

# REVOLADE<sup>®</sup> FILM-COATED TABLET

Eltrombopag olamine (25 mg, 50mg)

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## What Revolade is used for

Revolade may be used to treat a bleeding disorder called *immune (idiopathic) thrombocytopenic purpura (ITP)* in adult (aged 18 years and over) who have had their spleen removed and have received prior treatment with corticosteroids or immunoglobulins, and these medicines did not work. ITP is caused by a low blood platelet count (*thrombocytopenia*). People with ITP have an increased risk of bleeding, and may notice symptoms such as *petechiae* (pinpoint sized flat round red spots under the skin), bruising, nosebleeds, bleeding gums and not being able to control bleeding if they are cut or injured.

Revolade may also be used in previously treated adult (aged 18 years and over) with chronic ITP when surgery to remove the spleen is not an option.

Revolade may also be used to treat low platelet count (*thrombocytopenia*) in adult with chronic hepatitis C virus (HCV) infections, if they have any problems with side effects while on interferon treatment. Many people with hepatitis C have low platelet counts, not only as a result of the disease, but also due to some of the antiviral medicines that are used to treat it.

## How Revolade works

Eltrombopag the active substance in Revolade belongs to a group of medicines called *thrombopoietin receptor agonists*. It is used to help increase the number of platelets in your blood. Platelets are blood cells that help to reduce or prevent bleeding.

## Before you use Revolade

- When you must not use it

Do not take Revolade if you are allergic to eltrombopag or any of the other ingredients of this medicine.

Check with your doctor if you think this applies to you.

Revolade is not recommended for people aged under 18 years

## Pregnancy

Do not use Revolade if you are pregnant unless your doctor specifically recommends it. The effect of Revolade during pregnancy is not known.

-Tell your doctor if you are pregnant, think you may be pregnant, or are planning to have a baby.

-Use a reliable method of contraception while you're taking Revolade, to prevent pregnancy.

-If you do become pregnant during treatment with Revolade, tell your doctor.

## Breast-feeding mothers

Do not breast-feed while you are taking Revolade. It is not known whether Revolade passes into breast-milk. If you are breast-feeding or planning to breast-feed, tell your doctor.

- Before you start to use it

Your doctor needs to know before you take Revolade:

- if you have liver problems.

People who have low platelet counts as well as advanced chronic (long-term) liver disease are more at risk of side effects, including life-threatening liver damage and blood clots. If your doctor considers that the benefits outweigh the risks, you will be closely monitored during your treatment.

- if you are at risk of blood clots in your veins or arteries, or you know that blood clots are common in your family.

You may be at higher risk of blood clots:

- as you get older
- if you have had to stay in bed for a long time
- if you have cancer
- if you are taking the contraceptive birth control pill or hormone replacement therapy
- if you have recently had surgery or received a physical injury
- if you are very overweight (*obese*)
- if you are a smoker
- if you have advanced chronic liver disease
- if you have cataracts (the lens of the eye getting cloudy)
- 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.

Tell your doctor if any of these apply to you.

Revolade can make you dizzy and have other side effects that make you less alert. Don't drive or use machines unless you are sure you're not affected.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some everyday medicines interact with Revolade – including

prescription and non-prescription medicines and minerals. These include:

- antacid medicines to treat indigestion, heartburn or stomach ulcers
- medicines called statins, to lower cholesterol
- some medicines to treat HIV infection, such as lopinavir or ritonavir
- ciclosporin used in the context of transplantation or immune disease
- minerals such as iron, calcium, magnesium, aluminium, selenium and zinc which may be found in vitamin and mineral supplements
- medicines such as methotrexate and toptecan, to treat cancer

Talk to your doctor if you take any of these. Some of them are not to be taken with Revolade, or your dose may need adjusting, or you may need to alter the timing of when you take them. Your doctor will review the medicines you are taking, and suggest suitable replacements if necessary.

If you are also taking medicines to prevent blood clots there is a greater risk of bleeding. Your doctor will discuss this with you.

If you are taking corticosteroids, danazol, and/or azathioprine you may need to take a lower dose or to stop taking them while you're taking Revolade.

### How to use Revolade

#### - How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Do not change the dose or schedule for taking Revolade unless your doctor or pharmacist advises you to. While you are taking Revolade, you will be under the care of a doctor with specialist experience in treating your condition.

The usual starting dose for people with ITP is one 50 mg tablet of Revolade a day. People of East Asian origin (Chinese, Japanese, Taiwanese,

Thai or Korean) may need to start at a lower dose of 25 mg.

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

#### - When to use it

Do not take Revolade in the 4 hours before or 2 hours after:

- dairy foods such as cheese, butter, yoghurt or ice cream
- milk or milk shakes, drinks containing milk, yoghurt or cream
- antacids, a type of medicine for indigestion and heartburn
- some mineral and vitamin supplements including iron, calcium, magnesium, aluminium, selenium and zinc

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

#### - How long to use it

Revolade may take 1 to 2 weeks to work. Based on your response to Revolade your doctor may recommend that your daily dose is changed.

#### - If you forget to use it

Take the next dose at the usual time. Do not take more than one dose of Revolade in one day.

#### - If you use too much (overdose)

Contact a doctor or pharmacist immediately. If possible show them the pack, or this leaflet.

You will be monitored for any signs or symptoms of side effects and given appropriate treatment immediately.

### While you are using it

#### - Things you must do

Swallow the tablet whole, with some water.

Before you start taking Revolade, your doctor will carry out blood tests to check your blood cells, including platelets. These tests will be repeated at intervals while you are taking it.

Revolade can cause blood test results that may be signs of liver damage - an increase of some liver enzymes, especially bilirubin and alanine / aspartate transaminases. If you are taking interferon-based treatments together with Revolade to treat low platelet count due to hepatitis C, some liver problems can get worse. You will have blood tests to check your liver function before you start taking Revolade and at intervals while you are taking it. You may need to stop taking Revolade if the amount of these substances increases too much, or if you get other signs of liver damage.

#### - Things you must not do

Do not stop taking Revolade without talking to your doctor. If your doctor advises you to stop treatment, your platelet count will then be checked each week for four weeks.

Do not take Revolade with dairy foods or drinks as the absorption of the medicine is affected by the calcium in dairy products.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

#### - Things to be careful of

##### Eye examination

Your doctor will recommend that you are checked for cataracts as part of routine eye tests. If you do not have routine eye-tests your doctor should arrange regular testing. You may also be checked for the occurrence of any bleeding in or around your retina (the light sensitive layer of cells at the back of the eye).

##### Blood tests for platelet count

If you stop taking Revolade, your blood platelet count is likely to become low again within several days. The platelet count will be monitored, and your doctor will discuss appropriate precautions with you. A very high blood platelet count may increase the risk of blood clotting.

However blood clots can occur with normal or even low platelet counts. Your doctor will adjust your dose of Revolade to ensure that your platelet count does not become too high.

#### *Bleeding or bruising after you stop treatment*

Within two weeks of stopping Revolade, your blood platelet count will usually drop back down to what it was before you started taking

Revolade. The lower platelet count may increase your risk of bleeding or bruising. Your doctor will check your platelet counts for at least 4 weeks after you stop taking Revolade.

Some people may have bleeding in the digestive system following discontinuation of peginterferon, ribavirin, and Revolade. Contact your doctor if:

- You have black tarry stools (This may be a sign of gastrointestinal bleeding)
- You have blood in your stool
- You vomit blood or you vomit material that looks like coffee grounds

Tell your doctor if you have any bruising or bleeding after you stop taking Revolade.

#### *Tests to check your bone marrow*

In people who have problems with their bone marrow, medicines like Revolade could make this problem worse. Signs of bone marrow changes may show up as abnormal results in your blood tests. Your doctor may also carry out tests to directly check your bone marrow during treatment with Revolade.

#### *Heart Monitoring*

Your doctor may consider it necessary to monitor your heart during treatment with Revolade and consider performing an electrocardiogram test.

For more advice about suitable foods and drinks, talk to your doctor.

#### **Side Effects**

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

Symptoms needing attention: see a doctor

People taking Revolade for either ITP or hepatitis C could develop signs of potentially serious side effects. It is important to tell a doctor if you develop these symptoms.

#### *Higher risk of blood clots*

Certain people may have a higher risk of blood clots, and medicines like Revolade could make this problem worse. The sudden blocking of a blood vessel by a blood clot is an uncommon side effect and may affect up to 1 in 100 people.

If you develop signs and symptoms of a blood clot, such as:

- swelling, pain or tenderness in one leg
- sudden shortness of breath, especially together with sharp pain in the chest or rapid breathing
- abdominal (stomach) pain, enlarged abdomen, blood in your stools.

Get medical help immediately.

#### *Problems with your liver*

Revolade can cause changes that show up in blood tests, and may be signs of liver damage. Liver problems are common and may affect up to 1 in 10 people. Other liver problems are uncommon and may affect up to 1 in 100 people.

Tell your doctor immediately if you have any of these signs and symptoms of liver problems:

- Yellowing of the skin or the whites of the eyes (*jaundice*)
- Unusually dark-coloured urine

#### *Other possible side effects in people with ITP*

##### *Common side effects*

These may affect up to 1 in 10 people:

- feeling sick (nausea)
- diarrhoea
- cloudy lens in the eye (*cataract*)
- dry eyes
- unusual hair loss or thinning
- skin rash

- itching
- muscle pain, muscle spasm
- back pain
- bone pain
- tingling or numbness of the hands or feet
- heavy menstrual period
- mouth ulcers

#### *Common side effects that may show up in blood tests:*

- increase of liver enzymes
- increase in bilirubin (a substance produced by the liver)
- increased levels of some proteins

#### *Other possible side effects in people with hepatitis C*

##### *Very common side effects*

These may affect more than 1 in 10 people:

- headache
- decreased appetite
- difficulty in sleeping (*insomnia*)
- cough
- feeling sick (*nausea*), diarrhoea
- muscle pain, itching, lack of energy, high temperature, unusual hair loss, feeling weak, flu like illness, swelling in the hands or feet, chills

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

- decreased number of red blood cells (*anaemia*).

##### *Common side effects*

These may affect up to 1 in 10 people:

- infection of the urinary system
- inflammation of the nasal passages, throat and mouth, flu-like symptoms, dry mouth, sore or inflamed mouth, toothache
- weight loss
- sleep disorders, abnormal drowsiness, confusion, depression, anxiety, agitation
- dizziness, problems with attention and memory,
- tingling or numbness of the hands or feet
- inflammation in the brain
- eye problems, including: cloudy lens in the eye (*cataract*), dry eye, small yellow deposits in the retina, yellowing of the whites of the eye

- bleeding in or around the retina (in the back of the eye)
  - spinning sensation, fast or irregular heartbeat (*palpitations*), shortness of breath
  - cough bringing up phlegm
  - digestive system problems, including: being sick (*vomiting*), stomach pain, indigestion, constipation, swollen stomach, taste disturbances, inflammation of the stomach, piles (*haemorrhoids*), swollen blood vessels and bleeding in the gullet (*oesophagus*), irritation of the gut
  - liver problems, including blood clot, yellowing of the whites of the eye or skin (*jaundice*), tumour in the liver
  - skin changes, including: rash, dry skin, eczema, redness of the skin, itching, excessive sweating, unusual skin growths
  - joint pain, back pain, bone pain, pain in the hands or feet, muscle spasms
  - irritability, generally feeling unwell, chest pain and discomfort
  - injection site reaction
  - disturbances of heart rhythm
- Common side effects that may show up in blood tests:*
- increased blood sugar (glucose)
  - reduced number of white blood cells
  - reduced blood proteins
  - breakdown of red blood cells (*haemolytic anaemia*)
  - increased bilirubin (a substance produced by the liver)
  - changes in the enzymes that control blood clotting

You may report any side effects of adverse drug reactions directly to the

National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

**Storage and Disposal of Revolade**

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister.

This medicine does not require any special storage conditions.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**Product Description**

- What it looks like

Film-coated tablet.

25mg: Round, biconvex, white film-coated tablet debossed with 'GS NX3' and '25' on one side.

50mg: Round, biconvex, brown film-coated tablet debossed with 'GS UFU' and '50' on one side.

- Ingredients

- Active ingredient(s)  
Eltrombopag olamine 25 mg or 50 mg.

- Inactive ingredient(s)

*Tablet core*

Magnesium stearate, Mannitol (E421), Microcrystalline cellulose, Povidone (K30) Sodium starch glycolate Type A

*Tablet coating for 25mg*

Hypromellose, Macrogol 400 Polysorbate 80, Titanium dioxide (E171)

*Tablet coating for 50mg*

Hypromellose, Iron oxide red (E172), Iron oxide yellow (E172) Macrogol 400, Titanium dioxide (E171)

- MAL number

Revolade Film-Coated Tablet 25MG:

MAL20102010ACRZ

Revolade Film-Coated Tablet 50MG:

MAL20102011ACRZ

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**Product Registration Holder**

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