

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

The medicine is dispensed according to
a physician's prescription only

Revolade® 25 mg Film-coated tablets

Revolade® 50 mg Film-coated tablets

Each film-coated tablet contains

Eltrombopag (as olamine) 25 mg or 50 mg.

Inactive ingredients: see section 6 "Additional Information".

Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of previously treated patients from the age of 6 and up, with chronic idiopathic thrombocytopenic purpura (ITP), to increase platelet count and reduce or prevent bleeding.

For the treatment of thrombocytopenia (low blood platelet count) in adult patients with chronic hepatitis C virus infection (HCV) to allow initiation and maintenance of interferon-based therapy.

For the treatment of adult patients with Severe Aplastic Anaemia (SAA) who have had an insufficient response to immunosuppressive therapy.

Therapeutic group

Revolade belongs to a group of medicines called *thrombopoietin receptor agonists*.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:

You are sensitive (allergic) to the active ingredient or to any of the other ingredients in the medicine (listed in section 6).

Special warnings regarding the use of the medicine

☒ Talk to your physician before taking Revolade:

- If you have **liver problems**. People who have low platelet counts as well as advanced chronic liver disease are more at risk of side effects, including life-threatening liver damage and blood clots.

If your physician considers that the benefits of taking Revolade outweigh the risks, you will be closely monitored during the 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 physician** before starting treatment. You should not take Revolade unless your physician 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 physician will carry out tests to check that you do not have this blood condition before you start taking Revolade. If you have myelodysplastic syndrome and take Revolade, your myelodysplastic syndrome may get worse.

Tell your physician if any of these apply to you.

☒ Eye examinations

Your physician will recommend that you are checked for cataracts. If you do not have routine eye-tests, your physician will send you for tests. 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).

☒ Regular tests

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

☒ Blood tests for liver function

Revolade can cause blood test results that may be signs of liver damage- an increase of a number of 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 infections, 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 under "liver problems" in section 4 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 physician 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 physician 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 the following 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

☒ Bone marrow tests

In people who have problems with their bone marrow, medicines like Revolade could make them worse. Signs of bone marrow changes may show up as abnormal results in your blood tests. Your physician 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 sign of bleeding in your stomach or intestine after discontinuation of Revolade.

☒ Heart monitoring

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

☒ Children and adolescents

Revolade Tablets are not intended for children under the age of 6 with ITP. In addition, Revolade is not intended for children and adolescents under the age of 18, with a low platelet count due to chronic hepatitis C or severe aplastic anaemia.

☒ If you are taking, or have recently taken other medicines including non-prescription medicines and food supplements, tell the physician or the pharmacist. Especially if you are taking:

- antacid medicines to treat indigestion, heartburn or stomach ulcers (see also section 3 "How should you use the medicine?")
- medicines called statins, to lower cholesterol
- some medicines to treat HIV infection, such as lopinavir and/or ritonavir
- cyclosporin used in the context of transplants or immune diseases
- minerals such as iron, calcium, magnesium, aluminium, selenium and zinc which may be found in vitamin and mineral supplements (see also section 3 "How should you use the medicine?")
- medicines such as methotrexate and topotecan, to treat cancer
- fluvoxamine
- rifampicin

Talk to your physician if you take any of these. Some of them are to be taken with Revolade, or the dose may need adjusting, or you may need to alter the timing of when you take them. Your physician 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 physician 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 are taking Revolade.

☒ Using the medicine, food and drink

Do not take Revolade with dairy foods or drinks as the calcium in dairy products affects the absorption of the medicine. For more information, see section 3, "How should you use the medicine?".

☒ Pregnancy and breast-feeding

Don't use Revolade if you are pregnant unless your physician specifically recommends it. The effect of Revolade during pregnancy is not known.

Tell your physician if you are pregnant, think you may be pregnant or are planning to become pregnant.

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

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

Don't 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 physician.

☒ Driving and using machines

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.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the physician's instructions.

You should check with the physician or the pharmacist if you are unsure.

The dosage and way of treatment will be determined only by the physician.

Do not change your dose or schedule for taking Revolade unless your physician or pharmacist tells you to change it.

While you are taking Revolade, you will be under the care of a physician with specialist experience in treating your condition.

Usual dose

The usual starting dose for patients with ITP and SAA is one 50 mg tablet of Revolade a day. If you are of East Asian origin (Chinese, Japanese, Taiwanese, Thai or Korean) you 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. If you are of East Asian origin (Chinese, Japanese, Taiwanese, Thai or Korean) you should start on the **same 25 mg dose**.

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

Do not exceed the recommended dose

Swallow the tablet whole, with some water.

When to take the medicine

During **four hours before** taking Revolade as well as **two hours after** taking Revolade do not consume any of the following:

- **dairy foods** such as cheese, butter, yoghurt or ice cream
- **milk or milkshakes**, drinks containing milk, yoghurt or cream
- **antacids** - medicines for **indigestion and heartburn**

- some **mineral and vitamin supplements**, including: iron, calcium, magnesium, aluminium, selenium and zinc (see also section 3 "How should you use the medicine?")

- medicines such as methotrexate and topotecan, to treat cancer

- fluvoxamine

- rifampicin

Talk to your physician if you take any of these. Some of them are to be taken with Revolade, or the dose may need adjusting, or you may need to alter the timing of when you take them. Your physician 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 physician 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 are taking Revolade.

Don't 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 physician.

Driving and using machines

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.

4. SIDE EFFECTS

As with any medicine, use of Revolade may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Symptoms needing attention: see a physician

People taking Revolade for either ITP or low blood platelet counts due to hepatitis C could develop signs of potentially serious side effects. **It is important to tell a physician if you develop these symptoms.**

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 (bile not flowing properly) are uncommon and may affect up to 1 in 100 people.

Tell your physician immediately if you have any of these signs of liver problems:

- yellowing of the skin or the whites of the eyes (jaundice)
- unusually dark-coloured urine

Bleeding or bruising after stopping 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 physician will check your platelet count for at least 4 weeks after you stop taking Revolade.

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

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

- black tarry stools (discoloured bowel movements are an uncommon side effect that may affect up to 1 in 100 people)
- blood in your stool
- vomiting blood or material that looks like coffee grounds

Tell your physician **immediately** if you have one of these symptoms.

Possible additional side effects in patients with ITP

Common side effects

These may affect **up to 1 in 10** people:

- nausea
- diarrhea
- 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)
- high levels of some proteins.

Uncommon side effects

These may affect **up to 1 in 100** people:

- interruption of blood supply to part of the heart
- sudden shortness of breath, especially when accompanied with sharp pain in the chest and/or rapid breathing, which could be signs of a blood clot in the lungs (see "Higher risk of blood clots" in section 4 above)
- the loss of function of part of the lung caused by a blockage in the lung artery
- liver problems, including yellowing of the eyes and skin (see 'Liver problems' in section 4 above)
- heart beating faster, irregular heartbeat, bluish discolouration of the skin
- disturbances of heart rhythm (QT prolongation)
- inflammation of a vein
- localised swelling filled with blood from a break in a blood vessel (haematoma)
- sore throat and discomfort when swallowing, inflammation of the lungs, sinuses, tonsils, nose and throat
- flu (influenza)
- pneumonia
- loss of appetite
- painful swollen joints caused by uric acid (gout)
- problems sleeping, depression, lack of interest, mood changes
- feeling drowsy, migraine, shaking, problems with balance, speech and nerve function
- eye problems, including: blurred and less clear vision
- ear pain, spinning sensation (vertigo)
- problems with the nose, throat and sinuses, breathing problems when sleeping
- digestive system problems, including: vomiting, wind, frequent bowel movements, stomach pain and tenderness
- cancer of the rectum
- mouth problems, including: dry or sore mouth, sensitive tongue, bleeding gums
- skin changes, including: excessive sweating, itching bumpy rash, red spots, changes in appearance
- sunburn
- redness or swelling around a wound
- bleeding around a catheter (if present) into the skin
- sensation of a foreign body
- muscular weakness
- kidney problems, including: inflammation of the kidney, excessive urination at night, kidney failure, urinary tract infection, white cells in urine, appearance of protein in the urine
- generally feeling unwell (malaise), high temperature, feeling hot, chest pain
- cold sweat
- inflammation of the gum tissue
- infection of the skin
- oral herpes

Uncommon side effects that may show up in blood tests:

- decreased number of red blood cells (anaemia), white blood cells and platelets
- increased platelets count
- increased number of red blood cells
- changes in the make-up of the blood
- changes in levels of uric acid, calcium and potassium

Additional possible side effects in children with ITP

Very common side effects

These may affect **more than 1 in 10** children: