REVOLADE®

film coated tablets

Eltrombopag olamine

(el-TROM-boe-pag)

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.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.medsafe.govt.nz

Those updates may contain important information about the medicine and its use of which you should be aware.

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 with the medicine.

You may need to read it again.

What REVOLADE is used for

REVOLADE contains the active substance eltrombopag olamine, which belongs to a group of medicines called 'Thrombopoietin (TPO) receptor agonists'. TPO stimulates the production of platelets by attaching to certain receptors in the bone marrow.

REVOLADE is a medicine that is used to treat a number of conditions and helps to increase production of the number of platelets, a type of blood cell that helps to reduce or prevent bleeding.

Low platelet count (ITP)

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). Patients with ITP may suffer from an increased risk of bleeding.

The symptoms of ITP may include:

- Pinpoint sized flat round red spots under the skin (petechiae)
- Bruising (purpura)
- Nosebleeds
- Bleeding gums
- Not being able to control bleeding if cuts or injuries occur.

REVOLADE is not recommended in patients less than 18 years of age with ITP.

Hepatitis C virus (HCV)

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 in adults 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.

REVOLADE is not recommended to treat children with hepatitis C virus (HCV) infections (to treat low platelet counts).

Severe aplastic anaemia (SAA)

REVOLADE may also be used to treat adult patients with low blood counts caused by severe aplastic anaemia (SAA). This is a blood disorder in which the bone marrow is damaged and does not make enough blood cells, especially red and white blood cells and platelets. Red blood cells carry oxygen to tissues in the body. White blood cells fight infection and disease. Platelets help blood to clot.

The low number of blood cells puts a patient with this condition at risk of tiredness, infections, and bleeding. REVOLADE may be used to treat patients with these low blood counts:

- In combination with immunosuppressive therapy in adults or children from 2 years of age; or
- In adult patients when other medicines to treat SAA have not worked well enough.

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.

REVOLADE may be used to treat children from 2 to 17 years with low blood counts caused by severe aplastic anaemia. There are limited data on the use of REVOLADE in patients aged 65 years and older. Care should be taken when using REVOLADE if you are aged 65 years or above.

This medicine is available only with a doctor's prescription.

It is not addictive.

Before you take REVOLADE

When you must not take it

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). Some of the symptoms of an allergic reaction may include:
  - — Shortness of breath, wheezing or difficulty breathing;
  - — Swelling of the face, lips, tongue or other parts of the body;
  - — Rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack has passed, or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor if you think that any of these may apply to you.

Before you start to take it

Tell your doctor if you have any of the following medical conditions:

- Liver problems. Your doctor will request blood tests to check your liver function before and during treatment with REVOLADE. You may need a lower dose of REVOLADE
- Kidney problems
- If you have a history of formation of a clot inside a blood vessel, obstructing the flow of blood (thrombosis or you know that blood clots occur frequently in your family
- If you have another blood condition, such as myelodysplastic syndrome (MDS). Your doctor will carry out tests to check that you do not have this blood condition before you start REVOLADE. If you have MDS and take REVOLADE your MDS may get worse.
- History of bone disorders
- History of blood cancers
- Had or developed sensitivity to the sun
- History of problems with sight (cataracts).

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

Pregnancy

You should avoid becoming pregnant while taking REVOLADE as its effect on pregnancy is not known.

REVOLADE is only used during pregnancy if justified by medical need, as the effect of REVOLADE in pregnancy is not known.

You should use a reliable method of contraception (a way to prevent you from becoming pregnant).

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Breast-feeding

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

Female patients of childbearing potential and male patients

REVOLADE can harm an unborn baby.

If you are pregnant, think you may be pregnant or are planning to have a baby, you must use reliable birth control (contraception) while you are taking REVOLADE and for at least 7 days after you stop taking REVOLADE.

Ask your doctor about options of effective birth control.

If you do become pregnant while you are taking REVOLADE, tell your doctor immediately.

Taking other medicines

Tell your doctor or pharmacist if you:

- Are taking any other medicines
- Have taken any medicines recently, or
- Start taking new medicines.

This includes any vitamins, herbal medicines, mineral supplements, and other medicines you have bought without a prescription. There are certain medicines, including prescription, non-prescription medicines, and vitamins that interact with REVOLADE.

You should not take these at the same time or they may 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 medicines used to lower cholesterol (statins)
- Minerals such as aluminium, calcium, iron, magnesium, selenium and zinc which may be found in mineral supplements and complementary medicines.

There are certain groups of medicines, requiring additional platelet monitoring. These medicines include:

- A medicine used for transplantations or immune diseases (cyclosporin)
- Certain medicines used to treat human immunodeficiency virus (HIV) (lopinavir / ritonavir).
- Certain medicines used to treat low platelet count due to hepatitis C (interferon-based treatments).

Ask your doctor, pharmacist or healthcare provider if you are not sure whether your medicine is one of the medicines listed above.

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.

Taking REVOLADE with food and drink

Do not take REVOLADE with food or products rich in calcium.

REVOLADE is affected by calcium intake.

REVOLADE may be taken with food that is 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, pharmacist, or healthcare provider.

Your doctor will be able to advise on the most suitable meals to be eaten while you are taking REVOLADE.

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.

When to take it

Take REVOLADE once a day, every day, at about the same time each day.

Taking REVOLADE at the same time each day will help you remember when to take your tablets.

Don't take REVOLADE during the 2 hours before or 4 hours after you take:

- Antacid medication to treat indigestion
- Mineral supplements, containing aluminium, calcium, iron, magnesium, selenium or zinc
- Dairy products.

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

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

If you are unsure, ask your doctor or pharmacist for advice.

How much to take **Adult Immune thrombocytopenia patients**

- The usual starting dose for adult patients is one 50 mg REVOLADE tablet a day.
- Patients of East-/Southeast-Asian origin need to start at a lower dose of 25 mg per day.

Adult HCV patients

- The usual starting dose for adult HCV patients is one 25 mg REVOLADE tablet a day.
- Patients of East-/Southeast-Asian origin will start on the same 25 mg dose.

Patients with previously treated SAA

- The usual starting dose of REVOLADE for patients with previously treated SAA that reoccurred is one 50 mg REVOLADE tablet a day.
- Patients of East/Southeast-Asian origin need to start at a lower dose of 25 mg.

Severe aplastic anaemia

The usual starting dose for patients with SAA, given with standard immunosuppressive therapy is:

- Adult and adolescent patients 12 to 17 years of age: 150 mg once a day for 6 months. Patients of East/Southeast-Asian origin should receive a reduced dose of 75 mg once a day for 6 months.
- Paediatric patients aged 6 to 11 years: 75 mg once a day for 6 months. Patients of East/Southeast-Asian should receive a reduced dose of 37.5 mg once a day for 6 months.
- Paediatric patients aged 2 to 5 years: 2.5 mg/kg once a day for 6 months. Patients of East/Southeast-Asian origin should receive a reduced dose of 1.25 mg/kg once a day for 6 months.

Your doctor will prescribe the appropriate immunosuppressive therapy in addition to REVOLADE

You should not take more REVOLADE than your doctor prescribed**.**

Dose changes by your doctor

Based on your response to REVOLADE or if you have kidney, liver or other problems, or if you are elderly, your doctor will adapt the dose and may recommend that your daily dose of REVOLADE be increased or decreased.

How to take it

Swallow REVOLADE tablets whole with a full glass of water.

How long to take it

Keep taking your medicine for as long as your doctor tells you.

After you have stopped taking REVOLADE, your bleeding symptoms may come back.

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

If you forget to take it

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

This may increase the chance of you getting an unwanted side effect.

Simply resume your dosing with the next scheduled dose on the following day.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

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

If you take more REVOLADE than you should (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (call 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you have taken too much REVOLADE or if someone else has accidentally taken your medicine.

Do this even if there are no signs of discomfort or poisoning.

Medical treatment may be necessary.

Symptoms of an overdose may include:

- a mild rash
- feeling that your heart is beating slow
- fatigue.

Take the pack with you.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking REVOLADE

Monitoring during treatment

At the beginning of REVOLADE 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.

Your doctor may also recommend that you be checked for cataracts as part of any routine eye examination. This is a precaution as during HCV trials, an increased risk of cataracts was seen.

Things you must do

If you are about to be started on any new medicines, remind your doctor and pharmacist that you are taking REVOLADE.

Expect that at the beginning of REVOLADE 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.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

Sensitivity to sunlight

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, sunglasses and sunscreen.

If you have any further questions on the use of this product, ask your doctor or pharmacist. Things you must not do

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

If your doctor advises you to stop treatment with REVOLADE, your platelet count will then be checked each week for four weeks.

Do not take REVOLADE to treat any other complaints unless your doctor tells you to.

Do not give your medicines to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how REVOLADE affects you.

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 in the 4 weeks after you stop taking REVOLADE.

CATARACTS

Your doctor may recommend that you are checked for cataracts as part of any routine eye examination.

Symptoms of cataracts include blurred vision, or difficulty seeing.

LIVER PROBLEMS

You must have blood tests to check your liver before you start taking

REVOLADE and during REVOLADE treatment.

REVOLADE may damage your liver and cause serious, even life threatening, illness.

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 the 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:

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

HIGH PLATELET COUNTS & THE RISK OF BLOOD CLOTS

If your platelet count is too high during treatment with REVOLADE, you have a higher possibility of getting a blood clot. However, 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 may 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 straightaway if you have any signs or symptoms of a blood clot in the leg, such as:

- Swelling or
- Pain/tenderness of one leg.

When you stop taking REVOLADE

If your doctor advises you to stop taking REVOLADE, your platelet count will drop back down to what it was before you started taking REVOLADE. This is most likely to happen within four weeks after you stop taking REVOLADE. Your doctor will check your platelet counts for at least four weeks after you stop taking REVOLADE.

Tell your doctor or pharmacist if you have any bleeding after you stop taking REVOLADE.

The lower platelet counts may increase your risk of bleeding.

Possible side effects

As with all medicines, patients treated with REVOLADE may experience side effects, although not everybody gets them.

Do not be alarmed by these lists of possible side effects.

You may not experience any of them.

Some side effects could be serious.

SERIOUS SIDE EFFECTS (All indications)

STOP taking REVOLADE and seek medical help immediately if you experience the following serious side effects:

- Blood clots (thromboembolic events)
- Loss of liver function or liver problems, with symptoms such as yellowing of the skin or the white of the eyes (jaundice), unusual darkening of the urine, unusual tiredness, right upper stomach area pain.
- Liver failure (serious disturbance of liver function) (hepatic failure)
- Damage to the smallest blood vessels inside the kidney leading to loss of kidney function (thrombotic microangiopathy with acute renal failure).

Other possible serious side effects

Other possible side effects include the following lists. If the side effects become severe, please tell your doctor, pharmacist or healthcare provider.

ADULT PATIENTS WITH ITP

Stop taking REVOLADE and tell your doctor, pharmacist or healthcare provider immediately if you get any of these serious side effects while taking REVOLADE.

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

Very common side effects

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

- Diarrhoea
- Nausea
- Back pain

Very common side effects that may show up in blood tests:

- Increase in a liver enzyme.

Common side effects

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

- Dry mouth
- Rash
- Vomiting
- Cataract (a clouding of the lens in the eye)
- Sore throat or discomfort when swallowing (pharyngitis)
- Muscle pain (myalgia)
- Pain that affects muscles and tendons along with bones (musculoskeletal pain including musculoskeletal chest pain)
- Unusual hair loss or thinning
- Urinary tract infections.

Common side effects that may show up in blood tests:

- Increased level of

- bilirubin, which may cause a yellow discolouration of your skin, the whites of your eyes, body fluids (jaundice)
- a type of liver enzyme (aminotransferase).

PATIENTS WITH HCV

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

Very common side effects

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

- Fever
- Feeling very tired or fatigued
- Headache
- Nausea
- Flu-like symptoms
- Diarrhoea
- Loss of appetite
- Itching
- Cough
- Chills
- Muscle pain (myalgia)
- Unusual hair loss or thinning of the hair (alopecia)
- Difficulty sleeping
- Generalised swelling (oedema).

Very common side effects that may show up in blood tests:

- Reduced number of red blood cells (anaemia)
- Increased level of bilirubin, which may cause a yellow discolouration of your skin, the whites of your eyes, body fluids (jaundice).

Common side effects

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

- Liver failure (serious disturbance of liver function)
- Loss of functions of the liver due to side effects of REVOLADE treatment
- Blood clots
- Rash
- Cataract.

PATIENTS WITH SEVERE APLASTIC ANAEMIA (where other medicines have not worked well)

The following side effects have been reported to be associated with *Revolade* treatment in patients with severe aplastic anaemia (SAA).

Very common side effects

These may affect more than 1 in 10 SAA patients treated with Revolade.

- Nausea
- Feeling very tired (fatigue)
- Cough
- Headache
- Diarrhoea
- Shortness of breath
- Pain in arms, legs, hands and feet (pain in extremities)
- Pain in the mouth and throat (oropharyngeal pain)
- Dizziness
- Fever
- Abdominal pain
- Joint pain (arthralgia)
- Muscle spasms
- Runny nose
- Bruising
- Fever with very low number of neutrophils in the blood (white blood cells that are needed to fight infections) (febrile neutropenia).

Very common side effects that may show up in blood tests:

- Increase in some liver enzymes.

Common side effects

These may affect up to 1 in 10 people treated with Revolade:

- Rash.
- Runny nose
- Muscle spasms
- Cataract (a clouding of the lens in the eye).

Common side effects that may show up in blood tests:

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

Other side effects

- Yellowing or darkening of skin (skin discolouration).

PATIENTS WITH SEVERE APLASTIC ANAEMIA (given with standard immunosuppressive therapy)

The following side effects have been reported to be associated with REVOLADE treatment in patients with SAA when it is given with standard immunosuppressive therapy.

Common side effects

- More intense colour of the skin (hyperpigmentation)

Very common side effects

- Yellowing of the skin or whites of the eyes (due to jaundice or increased level of the pigment bilirubin in the blood)

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.

After taking REVOLADE

Storage

Do not store above 30°C. Store in a cool dark place.

Keep out of the reach and sight of children.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not store REVOLADE or any other medicine in the car, in the bathroom, near a sink, or on a windowsill.

Heat and dampness can destroy some medicines.

Disposal

Medicines should not be disposed of via wastewater or household waste.

If your doctor tells you to stop taking this medicine or the expiry date has passed, return it to your pharmacist for disposal.

Product Description

What REVOLADE looks like

Tablets

REVOLADE film-coated tablets are supplied in foil blisters in packs of 28 tablets. The tablets are available in two strengths.

- **25 mg tablets**

  REVOLADE film-coated tablets are round, biconvex, white, and debossed with 'GS NX3' and '25' on one side. They contain 32 mg of eltrombopag olamine, equivalent to 25 mg of eltrombopag.

- **50 mg tablets**

  REVOLADE film-coated tablets are round, biconvex, brown, and debossed with 'GS UFU' and '50' on one side. They contain 64 mg of eltrombopag olamine, equivalent to 50 mg of eltrombopag.

Ingredients

REVOLADE tablets contains the active ingredient eltrombopag olamine.

REVOLADE tablets also contain the following inactive ingredients:

- Hypromellose (E464)
- Macrogol 400 (E1521)
- Magnesium stearate (E572)
- Mannitol (E421)
- Microcrystalline cellulose (E460(i))
- Povidone (E1201)
- Sodium starch glycollate
- Titanium dioxide (E171).

25 mg

This tablet also contains:

- Polysorbate 80 (E433).

50 mg

This tablet also contains:

- Iron oxide red CI 77491 (E172)
- Iron oxide yellow CI 77492 (E172).

REVOLADE tablets do not contain lactose, sucrose, tartrazine or any other azo dyes.

Supplier

REVOLADE is supplied by:

Novartis New Zealand Limited

PO Box 99102
Newmarket, Auckland 1149
Telephone 0800 354 335

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