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

This medicine is dispensed with a doctor's prescription only

Revolade 25 mg
Revolade 50 mg
Film-coated tablets

Each film-coated tablet contains:
eltrombopag (as olamine) 25 mg or 50 mg

Inactive ingredients and allergens: see section 2 under ‘Important information about some of this medicine’s ingredients’, and section 6 ‘Additional information'.

Read the entire leaflet carefully before you start using this medicine.
This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or 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 to yours.

1. What is this medicine intended for?

- For the treatment of patients aged 6 years and above with primary immune thrombocytopenia (ITP) lasting 6 months or longer from diagnosis, which is refractory to other treatments (e.g. corticosteroids, immunoglobulins).

  ITP is caused by a low blood platelet count (thrombocytopenia). People with ITP have an increased risk of bleeding. Symptoms patients with ITP may include petechiae (small flat round red spots under the skin), bruising, nosebleeds, bleeding gums and not being able to control bleeding if they are cut or injured.

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

- For the treatment of severe aplastic anaemia (SAA) in combination with other medicines for treatment of SAA as first-line treatment of adults and children 6 years and older.

- For the treatment of adult patients with severe aplastic anaemia (SAA) who have had an insufficient response to immunosuppressive therapy.

  Severe aplastic anaemia (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).

Therapeutic group:
Revolade belongs to a group of medicines called antihemorrhagics, other systemic haemostatics.

Revolade contains eltrombopag, which 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.

2. Before using this medicine

Do not use this medicine if:

You are sensitive (allergic) to the active ingredient eltrombopag or to any of the other ingredients in this medicine (see section 6 - 'Additional information'). **Check with your doctor** if you think this applies to you.

Special warnings about using this medicine
Before treatment with Revolade, tell your doctor 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 doctor believes the benefits of taking Revolade outweigh the risks, you will be closely monitored during treatment.
- you are at risk of developing **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 developing 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 been injured
    - 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. Do not take Revolade unless your doctor believes the expected benefits outweigh the risk of blood clots.
- you have **cataracts** (the lens of the eye getting cloudy).
- you have another **blood-related** problem, such as myelodysplastic syndrome (MDS). Your doctor will carry out tests to ensure that you do not have this blood problem before you start taking Revolade. If you have MDS and take Revolade, your MDS may get worse.
  Tell your doctor if any of these apply to you.

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

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 set 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 some liver enzymes, especially bilirubin and alanine / aspartate transaminases. If you are receiving 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 set intervals while you are taking it. You may need to stop taking Revolade if the amount of these substances increases too much or if other signs of liver damage appear.
Read the information appearing 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 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

Bone marrow tests
In people who have problems with their bone marrow, medicines like Revolade could make the problems 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.

Elderly people (65 years and above)
There are limited data on the use of Revolade in patients aged 65 years and older. Caution should be exercised when using Revolade if you are aged 65 years or above.

Children and adolescents
- Revolade is not recommended for children under the age of 6 with ITP or with severe aplastic anaemia (SAA) as first-line treatment in combination with other medicines .

- Revolade is also not recommended for children and adolescents under 18 years with low platelet counts due to chronic hepatitis C or severe aplastic anaemia (SAA) who have had an insufficient response to immunosuppressive therapy.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications, dietary supplements and vitamins, tell your doctor or pharmacist. Especially if you are taking:

- antacid medicines to treat **indigestion, heartburn** or **stomach ulcers** (see also section 3 '*How to use this medicine*')
- medicines called statins, **to lower cholesterol**
- some medicines to treat **HIV infection**, such as lopinavir and/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** (see also section 3 '*How to use this medicine*')
- medicines such as methotrexate and topotecan, to treat **cancer**
- fluvoxamine
- rifampicin

Tell your doctor if you take any of these. Some of them are not 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 doctor will review the medicines you are taking and suggest a suitable replacement 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 are taking Revolade.

Using this medicine and food
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 to use this medicine'*.

Pregnancy and breast-feeding
Don't 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 become pregnant.
- **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.

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 doctor.

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.
Children should be cautioned against riding a bicycle, playing near a road, and the like.

Important information about some of this medicine's ingredients
Revolade contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to use this medicine?
Always use this medicine according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine.
Do not change the dose or schedule for taking Revolade unless your doctor or pharmacist told you to. While you are taking Revolade, you will be under the care of a doctor with specialist experience in treating your condition.

The recommended dosage is usually:
For treatment of ITP
Adults and children (6 to 17) – the usual starting dose for treatment of ITP 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**.

For treatment of hepatitis C
Adults - the usual starting dose for treatment of 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 will start on the **same 25 mg dose**.

For first-line treatment of SAA
The usual starting dose of Revolade for SAA patients, when it is given in combination with standard immunosuppressive therapy as first-line treatment for SAA is:
Adults and adolescents (12 and up) 150 mg once a day for 6 months. If you are of East Asian origin (Chinese, Japanese, Taiwanese, Thai or Korean) or in the event of liver damage you need to receive 75 mg once a day for 6 months.
Children ages 6-11 years - 75 mg once a day for 6 months. Children of East Asian origin (Chinese, Japanese, Taiwanese, Thai or Korean) or in the event of liver damage need to receive 75 mg once every two days for 6 months.

For treatment of refractory SAA
Adults - the usual starting dose for treatment of SAA is **one 50 mg tablet** of Revolade a day. If you are of East Asian origin (Chinese, Japanese, Taiwanese, Thai or Korean), you will need to start at a **lower dose of 25 mg**.

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.

Do not exceed the recommended dose.

Method of administration
Swallow the tablet whole, with a little water.

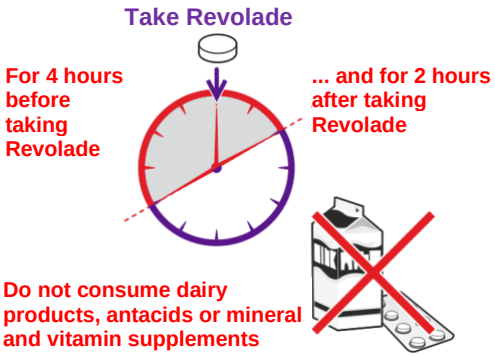
There is no information about crushing/splitting/chewing.

When to take the medicine

Make sure that -
- in the **4 hours before** you take Revolade
- and the **2 hours after** you take Revolade

you don't 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**
- certain types of **mineral and vitamin supplements**, including iron, calcium, magnesium, aluminium, selenium and zinc

If you do not adhere to this instruction, the medicine will not be properly absorbed into your body.



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

If you have accidentally taken a higher dose
If you have taken an overdose or if a child has accidentally swallowed some medicine, **immediately see a doctor or go to a hospital emergency room** and bring the medicine package with you.
You will be checked for any signs or symptoms of side effects and given appropriate treatment immediately.

If you forget to take the medicine
Take your next dose at the regular time. Do not take more than one dose of Revolade in one day.

Adhere to the treatment as recommended by the doctor.

If you stop taking this medicine
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. See additional information under '***Bleeding or bruising after you stop treatment***' in section 4.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects
Like with all medicines, using Revolade may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Symptoms needing attention: contact a doctor
People taking Revolade for treatment of ITP or low blood platelet count 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 developing 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.

Seek medical help immediately if you develop signs and symptoms of a blood clot, such as:
- **swelling, pain, a heat sensation, 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 treatment with Revolade, your blood platelet count will usually drop back down to the level it was before you started taking Revolade. The lower platelet count may increase the risk of appearance of bleeding or bruising. Your doctor will check your platelet count for at least four weeks after you stop taking Revolade.
Tell your doctor if you have any bleeding or bruising after stopping Revolade.

Certain 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 stools
- vomiting blood or a substance 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 adult patients with ITP:

Very common side effects
These may affect **more than 1 in 10** people:
- common cold
- 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 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 dry eye, eye pain and blurred vision
- vomiting
- flu
- cold sores (oral herpes)
- pneumonia
- irritation and inflammation (swelling) of the sinuses
- inflammation (swelling) and infection of the tonsils
- infection of the lungs, sinuses, nose and throat
- inflammation of the gum tissue
- loss of appetite
- feeling of tingling, prickling or numbness, commonly called “pins and needles”
- decreased skin sensations
- 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 damage to a blood vessel (haematoma)
- hot flushes
- mouth problems, including sore mouth, bleeding gums, mouth ulcers
- runny nose
- toothache
- abdominal 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
- feeling weak
- 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
- increased 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

Uncommon side effects
These may affect **up to 1 in 100** people:
- allergic reaction
- 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'*** earlier in section 4)
- the loss of function of part of the lung as a result of a blockage in the lung artery
- pain, swelling, and/or redness around a vein which could be signs of blood clot in a vein
- yellowing of the skin and/or abdominal pain which could be signs of a blockage in the bile tract, lesion on liver, liver damage due to inflammation (see ***'Liver problems'*** earlier in section 4)
- liver injury due to medication
- heart beating faster, irregular heartbeat, bluish discolouration of the skin, disturbances of heart rhythm (QT prolongation) which could be signs of a disorder related to the heart and the blood vessels
- blood clot
- flushing
- painful swollen joints caused by uric acid (gout)
- lack of interest, mood changes, crying that is difficult to stop, or occurs at unexpected times
- problems with balance, speech and nerve function, shaking
- painful or abnormal skin sensations
- paralysis on one side of the body
- migraine with aura
- nerve damage
- dilation or swelling of blood vessels that cause headache
- eye problems, including increased production of tears, cloudy lens in the eye (cataract), bleeding of the retina, dry eyes
- problems with the nose, throat and sinuses, breathing problems when sleeping
- mouth and throat blisters/sores
- loss of appetite
- digestive system problems including frequent bowel movements, food poisoning, blood in stool, vomiting of blood
- rectal bleeding, change in stool colour, abdominal bloating, constipation
- mouth problems, including dry or sore mouth, tongue pain, bleeding gums, discomfort in mouth
- sunburn
- feeling hot, feeling anxious
- redness or swelling around a wound
- bleeding around a catheter (if present) into the skin
- sensation of a foreign body

- kidney problems, including inflammation of the kidney, excessive urination at night, kidney failure, white cells in urine
- cold sweat
- generally feeling unwell
- infection of the skin
- skin changes, including skin discolouration, peeling, redness, itching and sweating
- muscular weakness
- cancer of rectum and colon
- abnormal eye test

Uncommon side effects that may show up in laboratory tests:
- changes in the shape of red blood cells
- presence of developing white blood cells which may be indicative of certain diseases
- increased number of platelets
- decreased levels of calcium
- decreased number of red blood cells (anaemia) caused by excessive destruction of red blood cells (haemolytic anaemia)
- increased number of myelocytes
- Increased number of young neutrophils (band)
- Increased blood urea
- increased levels of protein in urine
- increased levels of blood albumin
- increased levels of total protein
- decreased levels of blood albumin
- increased pH of urine
- increased level of haemoglobin

The following side effects have been reported to be associated with treatment with Revolade in children (aged 6 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)
- abdominal pain
- cough
- high temperature
- nausea

Common side effects
These may affect **up to 1 in 10** children:
- difficulty sleeping
- 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 chronic hepatitis C virus:

Very common side effects
These may affect **more than 1 in 10** people:
- headache
- loss of appetite
- cough
- nausea, diarrhoea
- muscle pain, muscle weakness
- itching
- feeling tired
- fever
- feeling weak
- flu-like illness
- 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
- 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, cold sores (oral herpes), sore throat and discomfort when swallowing
- digestive system problems, including vomiting, stomach pain, indigestion, constipation, swollen stomach, taste disturbances, haemorrhoids, stomach pain/discomfort, swollen blood vessels and bleeding in the oesophagus
- toothache
- liver problems, including tumour in the liver, yellowing of the skin or whites of the eyes (*jaundice*), liver injury due to medicines (see ***'Liver problems'*** earlier in section 4)
- 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 number of neutrophils
- decreased levels of blood albumin
- decreased level of haemoglobin
- increased levels of blood bilirubin (a substance produced by the liver)
- changes in the enzymes that control blood clotting

Uncommon side effects
These may affect **up to 1 in 100** people:
- painful urination
- disturbances of heart rhythm (QT prolongation)
- inflammation of the stomach and intestine (gastroenteritis), sore throat
- mouth blisters/sores, inflammation of the stomach
- skin changes, including change in colour, peeling, redness, itching, lesions and night sweats
- blood clots in a vein to the liver (possible liver and/or digestive system damage)
- abnormal blood clotting in small blood vessels with kidney failure
- rash, bruising at the injection site, chest discomfort
- decreased number of red blood cells (anaemia) caused by excessive destruction of red blood cells (haemolytic anaemia)
- confusion, agitation
- liver failure

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, 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
- nausea
- joint pain
- pain in extremities (arms, legs, hands and feet)
- dizziness
- feeling very tired
- fever
- chills
- itchy eyes
- bleeding of the gums
- abdominal pain

- muscle spasms
- runny nose

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 vision 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 eyes or skin
- nosebleed
- digestive system problems, including difficulty swallowing, mouth pain, swollen tongue, vomiting, loss of appetite, stomach pain/discomfort, swollen stomach, gas, constipation, intestinal motility disorder which can cause constipation, bloating, diarrhoea and/or above-mentioned symptoms, change in stool colour
- fainting
- skin problems, including small red or purple spots caused by bleeding into the skin (petechiae) rash, itching, hives, skin lesions
- back pain
- muscle pain
- bone pain
- weakness
- swelling of the lower limbs due to the accumulation of fluids
- abnormal coloured urine
- interruption in blood supply to spleen (splenic infarction)
- blisters/sores in the mouth

Common side effects that may show up in blood tests:
- increase in enzymes due to muscle breakdown (creatine phosphokinase)
- accumulation of iron in the body (iron overload)
- decrease in blood sugar level (hypoglycaemia)
- increased levels of blood bilirubin (a substance produced by the liver)
- decreased levels of white blood cells

Side effects of unknown frequency
Frequency cannot be estimated from the available data
- skin discolouration
- darkening of the skin
- liver injury due to medication

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?
Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:
Store below 30˚C.

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

6. Additional information
In addition to the active ingredient, this medicine also contains:
25 mg film-coated tablets
Microcrystalline cellulose, mannitol (E421), sodium starch glycolate (Type A), hypromellose, titanium dioxide (E171), magnesium stearate, povidone K30, macrogol 400, polysorbate 80.

50 mg film-coated tablets
Microcrystalline cellulose, mannitol (E421), sodium starch glycolate (Type A) , hypromellose, povidone K30, magnesium stearate, titanium dioxide (E171), iron oxide yellow (E172), macrogol 400, iron oxide red (E172).

What the medicine looks like and contents of the pack
Revolade 25 mg - film-coated tablets are round, biconvex, white, debossed with 'GS NX3' and '25' on one side.
Revolade 50 mg - film-coated tablets are round, biconvex, brown, debossed with 'GS UFU' and '50' on one side.

Package sizes: 14 or 28 tablets (not all pack sizes may be marketed).

Registration holder and importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in June 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Revolade 25 mg: 143 55 32036
Revolade 50 mg: 143 56 32037