

Package leaflet: Information for the user

Eltrombopag Rowex 12.5 mg film-coated tablets

Eltrombopag Rowex 25 mg film-coated tablets

Eltrombopag Rowex 50 mg film-coated tablets

Eltrombopag Rowex 75 mg film-coated tablets

eltrombopag

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Eltrombopag Rowex is and what it is used for
2. What you need to know before you take Eltrombopag Rowex
3. How to take Eltrombopag Rowex
4. Possible side effects
5. How to store Eltrombopag Rowex
6. Contents of the pack and other information

1 What Eltrombopag Rowex is and what it is used for

Eltrombopag Rowex 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.

Eltrombopag Rowex is used to treat a bleeding disorder called immune (primary) thrombocytopenia (ITP) in patients aged 1 year and above 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.

Eltrombopag Rowex can also be used to treat low platelet count (thrombocytopenia) in adults with hepatitis C virus (HCV) infections, if they have had 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 Eltrombopag Rowex may make it easier for you to complete a full course of antiviral medicine (peginterferon and ribavirin).

Eltrombopag Rowex may also be used to treat adult patients with low blood counts caused by severe aplastic anaemia (SAA). 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).

2 What you need to know before you take Eltrombopag Rowex

Do not take Eltrombopag Rowex:

- if you are allergic to eltrombopag or any of the other ingredients of this medicine (listed in section 6 under ‘What Eltrombopag Rowex contains’).

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

Warnings and precautions

Talk to your doctor before taking Eltrombopag Rowex:

- 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 this medicine outweigh the risks, you will be closely monitored during 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 Eltrombopag Rowex 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 Eltrombopag Rowex. If you have MDS and take this medicine, 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 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 Eltrombopag Rowex, 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

Eltrombopag 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 Eltrombopag Rowex 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 Eltrombopag Rowex and at intervals while you are taking it. You may need to stop taking Eltrombopag Rowex if the amount of these substances increases too much, or if you get other signs of liver damage.

Read the information ‘*Liver problems*’ in section 4 of this leaflet.

Blood tests for platelet count

If you stop taking Eltrombopag Rowex, 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 Eltrombopag Rowex 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 Eltrombopag Rowex 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 Eltrombopag Rowex.

Checks for digestive bleeding

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

Heart monitoring

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

Older people (65 years and above)

There are limited data on the use of eltrombopag in patients aged 65 years and older. Care should be taken when using Eltrombopag Rowex if you are aged 65 years or above.

Children and adolescents

Eltrombopag is not recommended for children aged under 1 year who have ITP. It is also not recommended for people under 18 years with low platelet counts due to hepatitis C or severe aplastic anaemia.

Other medicines and Eltrombopag Rowex

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 eltrombopag – including prescription and non-prescription medicines and minerals. These include:

- antacid medicines to treat indigestion, heartburn or stomach ulcers (see also ‘*When to take it*’ in section 3)
- 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 ‘*When to take it*’ in section 3)
- 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 Eltrombopag Rowex, 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 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 are taking Eltrombopag Rowex.

Eltrombopag Rowex with food and drink

Do not take Eltrombopag Rowex with dairy foods or drinks as the calcium in dairy products affects the absorption of the medicine. For more information, see ‘*When to take it*’ in section 3.

Pregnancy and breast-feeding

Don’t use Eltrombopag Rowex if you are pregnant unless your doctor specifically recommends it. The effect of eltrombopag 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 Eltrombopag Rowex, to prevent pregnancy.
- If you do become pregnant during treatment with Eltrombopag Rowex, tell your doctor.

Don’t breast-feed while you are taking Eltrombopag Rowex. It is not known whether eltrombopag passes into breast-milk.

If you are breast-feeding or planning to breast-feed, tell your doctor.

Driving and using machines

Eltrombopag Rowex 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.

Eltrombopag Rowex contains Isomalt and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3 How to take Eltrombopag Rowex

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 Eltrombopag Rowex unless your doctor or pharmacist advises you to. While you are taking Eltrombopag Rowex, you will be under the care of a doctor with specialist experience in treating your condition.

How much to take

For ITP

Adults and children (6 to 17 years) – the usual starting dose for ITP is one 50 mg tablet of Eltrombopag Rowex a day.

If you are of East-/Southeast-Asian origin you may need to start at a lower dose of 25 mg.

Children (1 to 5 years) — the usual starting dose for ITP is one 25 mg tablet of Eltrombopag Rowex a day.

For hepatitis C

Adults - the usual starting dose for hepatitis C is one 25 mg tablet of Eltrombopag Rowex a day.

If you are of East-/Southeast-Asian origin you will start on the same 25 mg dose.

For SAA

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

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

How to take the tablets

Swallow the tablet whole, with some water.

When to take it

Make sure that

- in the 4 hours before you take Eltrombopag Rowex

- and the 2 hours after you take Eltrombopag Rowex

you don't 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.

If you take more Eltrombopag Rowex than you should

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.

If you forget to take Eltrombopag Rowex

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

If you stop taking Eltrombopag Rowex

Don't stop taking Eltrombopag Rowex 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 also '*Bleeding or bruising after you stop treatment*' in section 4.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

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

Symptoms needing attention: see a doctor

People taking eltrombopag 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 doctor if you develop these symptoms.

Higher risk of blood clots

Certain people may have a higher risk of blood clots, and medicines like Eltrombopag Rowex 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

Eltrombopag Rowex 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 Eltrombopag Rowex, your blood platelet count will usually drop back down to what it was before starting Eltrombopag Rowex. 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 this medicine. Tell your doctor if you have any bleeding or bruising after stopping Eltrombopag Rowex.

Some people have bleeding in the digestive system after they stop taking peginterferon, ribavirin, and eltrombopag. 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 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 eltrombopag in adult patients with ITP:

Very common side effects (may affect more than 1 in 10 people)

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

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

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

Common side effects (may affect up to 1 in 10 people)

- flu (influenza), cold sore, 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, sore throat and discomfort when swallowing
- loss of appetite
- problems sleeping, depression
- decreased skin sensations, feeling of tingling, prickling or numbness, commonly called “pins and needles”, feeling drowsy, migraine
- eye problems including abnormal eye test, dry eye, eye pain and blurred vision, decreased vision
- ear pain, spinning sensation (vertigo)
- 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
- runny nose
- mouth problems including dry mouth, sore mouth, sensitive tongue, bleeding gums, mouth ulcers, toothache, vomiting, abdominal pain, digestive wind/gas
- abnormal liver function

- skin changes including excessive sweating, itching bumpy rash, red spots, changes in appearance of the skin, hair loss
- muscle pain, muscle spasm, muscle weakness, bone pain
- foamy, frothy or bubbly-looking urine (signs of protein in urine)
- heavy menstrual period
- high temperature, feeling hot, chest pain, feeling weak.

Common side effects that may show up in blood test:

- 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
- increase of liver enzymes (aspartate aminotransferase (AST)), increase in blood bilirubin (a substance produced by the liver)
- increased levels of some proteins, increased levels of creatinine
- increased levels of alkaline phosphatase.

Uncommon side effects (may affect up to 1 in 100 people)

- infection of the skin
- cancer of rectum and colon
- allergic reaction
- loss of appetite, 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, 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
- 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, interruption of blood supply to part of the heart
- possible pain, swelling, and/or redness around a vein which could be signs of blood clot in a vein, blood clot, flushing
- 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 caused by a blockage in the lung artery, problems with the nose, throat and sinuses, breathing problems when sleeping
- mouth problems, including dry or sore mouth, tongue pain, bleeding gums, discomfort in mouth, mouth and throat blisters/sores, digestive system problems including frequent bowel movements, food poisoning, blood in stool, vomiting of blood, rectal bleeding, change in stool colour, abdominal bloating, constipation
- 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
- painful or abnormal skin sensations, skin changes including skin discolouration, peeling, redness, itching and sweating, cold sweat
- muscular weakness
- kidney problems including inflammation of the kidney, excessive urination at night, kidney failure, white cells in urine
- feeling hot, feeling anxious, bleeding around a catheter (if present) into the skin, redness or swelling around a wound, generally feeling unwell, sensation of a foreign body
- sunburn.

Uncommon side effects that may show up in laboratory tests:

- changes in the shape of red blood cells, decreased number of red blood cells (anaemia) caused by excessive destruction of red blood cells (haemolytic anaemia), increased number of myelocytes, increased band

neutrophils, presence of developing white blood cells which may be indicative of certain diseases, increased number of platelets, increased level of haemoglobin

- decreased levels of calcium
- 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.

The following additional side effects have been reported to be associated with treatment with eltrombopag 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 (may affect more than 1 in 10 children)

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

Common side effects (may affect up to 1 in 10 children)

- difficulty in sleeping (insomnia)
- itchy, runny or blocked nose, sore throat, runny nose, nasal congestion and sneezing, pain in the nose and throat
- toothache, 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 eltrombopag in combination with peginterferon and ribavirin in patients with HCV:

Very common side effects (may affect more than 1 in 10 people)

- loss of appetite
- headache
- cough
- feeling sick (nausea), diarrhoea
- itching, swelling in the hands or feet, unusual hair loss
- muscle pain, muscle weakness
- fever, feeling tired, flu-like illness, feeling weak, chills.

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

- decreased number of red blood cells (anaemia).

Common side effects (may affect up to 1 in 10 people)

- infection of the urinary system, infection in the nose, sinuses, throat and upper airways, common cold (upper respiratory tract infection), inflammation of mucous membrane lining the bronchi, inflammation of the nasal passages, throat and mouth, flu-like symptoms, dry mouth, sore or inflamed mouth, toothache, flu (influenza), cold sore
- 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
- 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, 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 (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
- depression, anxiety, sleep problems, nervousness
- fever, headache.

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 level 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 (may affect up to 1 in 100 people)

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

The following side effects have been reported to be associated with treatment with eltrombopag in patients with severe aplastic anaemia (SAA):

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

Very common side effects (may affect more than 1 in 10 people)

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

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

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

Common side effects (may affect up to 1 in 10 people)

- interruption in blood supply to spleen (splenic infarction)
- anxiety, depression
- fainting
- 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
- nose bleed, runny nose

- 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
- skin problems including small red or purple spots caused by bleeding into the skin (petechiae) rash, itching, hives, skin lesion
- back pain, muscle pain, bone pain
- abnormal colored urine
- weakness (asthenia), swelling of the lower limbs due to the accumulation of fluids, generally feeling unwell, feeling cold.

Common side effects that may show up in the blood tests:

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

Not known side effects (frequency cannot be estimated from the available data)

- liver injury due to medication
- skin discolouration, darkening of the skin.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Eltrombopag Rowex

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 blister and the carton after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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.

6 Contents of the pack and other information

What Eltrombopag Rowex contains

- The active substance is eltrombopag olamine.
Eltrombopag Rowex 12.5 mg: Each film-coated tablet contains eltrombopag olamine equivalent to 12.5 mg eltrombopag.
Eltrombopag Rowex 25 mg: Each film-coated tablet contains eltrombopag olamine equivalent to 25 mg eltrombopag.
Eltrombopag Rowex 50 mg: Each film-coated tablet contains eltrombopag olamine equivalent to 50 mg eltrombopag.
Eltrombopag Rowex 75 mg: Each film-coated tablet contains eltrombopag olamine equivalent to 75 mg eltrombopag.
- The other ingredients are: cellulose microcrystalline, mannitol, povidone, isomalt (E953), calcium silicate, sodium starch glycolate, magnesium stearate (tablet core); hypromellose, titanium dioxide (E171), iron oxide red (E172), triacetin (tablet coating).

- Eltrombopag Rowex 12.5 mg, 25 mg and 50 mg film-coated tablets also contain iron oxide yellow (E172).

What Eltrombopag Rowex looks like and contents of the pack

Eltrombopag Rowex 12.5 mg are orange to brown, round, biconvex film-coated tablets (tablets) with “I” debossed on one side and with a diameter of approximately 5.5 mm.

Eltrombopag Rowex 25 mg are dark pink, round, biconvex film-coated tablets (tablets) with “II” debossed on one side and with a diameter of approximately 8 mm.

Eltrombopag Rowex 50 mg are pink, round, biconvex film-coated tablets (tablets) with “III” debossed on one side and with a diameter of approximately 10 mm.

Eltrombopag Rowex 75 mg are red to brown, round, biconvex film-coated tablets (tablets) with “IV” debossed on one side and with a diameter of approximately 12 mm.

Eltrombopag Rowex 12.5 mg, 25 mg, 50 mg and 75 mg is available in boxes containing 10, 14, 28, 30 or 84 film-coated tablets packed in blisters, boxes containing 10x1, 14x1, 28x1, 30x1 or 84x1 film-coated tablets packed in unit-dose blisters or multipacks containing 84 (3 packs of 28) film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

Rowex Ltd., Bantry, Co, Cork, Ireland.

Manufacturer(s):

Synthon B.V., Microweg 22, 6545 CM Nijmegen, The Netherlands.

Synthon Hispania S.L., c/ Castelló, 1, 08830 Sant Boi de Llobregat, Barcelona, Spain.

This medicine is authorised in the Member States of the European Economic Area under the following names:

AT	Eltrombopag Sandoz 12,5 mg – Filmtabletten Eltrombopag Sandoz 25 mg – Filmtabletten Eltrombopag Sandoz 50 mg – Filmtabletten Eltrombopag Sandoz 75 mg – Filmtabletten
BG	Eltrombopag Sandoz/Елтромбопaг Сандоз
HR	Eltrombopag Sandoz 12,5 mg filmom obložene tablete Eltrombopag Sandoz 25 mg filmom obložene tablete Eltrombopag Sandoz 50 mg filmom obložene tablete Eltrombopag Sandoz 75 mg filmom obložene tablete
CY	Eltrombopag/Sandoz
CZ	Eltrombopag Sandoz
DK	Eltrombopag Sandoz
EE	Eltrombopag Sandoz
DE	Eltrombopag - 1 A Pharma 12,5 mg Filmtabletten Eltrombopag - 1 A Pharma 25 mg Filmtabletten Eltrombopag - 1 A Pharma 50 mg Filmtabletten Eltrombopag - 1 A Pharma 75 mg Filmtabletten
EL	Eltrombopag/Sandoz
FI	Eltrombopag Sandoz 25 mg tabletti, kalvopäällysteinen Eltrombopag Sandoz 50 mg tabletti, kalvopäällysteinen Eltrombopag Sandoz 75 mg tabletti, kalvopäällysteinen
FR	ELTROMBOPAG SANDOZ 25 mg, comprimé pelliculé ELTROMBOPAG SANDOZ 50 mg, comprimé pelliculé ELTROMBOPAG SANDOZ 75 mg, comprimé pelliculé
HU	Eltrombopag Sandoz 12,5 mg filmtabletta Eltrombopag Sandoz 25 mg filmtabletta Eltrombopag Sandoz 50 mg filmtabletta

	Eltrombopag Sandoz 75 mg filmtabletta
IE	Eltrombopag Rowex 12.5 mg film-coated tablets
	Eltrombopag Rowex 25 mg film-coated tablets
	Eltrombopag Rowex 50 mg film-coated tablets
	Eltrombopag Rowex 75 mg film-coated tablets
IT	Eltrombopag Sandoz
LV	Eltrombopag Sandoz 12,5 mg apvalkotās tabletes
	Eltrombopag Sandoz 25 mg apvalkotās tabletes
	Eltrombopag Sandoz 50 mg apvalkotās tabletes
	Eltrombopag Sandoz 75 mg apvalkotās tabletes
LT	Eltrombopag Sandoz 12,5 mg plėvele dengtos tabletės
	Eltrombopag Sandoz 25 mg plėvele dengtos tabletės
	Eltrombopag Sandoz 50 mg plėvele dengtos tabletės
	Eltrombopag Sandoz 75 mg plėvele dengtos tabletės
NO	Eltrombopag Sandoz
PL	Eltrombopag Sandoz
PT	Eltrombopag Sandoz 25 mg Comprimido revestido por película
	Eltrombopag Sandoz 50 mg Comprimido revestido por película
	Eltrombopag Sandoz 75 mg Comprimido revestido por película
RO	Eltrombopag Sandoz 12,5 mg comprimate filmate
	Eltrombopag Sandoz 25 mg comprimate filmate
	Eltrombopag Sandoz 50 mg comprimate filmate
	Eltrombopag Sandoz 75 mg comprimate filmate
SK	Eltrombopag Sandoz
SI	Eltrombopag Sandoz 12,5 mg filmsko obložene tablete
	Eltrombopag Sandoz 25 mg filmsko obložene tablete
	Eltrombopag Sandoz 50 mg filmsko obložene tablete
	Eltrombopag Sandoz 75 mg filmsko obložene tablete
ES	Eltrombopag Sandoz 25 mg comprimidos recubiertos con película EFG
	Eltrombopag Sandoz 50 mg comprimidos recubiertos con película EFG
SE	Eltrombopag Sandoz

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