

REVOLADE® 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 (primary) thrombocytopenia (ITP) in patients (aged 6 years and over) who have already taken other medicines (corticosteroids or immunoglobulins), which have not worked. ITP is caused by a low blood platelet count (thrombocytopenia). People with ITP have an increased risk of bleeding. Symptoms patients with ITP may notice include 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 can 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. Taking Revolade may make it easier for you to complete a full course of antiviral medicine (peginterferon and ribavirin).

Revolade may be used to treat severe aplastic anaemia (SAA):

- in combination with standard immunosuppressive therapy as first treatment for adults and adolescent from 12 years of age.

- in adults when other medicines to treat SAA have not worked well enough.

SAA is a disease in which the bone marrow is damaged causing a deficiency of the red blood cells (anaemia), white blood cells (leukopenia), and platelets (thrombocytopenia).

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.

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

Talk to your doctor before taking 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 of taking Revolade 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 any of these apply to you tell your doctor before starting treatment. You should not take Revolade unless your doctor considers that the expected benefits outweigh the risk of blood clots

- 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. This includes medicines obtained without prescription and vitamins.

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 transplantations or immune diseases
- minerals such as iron, calcium, magnesium, aluminium, selenium and zinc which may be found in vitamin and mineral supplements
- medicines such as methotrexate and topotecan, 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.

For ITP: Adults and children (6 to 17 years)- the usual starting dose for ITP is one 50 mg tablet of Revolade a day. If you are of East/Southeast-Asian origin you may need to start at a lower dose of 25 mg.

For hepatitis C: Adults- the usual starting dose for hepatitis C is one 25 mg tablet of Revolade a day. If you are of East-/Southeast-Asian origin you will start on the same 25 mg dose.

For first line treatment for SAA: 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.

For SAA: Adults- the usual starting dose for SAA is one 50mg tablet of Revolade a day. If you are of East/Southeast-Asian origin you may need to start at a lower dose of 25 mg.

- When to use it

Make sure that-

- in the 4 hours before you take Revolade
- and the 2 hours after you take Revolade you do not consume any of the following:
- 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.

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

- 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.

- 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 calcium in dairy products affects the absorption of the medicine.

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. 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).

You will need regular tests

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.

Blood tests for liver function

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.

Read the information ‘Liver problems’ in Side Effect section of this leaflet.

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 also form 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.

Get medical help immediately if you have any of these signs of a blood clot:

- 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

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.

Checks for digestive bleeding

If you are taking interferon-based treatments together with Revolade you will be monitored for any signs of bleeding in your stomach or intestine after you stop taking Revolade.

Heart Monitoring

Your doctor may consider it necessary to monitor your heart during treatment with Revolade and carry out an electrocardiogram (ECG) test.

Older people (65 years and above)

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.

Children and adolescents

Revolade is not recommended for children aged under 6 year who have ITP. It is also not recommended for people under 18 years with low platelet counts due to hepatitis C. Revolade may be used with standard immunosuppressive therapy in adolescents from 12 years of age as the first treatment for severe aplastic anaemia (SAA).

Revolade is not recommended to treat children and adolescents with low blood counts caused by severe aplastic anemia when other medicines to treat SAA have not worked well enough.

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 low blood platelets counts due to 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.

Get medical help immediately if you develop signs and symptoms of a blood clot, such as:

- swelling, pain, heat, redness 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.

Liver Problems

Revolade can cause changes that show up in blood tests, and may be signs of liver damage. Liver problems (increased enzymes showing up in blood tests) 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.

If you have either of these signs of liver problems:

- Yellowing of the skin or the whites of the eyes (jaundice)
 - Unusually dark-coloured urine
- Tell your doctor immediately

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

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

Some people may have bleeding in the digestive system after they stop taking peginterferon, ribavirin, and Revolade. Symptoms include:

- black tarry stools (discoloured bowel movements are a uncommon side

effect that may affect up to 1 to 100 people)
 - blood in your stools
 - vomiting blood or something that looks like coffee grounds
 →Tell your doctor immediately if you have any of these symptoms.

The following side effects have been reported to be associated with treatment with Revolade in adults patients with ITP:

Very common side effects

These may affect more than 1 in 10 people:

- common cold
- feeling sick (nausea)
- diarrhoea
- cough
- infection in the nose, sinuses, throat and upper airways (upper respiratory tract infection)
- back pain

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

- increased of liver enzymes (alanine aminotransferase (ALT))

Common side effects

These may affect up to 1 in 10 people:

- muscle pain, muscle spasm, muscle weakness
- bone pain
- heavy menstrual period
- sore throat and discomfort when swallowing
- eye problems including abnormal eye test, dry eye, eye pain and blurred vision
- vomiting
- flu (influenza)
- cold sore
- pneumonia
- irritation and inflammation (swelling) of the sinuses
- inflammation (swelling) and infection of the tonsils
- infection of the lungs, sinuses, tonsils, nose and throat
- inflammation of the gum tissue
- loss of appetite
- feeling of tingling, prickling or numbness, commonly called “pins and needles”
- decreased skin sensation

- feeling drowsy
- ear pain
- pain, swelling and tenderness in one of your legs (usually the calf) with warm skin in the affected area (signs of a blood clot in a deep vein)
- localised swelling filled with blood from a break in a blood vessel (haematoma)
- hot flushes
- mouth problems including dry mouth, sore mouth, sensitive tongue, bleeding gums, mouth ulcers
- runny nose
- toothache
- stomach pain
- abnormal liver function
- skin changes including excessive sweating, itching bumpy rash, red spots, changes in appearance of the skin
- hair loss
- foamy, frothy or bubbly-looking urine (signs of protein in urine)
- high temperature, feeling hot
- chest pain
- problems sleeping, depression
- migraine
- decreased vision
- spinning sensation (vertigo)
- digestive wind/gas

Common side effects that may show up in blood tests:

- decreased number of red blood cells (anaemia)
- decreased number of platelets (thrombocytopenia)
- decreased number of white blood cells
- decreased haemoglobin level
- decreased number of eosinophils
- increased number of white blood cells (leukocytosis)
- increased levels of uric acid
- decreased levels of potassium
- increased levels of creatinine
- increased levels of alkaline phosphatase
- increase of liver enzymes (aspartate aminotransferase (AST))
- increase in blood bilirubin (a substance produced by the liver)
- increased levels of some proteins

The following additional side effects have been reported to be associated with treatment with Revolade in children (aged 1 to 17 years) with ITP:

If these side effects become severe, please tell your doctor, pharmacist or nurse.

Very common side effects

These may affect more than 1 in 10 children:

- infection in the nose, sinuses, throat and upper airways, common cold (upper respiratory tract infection)
- diarrhoea
- abdominal pain
- cough
- high temperature
- feeling sick (nausea)

Common side effects

These may affect up to 1 in 10 children:

- difficulty in sleeping (insomnia)
- toothache
- pain in the nose and throat
- itchy, runny or blocked nose
- sore throat, runny nose, nasal congestion and sneezing
- mouth problems including dry mouth, sore mouth, sensitive tongue, bleeding gums, mouth ulcers

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:

- headache
- loss of appetite
- cough
- feeling sick (nausea), diarrhoea
- muscle pain, muscle weakness
- itching
- feeling tired
- fever
- 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, depression, anxiety
- dizziness, problems with attention and memory, change in mood
- decreased brain function further to liver injury
- tingling or numbness of the hands or feet
- fever, headache
- 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 of the retina
- spinning sensation (vertigo)
- fast or irregular heartbeat (*palpitations*), shortness of breath
- cough bringing up phlegm, runny nose, flu (influenza), cold sore, sore throat and discomfort when swallowing
- digestive system problems, including: vomiting, stomach pain, indigestion, constipation, swollen stomach, taste disturbances, piles (*haemorrhoids*), stomach pain/discomfort, swollen blood vessels and bleeding in the gullet (oesophagus)
- toothache
- liver problems, including tumour in the liver, yellowing of the whites of the eyes or skin (jaundice), liver injury due to medication
- skin changes, including rash, dry skin, eczema, redness of the skin, itching, excessive sweating, unusual skin growths, hair loss
- joint pain, back pain, bone pain, pain in extremities (arms, legs, hands or feet), muscle spasms
- irritability, generally feeling unwell, skin reaction such as redness or swelling and pain at the site of injection, chest pain and discomfort,

build-up of fluid in the body or extremities causing swelling

- infection in the nose, sinuses, throat and upper airways, common cold (upper respiratory tract infection), inflammation of mucous membrane lining the bronchi
- depression, anxiety, sleep problems, nervousness

Common side effects that may show up in blood tests:

- increased blood sugar (glucose)
- decreased number of white blood cells
- decreased level of neutrophils
- decreased level of blood albumin
- decreased level of haemoglobin
- increased level of blood bilirubin (a substance produced by the liver)
- changes in the enzymes that control blood clotting

The following side effects have been reported to be associated with treatment in patients with severe aplastic anaemia (SAA) who have not had prior definitive immunosuppressive therapy for (SAA):

Possible side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.

Very common side effects that may show up in blood tests: may affect more than 1 in 10 people.

- increased level of liver enzyme called alanine aminotransferase
- increased level of a liver enzyme called aspartate aminotransferase
- increased level of the pigment bilirubin in the blood, which may produce a yellowing of the skin or the whites of the eyes (blood bilirubin increased)

Common: may affect up to 1 in 10 people.

- rash
- a more intensive colour of the skin (hyperpigmentation)
- nausea
- diarrhoea
- abdominal pain

The following side effects have been reported to be associated with treatment

with Revolade in patients with severe aplastic anaemia (SAA):

If these side effects become severe, please tell your doctor, pharmacist or nurse.

Very common side effects

These may affect more than 1 in 10 people:

- cough
- headache
- mouth and throat pain
- diarrhoea
- feeling sick (nausea)
- joint pain (arthralgia)
- pain in extremities (arms, legs, hands and feet)
- dizziness
- feeling very tired
- fever
- chills
- itchy eyes
- blisters in the mouth
- bleeding of the gums
- abdominal pain
- muscle spasms

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

- abnormal changes to the cells in your bone marrow
- increased levels of liver enzymes (aspartate aminotransferase (AST))

Common side effects

These may affect up to 1 in 10 people:

- anxiety
- depression
- feeling cold
- generally feeling unwell
- eye problems including: visions problems, blurred vision, cloudy lens in the eye (cataract), spots or deposits in eye (vitreous floaters), dry eye, itchy eye, yellowing of the whites of the eye or skin
- nose bleed
- digestive system problems including: difficulty swallowing, mouth pain, swollen tongue, vomiting, loss of appetite, stomach pain/discomfort, swollen stomach, digestive wind/ gas, constipation, intestinal motility disorder which can cause constipation, bloating, diarrhea and/or above

mentioned symptoms, change in stool colour

- fainting
- skin problems including: Small red or purple spot caused by bleeding into the skin (petechiae) rash, itching, hives, skin lesion
- back pain
- muscle pain
- bone pain
- weakness (asthenia)
- swelling of the lower limbs, due to the accumulation of fluids
- abnormal coloured urine
- interruption in blood supply to spleen (splenic infarction)
- runny nose

Common side effects that may show up in blood tests:

- increase in enzymes due to muscle breakdown (creatin phosphokinase)
- accumulation of iron in the body (iron overload)
- decrease in blood sugar level (hypoglycaemia)
- increased levels of bilirubin (a substance produced by the liver)
- decreased levels of white blood cells

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Revolade

- Storage

Do not store above 30°C.

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, Microcrystalline cellulose, Povidone 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: MAL20102010ARZ

Revolade Film-Coated Tablet 50MG: MAL20102011ARZ

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Information issued date:

15 Sep 2022 EU 18 Aug 2023

1L SAA CDS 15 Sep 2022

Date of Revision

30/10/2024

Serial Number

NPRA(R1/5) 28022025/043