- have a history of blood cancers
- have had or develop sensitivity to the sun
- have a history of cataracts (problems with sight)
- are pregnant or plan to become pregnant
- are breast feeding.

Taking other medicines

There are certain groups of medicines, including prescription and non-prescription medicines and vitamins that interact with REVOLADE that you should not take at the same time or that require a dose adjustment while receiving a course of REVOLADE. These medications include some products within the following groups:

- antacid medicines to treat stomach ulcers or heartburn
- certain drugs used to lower cholesterol (statins)
- certain drugs used to treat human immunodeficiency virus (HIV) (lopinavir / ritonavir)
- minerals such as aluminium, calcium, iron, magnesium,

selenium and zinc which may be found in mineral supplements and complementary medicines.

Your doctor will review the medicines you are currently taking to make sure you are not taking something that cannot be taken with the REVOLADE. If you require any of these medications and a suitable substitute is not available, please discuss this with your doctor.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking REVOLADE with food and drink

REVOLADE is affected by calcium intake. REVOLADE may be taken with food low in calcium such as:

- fruits such as pineapple, raisins and strawberries
- lean ham, chicken or beef
- unfortified fruit juice, soy milk and grain. (Unfortified means no added calcium, magnesium or iron).

Please discuss this matter with your doctor; they will be able to advise on the most suitable meals to be eaten while you are taking REVOLADE.

Don't take REVOLADE during the 4 hours before or after you take:

- **antacid medication**
to treat indigestion
- **mineral supplements,**
such as aluminium, calcium, iron, magnesium, selenium or zinc
- **dairy products.**

If you do, the medicine will not be properly absorbed into your body.

One way to avoid issues with these products would be to take them in the morning and REVOLADE in the evening. Ask your doctor or pharmacist for advice if you are unsure.

Pregnancy and breast-feeding

You should avoid becoming pregnant while taking REVOLADE because the effect of REVOLADE on pregnancy is not known. You should use a reliable method of contraception (a way to prevent you from becoming pregnant).

If you become pregnant during treatment, tell your doctor.

Breast feeding is not recommended while you are taking REVOLADE. It is not known whether REVOLADE passes into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are unsure.

Phototoxicity

REVOLADE may cause you to sunburn more easily. As a safety precaution, while taking REVOLADE, you should avoid exposure to high-intensity artificial UV light such as tanning beds and being unprotected when in direct sunlight. If you do need to be in the sun, use protective clothing, sun glasses and sunscreen.

Cataracts

In animal studies it was found that REVOLADE caused the development of cataracts (a clouding of the lens in the eye). In HCV trials in humans an increased risk in the incidence of cataracts has also been seen. Your doctor may recommend that you are checked for cataracts as part of any routine eye examination.

HOW TO TAKE REVOLADE

Always take REVOLADE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to take and when to take it

REVOLADE should be taken at least 4 hours before or at least 4 hours after antacids, dairy products or some mineral supplements such as iron, calcium, magnesium, aluminium, selenium and zinc.

One way to avoid issues with these products would be to take them in the morning and REVOLADE in the evening.

The usual starting dose for ITP patients is one 50 mg REVOLADE tablet a day. People of East Asian origin (Chinese, Japanese, Taiwanese, Korean or Thai) need to start at a lower dose of 25 mg.

The usual starting dose for HCV patients is one 25 mg REVOLADE tablet a day. People of East Asian origin (Chinese, Japanese, Taiwanese, Korean or Thai) will start on the same 25 mg dose.

Based on your response to REVOLADE your doctor will adapt the dose and may recommend that your daily dose of REVOLADE be increased or decreased.

Please expect that at the beginning of therapy your platelet count and other routine blood parameters will need to be monitored frequently. Your doctor will also carry out blood tests to check your liver function before and during treatment with REVOLADE.

How to take it

Swallow REVOLADE with a glass of water.

If you take more REVOLADE than you should (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (In Australia call 13 11 26. In New Zealand call 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much REVOLADE. Do this

even if there are no signs of discomfort or poisoning. If you are not sure what to do, contact your doctor or pharmacist.

If you forget to take REVOLADE

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of REVOLADE, ask your doctor or pharmacist.

Once you have started taking REVOLADE

Do not stop taking REVOLADE before talking to your doctor or pharmacist.

After you have stopped taking REVOLADE, your bleeding symptoms may come back. Tell your doctor or pharmacist if you have any bleeding in the 4 weeks after you stop taking REVOLADE.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

WHAT ARE THE POSSIBLE SIDE-EFFECTS

Like all medicines, REVOLADE can cause side effects, although not everybody gets them.

The following side effects have been reported to be associated with treatment with REVOLADE in patients with ITP.

Very common side effects

These may affect more than 1 in 10 people treated with REVOLADE.

- Nausea and diarrhoea

Common side effects

These may affect up to 1 in 10 people treated with REVOLADE.

- Increase of liver enzymes called aspartate and alanine transaminases,
- Dry mouth
- Vomiting
- Alopecia (unusual hair loss or thinning)
- Rash
- Back pain
- Musculoskeletal chest pain, musculoskeletal pain (pain that affects muscles and tendons along with bones)
- Myalgia (aching muscles)
- Pharyngitis (sore throat and discomfort when swallowing)

Urinary tract infection (infection in the system that produces urine).

The following side effects have been reported to be associated with treatment with REVOLADE in combination with peginterferon and ribavirin in patients with HCV.

Very common side effects

These may affect more than 1 in 10 people treated with REVOLADE and antiviral agents.

- Fever
- Fatigue
- Chills
- Headache
- Cough
- Nausea
- Diarrhoea
- Unusual hair loss or thinning
- Muscle pain
- Itching
- Feeling weak
- Difficulty sleeping
- Loss of appetite
- Flu-like symptoms
- Oedema peripheral (swelling of the hands, ankles or feet)

Very common side effects that may show up in blood tests

- Anaemia (reduced number of red blood cells)

Common side effects that may show up in blood tests

These may affect up to 1 in 10 people treated with REVOLADE and antiviral agents.

- Increase in bilirubin (a substance produced by the liver)

Tell your doctor immediately if you get any of these symptoms. These symptoms may persist after you stop taking REVOLADE.

Liver problems

REVOLADE may damage your liver and cause serious, even life threatening, illness. You must have blood tests to check your liver before you start taking REVOLADE and during treatment. When you are given certain antiviral treatments together with REVOLADE for the treatment of thrombocytopenia due to hepatitis C virus (HCV) infections some liver problems can get worse.

Your doctor will order these blood tests and any other tests required. In some cases REVOLADE treatment may need to be stopped. Tell your doctor right away if you have any of these signs and symptoms of liver problems:

- jaundice (yellowing of the skin or the whites of the eyes)
- unusual darkening of the urine
- unusual tiredness
- right upper stomach area pain

Bleeding after you stop treatment

When you stop taking REVOLADE, your blood platelet count will drop back down to what it was before you started taking REVOLADE. These effects are most likely to happen

within 4 weeks after you stop taking REVOLADE. The lower platelet counts may increase your risk of bleeding. Your doctor will check your platelet counts for at least 4 weeks after you stop taking REVOLADE. Tell your doctor or pharmacist if you have any bruising or bleeding after you stop taking REVOLADE.

You may have problems with your bone marrow

People with the disease for which you are being treated may have problems with their bone marrow. Medicines like REVOLADE could make this problem worse. Your doctor may also carry out tests to check your bone marrow during treatment with REVOLADE.

High platelet counts and higher chance for blood clots

You have a higher chance of getting a blood clot if your platelet count is too high during treatment with REVOLADE, but blood clots can occur with normal or even low platelet counts. If you have cirrhosis of the liver you are at risk of a blood clot in a blood vessel that feeds your liver (portal vein thrombosis). You may have severe complications from some forms of blood clots, such as clots that travel to the lungs or that cause heart attacks or strokes. Your doctor will check your blood platelet counts, and change your dose or stop REVOLADE if your platelet counts get too high. Tell your doctor right away if you have signs and symptoms of a blood clot in the leg, such as swelling or pain/tenderness of one leg.

If any of the side effects listed in this leaflet get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

STORAGE

Do not store above 30°C.

Keep out of the reach and sight of children.

Do not use REVOLADE after the expiry date which is stated on the carton.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

PRODUCT DESCRIPTION

What REVOLADE looks like

REVOLADE is presented in packs of 28 tablets.

25 mg tablets

REVOLADE film-coated tablets are round, biconvex, white, debossed with 'GS NX3' and '25' on one side.

50 mg tablets

REVOLADE film-coated tablets are round, biconvex, brown, debossed with 'GS UFU' and '50' on one side.

75 mg tablets

REVOLADE film-coated tablets are round, biconvex, pink, debossed with 'GS FSS' and '75' on one side.

Ingredients

REVOLADE contains the active ingredient eltrombopag olamine.

REVOLADE also contains hypromellose, macrogol 400, magnesium stearate, mannitol, cellulose - microcrystalline, povidone, sodium starch glycollate, titanium dioxide (E171).

25 mg

The 25 mg tablet also contains polysorbate 80.

50 mg

The 50 mg tablet also contains iron oxide red CI77491 (E172) and iron oxide yellow CI77492 (E172).

75 mg

The 75 mg tablet also contains iron oxide black CI77499 and oxide red CI77491 (E172).

SUPPLIER

Your REVOLADE is supplied by:

GlaxoSmithKline Australia Ltd
Level 4, 436 Johnston St,
Abbotsford, Victoria, 3067
AUSTRALIA.

or

GlaxoSmithKline NZ Ltd
Private Bag 106600
Downtown
Auckland 1143
NEW ZEALAND

WHERE TO GO FOR FURTHER INFORMATION

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you the individual advice you need.

In Australia: For more information on Revolade please go to www.gsk.com.au/revolade or your doctor or pharmacist.

In New Zealand: For more information on Revolade please go to your doctor or pharmacist.

This leaflet was prepared on 27 August 2013.

The information provided applies only to REVOLADE®.

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25 mg tablets AUST R 158419

50 mg tablets AUST R 158356

75 mg tablets AUST R 200121

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