

# REVOLADE®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

## 1. Why am I using REVOLADE?

REVOLADE contains the active ingredient eltrombopag. REVOLADE is used to treat certain blood disorders where the body does not produce enough platelets which are used to reduce bleeding. REVOLADE may also be used in adult patients infected with the hepatitis C virus (HCV) that have low platelet numbers from the disease itself or other medicines they may be taking to treat it.

For more information, see Section [1. Why am I using REVOLADE?](#) in the full CMI.

## 2. What should I know before I use REVOLADE?

Do not use if you have ever had an allergic reaction to eltrombopag or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use REVOLADE?](#) in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with REVOLADE and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

## 4. How do I use REVOLADE?

- Take REVOLADE at the same time each day by swallowing it with a glass of water.
- Take REVOLADE at least 2 hours BEFORE or at least 4 hours AFTER any dairy products, antacids, or mineral supplements you may be taking for example: iron, calcium, magnesium, aluminium, selenium, and zinc.

More instructions can be found in Section [4. How do I use REVOLADE?](#) in the full CMI.

## 5. What should I know while using REVOLADE?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● Remind any doctor, dentist, nurse, or pharmacist you visit that you are taking REVOLADE</li><li>● Have the blood tests your doctor instructs you to do</li><li>● Avoid artificial UV exposure and take extra precautions in the sun</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>● Do NOT stop taking REVOLADE or change the dose unless your doctor tells you to.</li><li>● Do NOT take REVOLADE with products high in calcium</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>● Be careful before you drive or use any machines or tools until you know how REVOLADE affects you.</li></ul>

<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Tell your doctor if you drink alcohol.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store it in a cool, dark, dry place below 30°C, away from moisture, heat, or sunlight.</li> </ul>

For more information, see Section [5. What should I know while using REVOLADE?](#) in the full CMI.

## 6. Are there any side effects?

More common side effects include: cough, headache, nausea, flu-like symptoms, urinary tract infection, generalised pain in muscle or joints, vomiting, diarrhoea, feeling tired, trouble sleeping, thinning or loss of hair, rash, itching, bruising, loss of appetite, dry mouth, dizziness, sensitivity to light, vision problems, more prone to sunburn and cloudy, infrequent or strange smelling wee that is painful to pass. More serious side effects include yellowing of the skin or the whites of your eyes, severe abdominal/upper right tummy pain, shortness of breath, trouble swallowing or breathing, wheezing, swelling of the abdomen, face or tongue, itchy rash, dark wee or less wee than usual, chest pain, sudden facial paralysis or drooping, confusion or trouble speaking, painful redness, swelling or tenderness under skin. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

## **REVOLADE®** (Reh-VOE-layd)

**Active ingredient(s):** *(el-TROM-boe-pag)*

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### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using REVOLADE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using REVOLADE.**

#### **Where to find information in this leaflet:**

- [1. Why am I using REVOLADE?](#)
- [2. What should I know before I use REVOLADE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use REVOLADE?](#)
- [5. What should I know while using REVOLADE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

# 1. Why am I using REVOLADE?

**REVOLADE contains the active ingredient eltrombopag.** REVOLADE belongs to a class of medicines called thrombopoietin receptor agonists, which help increase and maintain platelets in your blood. Platelets help blood to stick (or "clot") to reduce or prevent bleeding.

**REVOLADE is used to treat several conditions including:**

- **Low platelet count (ITP)**

Low platelet count is a bleeding disorder known as idiopathic thrombocytopenic purpura (ITP). Patients with this condition may be at a higher risk of bleeding.

The symptoms of this condition include:

- Small red spots under the skin
- Bruising
- Nosebleeds
- Prolonged bleeding

REVOLADE helps to increase and maintain the number of platelets.

- **Hepatitis C virus (HCV)**

Many patients with HCV have low platelet numbers (thrombocytopenia) because of the disease itself, as well from some medicines that are used to treat it.

REVOLADE is used to help increase and maintain the platelet count prior to, and while on, treatment for HCV.

- **Severe aplastic anaemia (SAA)**

Severe aplastic anaemia is a condition where the bone marrow does not make enough blood cells, especially red and white cells, and platelets. Red blood cells carry oxygen in the body. White blood cells fight infection and disease. If you have a low number of blood cells, you may feel tired or be more prone to infections and bleeding.

REVOLADE can be used to treat patients with low blood counts:

- Together with other medicines that reduce the immune system in adults or children from 2 years of age; or
- In adult patients when other medicines to treat SAA have not worked well enough.

## **2. What should I know before I use REVOLADE?**

### **Monitoring**

Your doctor will request blood tests to check your platelet numbers as well as your kidney, liver, eye and bone marrow function before and during treatment with REVOLADE.

## Warnings

### Do not use REVOLADE if:

- you are allergic to eltrombopag, or any of the ingredients listed at the end of this leaflet
- you are pregnant or breastfeeding
- you are a child under 18 years of age with hepatitis C virus (HCV) infection

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Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue; or rash, itching or hives on the skin.

### Check with your doctor if you or if you have a family history of:

- liver problems
- eye problems
- kidney problems
- skin cancer
- blood problems e.g. anaemia, haemophilia,
- stroke
- heart attack

During treatment, you may be at risk of developing certain side effects. These may be increased if you have had or if you have a family history of the conditions above. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant. You should avoid becoming pregnant while taking REVOLADE as it can harm your unborn baby.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed. Breastfeeding is not recommended while you are taking REVOLADE.

- **Contraception**

You must use a reliable method of contraception during treatment with REVOLADE and for AT LEAST 7 days AFTER you stop taking REVOLADE.

Ask your doctor about options for effective birth control.

## **Use in children and adolescents under 18 years of age**

REVOLADE may be used to treat children from 1 to 17 years of age with a condition called chronic immune thrombocytopenia ("ITP" or low platelet count) who have failed other treatments and require an increase in platelet numbers in the blood for a planned surgery or those that may be at high risk of bleeding.

REVOLADE may be used to treat children from 2 to 17 years of age with low blood counts caused by severe aplastic anaemia.

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

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

**Some medicines may interfere with REVOLADE and affect how it works.**

**Medicines that may be affected by taking them with REVOLADE include:**

- Some medicines used to lower cholesterol (statins) such as rosuvastatin
- Some medicines used to treat low platelet counts arising from treatment of hepatitis C (interferon therapy)

**Medicines that may reduce the effect of REVOLADE include:**

- Antacids that treat heartburn or stomach ulcers.
- Certain drugs used to treat human immunodeficiency virus (HIV) such as lopinavir or ritonavir.
- Minerals such as aluminium, calcium, iron, magnesium, selenium, and zinc which may be found in mineral supplements and complementary medicines.
- A medicine called cyclosporin which is used during transplants or to manage immune disorders

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect REVOLADE.**

## **4. How do I use REVOLADE?**

### **How much to take**

Take REVOLADE exactly as instructed by your doctor, even this differs from the information in this leaflet.

### **Low platelet count (ITP) in adults and children 6-17 years old:**

- The usual starting dose for adult and paediatric ITP patients 6 to 17 years of age 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.

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### **Low platelet count (ITP) in children 1-5 years old:**

- The usual starting dose for paediatric ITP patients 1 to 5 years of age is one 25 mg REVOLADE tablet a day.
- Paediatric ITP patients 1 to 5 years of age of East-/Southeast-Asian origin need to start at a dose of one 25 mg REVOLADE tablet once daily.

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### **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.

## **Initial (first-time) treatment of SAA, while taking other medicines that reduce the immune system at the same time:**

The usual starting dose of REVOLADE for the initial (first time) treatment of SAA patients, who are taking other medicines that reduce the immune system at the same time is:

- **For adult and adolescent patients 12 years 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 6 to 11 years of age:** 75 mg once a day for 6 months. Patients of East-/Southeast-Asian origin should receive a reduced dose of 37.5 mg once a day for 6 months.
- **Paediatric patients 2 to 5 years of age:** 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 therapy to reduce your immune system, that is to be taken in addition to REVOLADE.

## **Adult patients with previously treated SAA**

- The usual starting dose of REVOLADE for patients with previously treated SAA that has come back is one 50 mg REVOLADE tablet a day.

- Patients of East-/Southeast-Asian origin need to start at a lower dose of 25 mg.

Based on how you respond to REVOLADE, or if you have kidney problems, liver problems or are elderly (over 65 years of age), your doctor may increase or decrease your dose of REVOLADE.

## **When to take REVOLADE**

- Take REVOLADE at the same time each day by swallowing it with a glass of water.
- Take REVOLADE at least 2 hours BEFORE or at least 4 hours AFTER any dairy products, antacids (medicines that correct acid imbalance in your tummy), or mineral supplements you may be taking for example: iron, calcium, magnesium, aluminium, selenium, and zinc.

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You could take any supplements, antacids or products containing dairy in the morning and REVOLADE in the evening.

## **If you forget to use REVOLADE**

**If it is almost time for your next dose, skip the dose you missed and take your next dose the following day.**

**Do not take a double dose to make up for the dose you missed.**

## **If you use too much REVOLADE**

If you think that you have used too much REVOLADE, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using REVOLADE?**

### **Things you should do**

- Use effective contraception to avoid pregnancy while taking REVOLADE and do this for AT LEAST 7 days after stopping treatment with REVOLADE.
- Avoid exposure to high intensity artificial UV light (e.g., from tanning beds).
- Protect yourself from the sun with sunscreen, sunglasses, protective clothing, and shade.
- Attend all your doctor's appointments so that your progress can be checked.
- Remind any doctor, dentist, or pharmacist you visit that you are using REVOLADE.

## **Call your doctor straight away if you:**

- Become pregnant while taking REVOLADE.
- Continue to have any bleeding or bruising in the 4 weeks AFTER you stop taking REVOLADE.

For the first 4 weeks after treatment, your doctor will check your platelet counts as higher risk of bleeding may occur.

## **Things you should not do**

- Do NOT stop using this medicine suddenly. Your bleeding may come back.
- Do NOT take REVOLADE with products that are rich in calcium e.g., dairy or calcium supplements

## **Additional tests**

- Your doctor may request you to have blood tests to monitor your blood counts to ensure REVOLADE is working correctly and prevent unwanted side effects.
- Your doctor may also have your kidney, liver and eye function tested regularly.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how REVOLADE affects you.**

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

## **Looking after your medicine**

Store REVOLADE in a cool, dark, dry place below 30°C, away from moisture, heat, or sunlight.

Do not store REVOLADE:

- in the bathroom or near a sink, or
- in the car or on windowsills.

**Keep it where young children cannot reach it.**

## **When to discard your medicine**

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>General wellness</b></p> <ul style="list-style-type: none"> <li>• Headache, cough, dizziness, feeling tired, nausea, dry mouth</li> <li>• Loss of appetite, trouble sleeping</li> </ul> <p><b>Hair problems</b></p> <ul style="list-style-type: none"> <li>• Unusual loss or thinning of hair</li> </ul> <p><b>Signs of infection</b></p> <ul style="list-style-type: none"> <li>• Cold-like symptoms including chills, runny nose, fever, sneezing, congestion, sore throat</li> </ul> <p><b>Tummy problems</b></p> <ul style="list-style-type: none"> <li>• Diarrhoea, vomiting</li> </ul> <p><b>Skin problems</b></p> <ul style="list-style-type: none"> <li>• Rash, itching, bruising, increased risk of sunburn (from sensitivity to light)</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p><b>If these side effects become severe, please tell your doctor, pharmacist, or healthcare provider.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Prolonged bleeding</li> </ul> <p><b>Generalised pain/ soreness</b></p> <ul style="list-style-type: none"> <li>● Back pain, muscle pain or spasm, pain in the nose or throat, toothache, joint pain, or pain in arms, legs, or feet</li> </ul> <p><b>Eye problems</b></p> <ul style="list-style-type: none"> <li>● Poor vision (may be a sign of a cataract) or sensitivity to light</li> <li>●</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Blood problems</b></p> <ul style="list-style-type: none"> <li>● Trouble speaking, facial drooping (signs of stroke)</li> </ul> <p><b>Skin problems</b></p> <ul style="list-style-type: none"> <li>● Redness, tenderness or swelling (may be a sign of blood clot)</li> </ul>	<p><b>STOP TAKING REVOLADE and seek help immediately.</b></p> <p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Liver problems</b></p> <ul style="list-style-type: none"> <li>• Yellow eyes or skin, swollen abdomen, confusion, severe pain in the upper right area of your tummy (may be signs of liver injury)</li> </ul> <p><b>Kidney problems</b></p> <ul style="list-style-type: none"> <li>• Chest pain, swelling of the legs, ankles, and feet, less wee going to the toilet than expected (may be signs of kidney injury)</li> <li>• Cloudy, infrequent, strange smelling wee that is painful to pass (signs of a urinary tract infection)</li> </ul> <p><b>Signs of an allergic reaction</b></p> <ul style="list-style-type: none"> <li>• Trouble breathing/ swallowing, shortness of breath, swelling of face, throat or tongue, itchy rash, wheezing.</li> </ul>	<p><b>notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

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

### **What REVOLADE contains**

<b>Active ingredient (main ingredient)</b>	Eltrombopag olamine
<b>Other ingredients (inactive ingredients)</b>	Hypromellose (E464) Macrogol 400 (E1521)

	<p>Magnesium stearate (E572)</p> <p>Mannitol (E421)</p> <p>Microcrystalline cellulose (E460(i))</p> <p>Povidone (E1201)</p> <p>Sodium starch glycollate</p> <p>Titanium dioxide (E171)</p> <p>Polysorbate 80 (E433) (12.5 mg tablet and 25 mg tablet only)</p> <p>Iron oxide red CI77491 (E172) (50 mg tablet only)</p> <p>Iron oxide yellow CI77492 (E172) (50 mg tablet only)</p>
<b>Potential allergens</b>	<p>REVOLADE tablets do not contain lactose, sucrose, tartrazine, or any other azo dyes.</p>

**Do not take this medicine if you are allergic to any of these ingredients.**

## What REVOLADE looks like

REVOLADE is supplied in packs of 28 tablets. REVOLADE tablets are round, biconvex, film coated tablets, and available in different strengths.

### **12.5 mg\* (AUST R 236115)**

White, imprinted with 'GS MZ1' and '12.5' on one side. The reverse face is plain. They contain 16 mg of eltrombopag olamine, equivalent to 12.5 mg of eltrombopag.

### **25 mg (AUST R 158419)**

White, imprinted with 'GS NX3' and '25' on one side. The reverse face is plain. They contain 32 mg of eltrombopag olamine, equivalent to 25 mg of eltrombopag.

### **50 mg (AUST R 158356)**

Brown, imprinted with 'GS UFU' and '50' on one side. The reverse face is plain. They contain 64 mg of eltrombopag olamine, equivalent to 50 mg of eltrombopag.

### **75 mg\* (AUST R 200121)**

Pink, imprinted with 'GS FSS' and '75' on one side. The reverse face is plain. They contain 96 mg of eltrombopag olamine equivalent to 75 mg of eltrombopag.

\*Not all strengths and pack sizes may be distributed in Australia.

## **Who distributes REVOLADE**

REVOLADE is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW, 2113

AUSTRALIA

Telephone 1 800 671 203

[www.novartis.com.au](http://www.novartis.com.au)

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