Package leaflet

Package leaflet: Information for the user

Tocieta 25 mg, filmomhulde tabletten
Tocieta 50 mg, filmomhulde tabletten
Tocieta 75 mg, filmomhulde tabletten
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.
- The information in this leaflet is for you or your child – but in the leaflet it will just say "you".

What is in this leaflet
1. What [Product name] is and what it is used for
2. What you need to know before you take [Product name]
3. How to take [Product name]
4. Possible side effects
5. How to store [Product name]
6. Contents of the pack and other information

1 What [Product name] is and what it is used for

[Product name] 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.

[Product name] 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.

[Product name] 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 [Product name] may make it easier for you to complete a full course of antiviral medicine (peginterferon and ribavirin).

[Product name] 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 [Product name]

Do not take [Product name]:
– if you are allergic to eltrombopag or any of the other ingredients of this medicine (listed in section 6 under *'What [Product name] contains'*).
Check with your doctor if you think this applies to you.

Warnings and precautions
Talk to your doctor before taking [Product name]:
– 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 [Product name] 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 [Product name]. 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 [Product name] , 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 [Product name] 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 [Product name] and at intervals while you are taking it. You may need to stop taking [Product name] 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 [Product name], 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 [Product name] 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 [Product name] 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 [Product name].

Checks for digestive bleeding
If you are taking interferon-based treatments together with [Product name] 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 [Product name] 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 [Product name] 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 [Product name]
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 [Product name], 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 [Product name].

[Product name] with food and drink
Do not take [Product name] 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 [Product name] 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 [Product name], to prevent pregnancy.
– If you do become pregnant during treatment with [Product name], tell your doctor.

Don't breast-feed while you are taking [Product name]. 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
[Product name] 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.

[Product name] 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 [Product name]

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 [Product name] unless your doctor or pharmacist advises you to. While you are taking [Product name], 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 [Product name] 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 [Product name] a day.

For hepatitis C
Adults - the usual starting dose for hepatitis C is one 25 mg tablet of [Product name] 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 [Product name] a day. If you are of East-/Southeast-Asian origin you may need to start at a lower dose of 25 mg.

[Product name] may take 1 to 2 weeks to work. Based on your response to [Product name] 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 [Product name]
– and the 2 hours after you take [Product name]

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 [Product name] 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 [Product name]
Take the next dose at the usual time. Do not take more than one dose of [Product name] in one day.

If you stop taking [Product name]
Don't stop taking [Product name] 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 [Product name] 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
[Product name] 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 [Product name], your blood platelet count will usually drop back down to what it was before starting [Product name]. 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 [Product name].

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 a 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)
- 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 liver enzyme alanine aminotransferase (ALT)

Common side effects (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, 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 break in a blood vessel (haematoma)
- hot flushes
- mouth problems including dry mouth, sore mouth, sensitive tongue, 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 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
- increased levels of creatinine
- increased levels of alkaline phosphatase
- increased liver enzyme aspartate aminotransferase (AST)
- increased blood bilirubin (a substance produced by the liver)
- increased levels of some proteins

Uncommon side effects (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 caused by a blockage in the lung artery
- possible 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
- 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

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 band neutrophils
- 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 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)
- diarrhoea
- abdominal pain
- cough
- high temperature
- feeling sick (nausea)

Common side effects (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 eltrombopag in combination with peginterferon and ribavirin in patients with HCV:

Very common side effects (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 (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)
- 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
- 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 level of blood albumin
- decreased level of haemoglobin
- increased 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)
- painful urination
- disturbances of heart rhythm (QT prolongation)
- stomach flu (gastroenteritis), sore throat
- mouth blisters/sores, inflammation of the stomach
- skin changes including change in colour, peeling, redness, itching, lesion 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 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)
- 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
- abdominal pain
- muscle spasms

Very common side effects that may show up in the blood tests:
- abnormal changes to the cells in your bone marrow
- increased liver enzyme aspartate aminotransferase (AST)

Common side effects (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
- 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, 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 lesion
- bleeding of the gums
- 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 the blood tests:
- increase in enzymes due to muscle breakdown (creatine phosphokinase)
- accumulation of iron in the body (iron overload)
- decreased blood sugar levels (hypoglycaemia)
- increased blood bilirubin (a substance produced by the liver)
- decreased levels of white blood cells

Not known side effects (frequency cannot be estimated from the available data)
- skin discolouration
- darkening of the skin
- liver injury due to medication

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 listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store [Product name]

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 [Product name] contains

- The active substance is eltrombopag olamine.
  [Product name] 25 mg: Each film-coated tablet contains eltrombopag olamine equivalent to 25 mg eltrombopag.
  [Product name] 50 mg:Each film-coated tablet contains eltrombopag olamine equivalent to 50 mg eltrombopag.
  [Product name] 75 mg: Each film-coated tablet contains eltrombopag olamine equivalent to 75 mg eltrombopag.

- The other ingredients are: cellulose microcrystalline, mannitol, povidone, isomalt (E 953), calcium silicate, sodium starch glycolate, magnesium stearate (tablet core); hypromellose, titanium dioxide (E171), iron oxide red (E 172), triacetin (tablet coating).

- [Product name] 25 mg <and> <50 mg> film-coated tablets also contain iron oxide yellow (E172).

What [Product name] looks like and contents of the pack

[Product name] 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.
[Product name] 50 mg are pink, round, biconvex film-coated tablets (tablets) with "III" debossed on one side and with a diameter of approximately 10 mm.
[Product name] 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.

[Product name] 25 mg, 50 mg and 75 mg is available in boxes containing 14, 28 or 84 film-coated tablets in blisters, or boxes containing 14x1, 28x1 or 84x1 film-coated tablets in unit-dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Vergunninghouder:
Zentiva k.s., U kabelovny 130, 102 37 Praag 10 – Dolní Měcholupy, Tsjechië

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

Synthon B.V., Microweg 22, 6545 CM Nijmegen, Nederland

Dit medicijn is in het register ingeschreven onder:
Tocieta 25 mg, filmomhulde tabletten RVG 130862
Tocieta 50 mg, filmomhulde tabletten RVG 130863
Tocieta 75 mg, filmomhulde tabletten RVG 130864

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:
Bulgarije, Hongarije, Kroatië, Nederland, Roemenië, Slowakije, Tsjechische Republiek: Tocieta

D**eze bijsluiter is voor het laatst goedgekeurd in**