

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **REVOLADE**[®]

eltrombopag tablets

Read this carefully before you start taking **REVOLADE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **REVOLADE**.

Serious Warnings and Precautions

Your risk of experiencing liver problems is increased if you have chronic (long-term) liver disease and you take **REVOLADE** with pegylated interferon and ribavirin (drugs used to treat hepatitis C). The side effects you may experience can include liver failure and death. Your healthcare professional may monitor your liver symptoms closely while you are taking **REVOLADE**.

What is REVOLADE used for?

- **Chronic immune thrombocytopenia (ITP):** **REVOLADE** is used to treat chronic immune thrombocytopenia (ITP) in adults and children (1 year of age and older). ITP is a bleeding disorder caused by a low blood platelet count. **REVOLADE** is taken:
 - to increase platelet counts.
 - when other medications have not worked.
- **Severe Aplastic Anemia (SAA):** **REVOLADE** is used to treat adults with low blood counts caused by severe aplastic anemia (SAA). SAA is a disease in which the body is not producing enough red blood cells, white blood cells and platelets. **REVOLADE** is used when other drugs don't work.
- **Chronic hepatitis C (HCV) associated thrombocytopenia:** **REVOLADE** is used to treat HCV infections. Many patients with HCV have low platelet counts due to some of the medicines that are used to treat the disease. Taking **REVOLADE** may make it easier to complete a full treatment plan of antiviral medicine.

How does REVOLADE work?

REVOLADE is believed to act in the similar way as thrombopoietin, which is a hormone made by the body. Thrombopoietin activates the production of platelets by attaching to certain targets in the bone marrow. The medicinal ingredient in **REVOLADE**, eltrombopag, attaches to the same targets in the bone marrow and activates the production of platelets. This leads to an increased production of platelets, improving platelet counts and other types of blood cells.

What are the ingredients in REVOLADE?

Medicinal ingredients: eltrombopag as eltrombopag olamine

Non-medicinal ingredients: Tablets: Hypromellose, macrogol, magnesium stearate, mannitol, microcrystalline cellulose, povidone, sodium starch glycolate and titanium dioxide.

25 mg tablets also contain polysorbate.

50 mg tablets also contain iron oxide yellow and iron oxide red.

REVOLADE comes in the following dosage forms:

Tablets: 25 mg and 50 mg.

Do not use REVOLADE if:

- you are allergic to REVOLADE or to any of its other ingredients
- you have severe liver problems

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take REVOLADE. Talk about any health conditions or problems you may have, including if you:

- Have liver problems.
- Have kidney problems.
- Have a history of formation of a clot inside a blood vessel, obstructing the flow of blood (thrombosis), or you know that thrombosis occurs frequently in your family. The risk of blood clots may be increased in certain conditions. For example if you: are elderly, have been bedridden, have cancer, are taking the birth control pill, or hormone replacement therapy, have recently had surgery or had an injury, are overweight, if you are a smoker.
- Have a blood condition caused by chemotherapy or have another blood condition, such as myelodysplastic syndrome (MDS). Your healthcare professional 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.
- Are taking direct acting antiviral drugs to treat chronic hepatitis C virus.
- Have a history of problems with sight (cataracts). Taking REVOLADE may cause the development of cataracts (a clouding of the lens in the eye). Your healthcare professional may recommend eye examinations before and during your treatment with REVOLADE.
- Are pregnant or plan to become pregnant. You should avoid becoming pregnant while taking REVOLADE. Use effective birth control during treatment. Tell your healthcare professional right away if you become pregnant or think you may be pregnant during treatment with REVOLADE.
- Are breast-feeding or planning to breastfeed. Breast-feeding is not recommended while you are taking REVOLADE.
- Are over 65 years of age.
- Are of Asian descent.

Other warnings you should know about:

Pegylated interferon and ribavirin drugs

Read the Product Monograph for these two drugs (pegylated interferon and ribavirin) for their key safety information. Both are used with REVOLADE when you are being treated for HCV and ITP.

Ending treatment with REVOLADE

If you stop taking REVOLADE, your blood platelet count is likely to become low again within weeks. This may increase your risk of bleeding. The risk is increased if you are taking blood

thinner medications when you end treatment with REVOLADE. The platelet count will be monitored, and your healthcare professional will discuss appropriate therapy with you.

Monitoring and tests:

Your healthcare professional will conduct the following tests:

- Blood test: Before you start taking REVOLADE, blood tests will be conducted to check your blood cells, including platelets. These tests will also be completed throughout and following the end of your treatment with REVOLADE. Your Healthcare professional may modify your dosage if your platelet levels are too high.
- Liver function test: You will have blood tests to check your liver function before you start taking REVOLADE and during your treatment. Your Healthcare professional may need to stop your treatment if your liver function test shows signs of liver damage
- Bone marrow exam: Your healthcare professional may examine your bone marrow before, during and after treatment with REVOLADE. Your Healthcare professional may end your treatment if new genetic disorders are identified.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with REVOLADE:

- Antacid medicines to treat stomach ulcers, indigestion or heartburn
- Certain medicines used to lower cholesterol (statins)
- Minerals such as aluminum, calcium, iron, magnesium, selenium and zinc which may be found in mineral supplements.
- Cyclosporine and lopinavir/ritonavir (medicines to treat HIV infection). Your healthcare professional will monitor your platelet counts if you take REVOLADE with cyclosporine and lopinavir/ritonavir.

Do **NOT** take REVOLADE with dairy products. Examples include but not limited to are:

- Milk
- Ice cream
- Yogurt

- 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).

Speak to your healthcare professional about the most suitable meals to be eaten while you are taking REVOLADE.

How to take REVOLADE:

- Swallow tablets whole with some water. **Do NOT** crush tablets and then mix with food or liquids. If your child is not able to swallow the tablets whole, talk to your healthcare professional.
- To help your body absorb the medicine properly, take REVOLADE at least **2 hours before or 4 hours after** you take:
 - antacid medication (to treat indigestion);

- mineral supplements (such as aluminium, calcium, iron, magnesium, selenium or zinc), or
- dairy products.
- One way to avoid issues with these products would be to take them in the morning and take REVOLADE in the evening. Ask your healthcare professional for advice if you are unsure.
- Take REVOLADE as long as your healthcare professional advises you to do so. Your daily dose may change depending on your response to REVOLADE or the condition of your liver.
- Do not take REVOLADE for more than one year at a time if you are being treated for HCV Associated Thrombocytopenia. Your treatment should be reassessed by your healthcare professional after one year. Once your anti-viral therapy ends, treatment with REVOLADE will be stopped

Usual adult dose (18 years and older):

For ITP and SAA treatment:

The recommended starting dose for ITP and SAA treatment: 50 mg once a day.

The maximum recommended dose for ITP treatment: 75 mg once a day.

The maximum recommended dose for SAA treatment: 150 mg once a day.

For HCV treatment:

The recommended starting dose: 25 mg once a day.

The maximum recommended dose: 100 mg once a day

For HCV, ITP and SAA treatment (East/Southeast-Asian origin):

The recommended starting dose: 25 mg once a day.

Usual children dose (1 to 17 years old):

For ITP treatment:

The recommended starting dose for 1 to 5 years of age: 25 mg once a day.

The recommended starting dose for 6 to 17 years of age: 50 mg once a day.

The recommended starting dose for 6 to 17 years of age of East/Southeast-Asian origin: 25 mg once a day.

Overdose:

If you think you, or a person you are caring for, have taken too much REVOLADE, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you missed a dose of this medication, take it as soon as you remember. But if it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Go back to the regular dosing schedule. Do not take two doses at the same time

What are possible side effects from using REVOLADE?

These are not all the possible side effects you may feel when taking REVOLADE. If you experience any side effects not listed here, contact your healthcare professional.

The side effects of REVOLADE are:

- Abdominal pain/discomfort
- Abnormal colour of urine or feces
- Altered sense of taste
- Back pain
- Chills
- Cold sweats
- Constipation, passing gas
- Cough, runny nose
- Enlarged tonsils
- Decreased or increased appetite
- Diarrhea
- Dry mouth
- Fatigue
- Feeling unwell, feeling pain
- Fever or feeling hot
- Groin pain
- Headache
- Head lice
- Increased sweating
- Indigestion
- Itchy skin, rash, red or purple round spots on skin
- Lack of energy, weakness
- Motion sickness
- Muscle spasms
- Nausea
- Night sweats
- Shortness of breath when walking
- Sleepiness or trouble sleeping
- Swelling of face, arms, legs, hands, ankles or feet
- Swollen/inflamed wounds
- Toothache
- Vomiting
- Weight loss

REVOLADE can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
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Bone marrow changes: anemia, weakness and fatigue due to decreased red blood cells, infections due to decreased white blood cells, bruising due to low blood platelets		✓	
Decreased red blood cells: fatigue, loss of energy, weakness, shortness of breath		✓	
Febrile neutropenia: fever with low white blood cell count		✓	
Upper respiratory tract infection: runny nose, nasal congestion, cough, and sneezing		✓	
COMMON			
Anxiety: feelings of nervousness, restlessness, or panic, increased heart rate, rapid breathing (hyperventilation), sweating, trembling, trouble sleeping		✓	
Aseptic Meningitis (inflammation of the protective lining of the brain that is not caused by infection): fever, headache, stiff neck, sensitivity to light, loss of appetite, nausea/vomiting		✓	
Blood clots: swelling, pain or tenderness in one part of the body, sudden shortness of breath especially when accompanied with sharp pain in the chest and/or rapid breathing, abdominal pain, enlarged abdomen, blood in stool		✓	
Bulimia nervosa (Eating Disorder): preoccupation with weight/weight gain, repeated episodes of eating large amounts of food in one sitting (binging), forced vomiting or exercise for the purpose of weight loss		✓	
Depression: difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive)		✓	
Eye disorders: Cataracts: clouded, blurred or dim vision, seeing halos around lights, fading or yellowing of colours Blurred Vision Dry Eye Visual impairment: changes in vision		✓	

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Eye floaters: spots in vision that appear as specks or strings of floating material; spots that move with eye movement			
Fainting or dizziness: fainting, dizziness when standing up or sitting down		✓	
Hemorrhoids (swollen veins in the wall of your rectum and anus): lumps on anus, painful or swollen anus, bleeding from anus or rectum, itching or mucus in rectum		✓	
High levels of iron in the blood: fatigue, weakness, irregular heartbeat, joint pain, stomach pain		✓	
Liver Problems including Hepatitis B and liver tumors: jaundice (yellow colour to skin, whites of the eyes), unusual dark urine, unusual tiredness, right upper stomach area pain, tenderness in the upper right part of the abdomen, swollen abdomen, right shoulder pain and signs of shock and blood loss, bleeding easily, mental disorientation or confusion, sleepiness, coma		✓	
Low blood sugar: thirst, frequent urination, hunger, nausea and dizziness, fast heartbeat, tingling trembling, nervousness, sweating		✓	
Lung infections such as bronchitis and pneumonia: cough, production of mucus, fatigue, shortness of breath, chest discomfort/pain when breathing or coughing, fever, chills		✓	
Muscle aches: aching muscles, tenderness or weakness		✓	
Numbness or tingling of the skin: sensation of tingling, pain or numbness in hands, fingers and toes		✓	
Oral Problems: herpes infection, bleeding gums, pain, burning sensation, swollen tongue, or blisters inside the mouth		✓	
Osteoporosis (thin, fragile bones): pain in lower back, hips, and feet, difficulty walking, broken bones, abnormal curvature of the upper spine, loss of height		✓	
Pain in the nose and throat: sore throat, pain/discomfort when swallowing		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Sepsis (infection of the blood): rapid heartbeat, fever, shaking chills, rapid breathing, nausea, vomiting, decreased urination		✓	
Sinus tachycardia (abnormally fast heartbeat): dizziness, light headedness, shortness of breath, racing heart		✓	
Skin infections: redness, swelling, tenderness/pain, fever, heat, bumps on the skin that are red and painful		✓	
Skin or joint injury: pain, inflammation, redness, swelling, joint stiffness, decreased joint movement, skin irritation, skin infection		✓	
Spleen tissue deaths: severe pain in upper left side of abdomen that can radiate to left shoulder		✓	
Unusual hair loss or thinning		✓	
Urinary tract infections: pain and/or burning when urinating, blood in the urine, increased urge to urinate		✓	
Viral infection: flu-like symptoms including fever, fatigue, headache, body aches, diarrhea, nausea, vomiting		✓	
Vitamin D deficiency: fatigue, bone pain, muscle weakness, aches, or cramps, mood changes		✓	
UNCOMMON			
Allergic reactions: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing		✓	
Chest pain not caused by heart problems: sharp or aching pain in the chest that may worsen when moving the torso, raising the arms, when breathing deeply, sneezing, or coughing		✓	
Damage occurring inside the kidney leading to loss of kidney function: decreased urine, swollen legs, high blood pressure		✓	
Hemorrhage (bleeding problems): Bleeding uncontrollably, blood in your stool or urine, long-lasting headache, feeling dizzy or confused, nose bleeds, coughing up blood, increased bruising		✓	
Pain that affects the muscles, tendons, and bones: muscle pain, limb pain, joint pain and bone pain		✓	

Serious side effects and what to do about them			
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	Only if severe	In all cases	
Rectal Cancer: change in bowel habits (e.g. more frequent bowel movements), dark or narrow stool, abdominal pain, weakness		✓	
UNKNOWN			
Skin discolouration: changes to the colour of the skin, including darkening (hyperpigmentation) or yellowing		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

Store below 30°C, protect from freezing.
Keep out of reach and sight of children.

If you want more information about REVOLADE:

Talk to your healthcare professional

- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer’s website <http://www.novartis.ca>, or by calling 1-800-363-8883.

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