PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

ELTOP 25 ELTOP 50 ELTOP 75

Film-coated tablets **Film-coated tablets** **Film-coated tablets**

Each **Eltop 25** tablet contains:
Eltrombopag (as olamine) 25 mg
Each **Eltop 50** tablet contains:
Eltrombopag (as olamine) 50 mg
Each **Eltop 75** tablet contains:
Eltrombopag (as olamine) 75 mg

For the list of inactive and allergenic ingredients in the preparation, see in section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the 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.

1. WHAT IS THE MEDICINE INTENDED FOR?

- For the treatment of adults with primary immune thrombocytopenia (ITP), which is refractory to other treatments (e.g., corticosteroids, immunoglobulins).
- For the treatment of children 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 are at increased risk of bleeding. Symptoms of patients with ITP may include petechia (small flat round red spots under the skin), bruising, nosebleeds, bleeding gums and inability 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 anemia (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 anemia (SAA) for whom immunosuppressive therapy did not result in an adequate response.
  Severe aplastic anemia (SAA) is a disease in which the bone marrow is damaged, causing a deficiency in red blood cells (anemia), white blood cells (leukopenia) and platelets (thrombocytopenia).

Therapeutic group:

Eltop belongs to a group of medicines called antihemorrhagics, other systemic hemostatics.

Eltop contains eltrombopag, which belongs to a group of medicines called thrombopoietin receptor agonists. It is used to help increase the number of platelets in the blood. Platelets are blood cells that help to reduce or prevent bleeding.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
you are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see in section 2 “Important information about some of the ingredients of the medicine” and section 6 “Further information”).
Check with the doctor if you think this applies to you.

Special warnings regarding use of the medicine

Before treatment with Eltop, tell the doctor if:

- you have **liver problems.** People who have low platelet counts as well as advanced chronic liver disease are at increased risk of side effects, including life-threatening liver damage and blood clots. If your doctor believes the benefits of taking **Eltop** 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 increased risk of developing blood clots:**
  - as you get older
  - if you have had to stay in bed for a prolonged period of time
  - if you have cancer
  - if you are taking birth control pills or hormone replacement therapy
  - if you have recently had surgery or been injured
  - if you are very overweight (obese)
  - if you smoke
  - if you have advanced chronic liver disease

  If any of these apply to you, **tell your doctor** before starting treatment. Do not take **Eltop** unless your doctor believes the expected benefits outweigh the risk of blood clots.
- you have a **cataract** (the lens of the eye becomes 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 **Eltop**. If you have MDS and take **Eltop**, 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 cataract. 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 **Eltop**, your doctor will perform 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

Eltop can cause blood test results that may be indicative of liver damage – an increase of liver enzymes, especially bilirubin and alanine/aspartate transaminases. If you are receiving interferon-based treatments together with **Eltop** 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 **Eltop** and at set intervals while you are taking it. You may need to stop taking **Eltop** if the amount of these substances increases too much or if other signs of liver damage appear. **Read the information in section 4 "Liver problems".**

Blood tests for platelet count

If you stop taking **Eltop**, 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 may also form with normal or even low platelet counts. Your doctor will adjust your dosage of **Eltop** to ensure that your platelet count does not become too high.

Seek medical help immediately if you have any of the following signs of a **blood clot:**
- **swelling, pain** or tenderness **in one leg**
- **sudden shortness of breath** especially together with sharp pain in the chest or rapid breathing
- abdominal (stomach) pain, enlarged abdomen, blood in your stools

Bone marrow tests

In people with bone marrow problems, medicines like **Eltop** could make them worse. Signs of bone marrow changes can 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 **Eltop**.

Tests for bleeding in the digestive system

If you are taking interferon-based treatments together with **Eltop**, you will be monitored for any sign of gastric or intestinal bleeding after you stop taking **Eltop**.

Heart monitoring

Your doctor may consider it necessary to monitor your heart during treatment with **Eltop** and carry out an ECG test.

Elderly people (65 years and above)

There are limited data on the use of **Eltop** in patients aged 65 years and older. If you are aged 65 years or above, caution should be exercised when using **Eltop**.

Children and adolescents

- **Eltop** is not intended for children under the age of 6 with ITP or with severe aplastic anemia (SAA) as first-line treatment in combination with other medicines.
- **Eltop** is not intended for children and adolescents under 18 years of age with a low platelet count due to chronic hepatitis C or severe aplastic anemia (SAA) for whom treatment with an immunosuppressive medicine did not achieve an adequate response.

Drug interactions

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

- antacid medicines to treat **indigestion, heartburn** or **stomach ulcers** (see also section 3 “How should the medicine be used?”)
- medicines called statins, **to lower cholesterol**
- certain 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, aluminum, selenium and zinc that can be found in **vitamin and mineral supplements** (see also section 3 “How should the medicine be used?”)
- medicines such as methotrexate and topotecan, to treat **cancer**
- fluvoxamine
- rifampicin

Tell your doctor if you take any of these medicines. Some of them are not to be taken with **Eltop**, or the dosage may need to be adjusted, 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 dosage or to stop taking them while you are taking **Eltop**.

Use of the medicine and food

Do not take **Eltop** with dairy foods or drinks as the calcium in dairy products affects the absorption of the medicine. For further information, see section 3 “How should the medicine be used?”.

Pregnancy and breastfeeding

Do not use Eltop if you are pregnant unless your doctor specifically recommended it.
The effect of **Eltop** 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 taking **Eltop**, to prevent pregnancy.
- **If you become pregnant during treatment** with **Eltop**, tell your doctor.

Do not breastfeed while you are taking Eltop. It is not known whether **Eltop** passes into breast milk. **If you are breastfeeding,** or planning to breastfeed, tell your doctor.

Driving and operating machinery

Eltop can cause you to feel dizzy and cause other side effects that may make you less alert.
Do not drive or operate machinery unless you are sure you are not affected. Children should be cautioned against riding a bicycle, playing near the road, and the like.

Important information about some of the ingredients of the medicine

Eltop contains lactose. If the doctor told you that you have an intolerance to certain sugars, consult the doctor before taking this medicine.
Eltop contains less than 1 mmol (23 mg) sodium per tablet; namely, it is considered 'sodium-free'.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only.
Do not change the dose or schedule for taking **Eltop** unless your doctor or pharmacist told you to do so. While you are taking **Eltop**, 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 Eltop** 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 Eltop** a day. If you are of East Asian origin (Chinese, Japanese, Taiwanese, Thai or Korean), you should start at **the same 25 mg dose.**

For first-line treatment of SAA

The usual starting dose of **Eltop** for SAA patients, when it is given in combination with standard immunosuppressive therapy as first-line treatment for SAA is:
Adults and adolescents (12 years and above) – **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 Eltop** 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.**

Eltop may have an effect within one to two weeks. Based on your response to **Eltop**, your doctor may recommend that your daily dosage is changed.

Do not exceed the recommended dose.

Method of administration

Swallow the tablet with a little water.
If necessary, the tablet can be halved for immediate use.
There is no information about crushing/chewing.

When to take the medicine

Make sure that:
- in the **4 hours before** taking **Eltop**
- and the **2 hours after** taking **Eltop**

you do not consume any of the following:
- **dairy foods** such as cheese, butter, yogurt or ice cream
- **milk or milkshake**, drinks containing milk, yogurt or cream
- antacids – medicines against indigestion and heartburn
- certain types of **mineral and vitamin supplements,** including iron, calcium, magnesium, aluminum, 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 accidentally took a higher dosage

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

If you forgot to take the medicine

Take your next dose at the scheduled time. Do not take more than one dose of **Eltop** in one day.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine

Do not stop taking **Eltop** without talking to your doctor. If your doctor advises you to stop the treatment, your platelet count will then be checked each week for four weeks. See additional information in section 4 “Bleeding or bruising after stopping treatment”.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Eltop** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Symptoms needing attention: refer to a doctor

People taking **Eltop** for treatment of ITP or low blood platelet count due to hepatitis C may develop signs of potentially serious side effects. **It is important to tell a doctor if you develop these symptoms.**

Increased risk of developing blood clots

Certain people may have a higher risk of blood clots and medicines like **Eltop** may 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 sensation of 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

Eltop 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 any of these signs of liver problems:

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

tell your doctor immediately.

Bleeding or bruising after stopping treatment

Within two weeks of stopping treatment with **Eltop**, your blood platelet count will usually drop back down to the level it was before you started taking **Eltop**. 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 **Eltop**.

Tell your doctor if you have any bleeding or bruising after stopping **Eltop**.

Certain people have **bleeding in the digestive system** after they stop taking peginterferon, ribavirin and **Eltop**. Symptoms include:

- black, tarry stools (bowel movements of a different color than usual 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 Eltop in adult patients with ITP:

Very common side effects – effects that occur in more than one user in ten:

- common cold
- nausea
- diarrhea
- 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 – effects that occur in 1-10 in 100 users:

- muscle pain, muscle spasm, muscle weakness
- bone pain
- heavy menstrual bleeding
- 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 leg (usually in the back part between the knee and the ankle), with hot skin in the affected area (signs of a blood clot in a deep vein)
- localized swelling filled with blood due to damage to a blood vessel (hematoma)
- hot flushes
- mouth problems, including sore mouth, bleeding gums, mouth ulcers
- runny nose
- toothache
- abdominal pain
- abnormal liver function
- skin changes, including excessive sweating, itchy, bumpy rash, red spots, changes in the appearance of the skin
- hair loss
- foamy, frothy or bubbly-looking urine (signs of protein in urine)

- high fever, feeling hot
- chest pain
- feeling weak
- sleeping problems, depression
- migraine
- decreased vision
- spinning sensation (vertigo)
- digestive wind.

Common side effects that may show up in blood tests:

- decreased number of red blood cells (anemia)
- decreased number of platelets (thrombocytopenia)
- decreased number of white blood cells
- decreased hemoglobin levels
- 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 enzyme (aspartate aminotransferase [AST])
- increase in blood bilirubin (a substance produced by the liver)
- increased levels of some proteins.

Uncommon side effects – effects that occur in 1-10 in 1,000 users:

- 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 in section 4 “Increased risk of developing blood clots”)
- 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 that could be signs of blood clot in a vein
- yellowing of the skin and/or abdominal pain that could be signs of a blockage in the bile tract, lesion in the liver, liver damage due to inflammation (see section 4 “Liver problems”)
- liver injury due to medicines
- palpitations, irregular heartbeat, bluish discoloration of the skin, heart rhythm disturbances (QT prolongation) that could be signs of a disorder related to the heart and the blood vessels
- blood clot
- flushing
- swollen and painful joints caused by uric acid (gout)
- loss of interest, mood changes, crying that is difficult to stop or that 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, clouding of the lens of the eye (cataract), bleeding of the retina, dry eyes
- problems with the nose, throat and sinuses, breathing problems when sleeping
- blisters/sores in the mouth and throat
- loss of appetite
- digestive system problems including frequent bowel movements, food poisoning, blood in stool, vomiting of blood
- rectal bleeding, change in stool color, abdominal bloating, constipation
- mouth problems, including dry or sore mouth, tongue pain, bleeding gums, discomfort in the 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 blood cells in urine
- cold sweat
- general unwell feeling
- infection of the skin
- skin changes, including discoloration, peeling, redness, itching and sweating
- muscular weakness
- cancer of the rectum and colon
- abnormal eye examination.

Uncommon side effects that may show up in laboratory tests:
- changes in the shape of red blood cells
- presence of young white blood cells which may be a sign of certain diseases
- increased number of platelets
- decreased levels of calcium
- decreased number of red blood cells (anemia) caused by excessive destruction of red blood cells (hemolytic anemia)
- increased number of myelocytes
- increased number of young neutrophils (bands)
- increased levels of 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 levels of hemoglobin.

The following additional side effects have been reported to be associated with treatment with Eltop in children (aged 6 to 17 years) with ITP:

If these side effects become severe, report to a doctor, pharmacist or nurse.

Very common side effects – effects that occur in more than one child in ten:
- infection in the nose, sinuses, throat and upper airways, common cold (upper respiratory tract infection)

- abdominal pain
- cough
- high fever
- nausea.

Common side effects – effects that occur in 1-10 in 100 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 Eltop in combination with peginterferon and ribavirin in patients with chronic hepatitis C virus:

Very common side effects – effects that occur in more than one user in ten:

- headache
- loss of appetite
- cough
- nausea, diarrhea
- 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 (anemia).

Common side effects – effects that occur in 1-10 in 100 users:

- 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, mood changes
- decreased brain function due to liver injury
- tingling or numbness of the hands or feet
- headache
- eye problems, including clouding of the lens of 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, hemorrhoids, stomach pain/discomfort, swollen blood vessels and bleeding in the esophagus
- toothache
- liver problems, including tumor in the liver, yellowing of the skin or whites of the eyes (jaundice), liver injury due to medicines (see in section 4 “Liver problems”)
- 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 the extremities (arms, legs, hands or feet), muscle spasms
- irritability, general unwell feeling, 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 the mucous membrane lining the bronchi
- depression, anxiety, sleep problems, nervousness.

Common side effects that can 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 hemoglobin
- increased levels of blood bilirubin (a substance produced by the liver)
- changes in the enzymes that control blood clotting.

Uncommon side effects – effects that occur in 1-10 in 1,000 users:

- painful urination
- heart rhythm disturbances (QT prolongation)
- gastric and intestinal inflammation (gastroenteritis), sore throat
- mouth blisters/sores, inflammation of the stomach
- skin changes, including change in color, 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 (anemia) caused by excessive destruction of red blood cells (hemolytic anemia)
- confusion, agitation
- liver failure.

<u>The following side effects have been reported to be associated with treatment with Eltop in patients with severe aplastic anemia (SAA)</u>:

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

Very common side effects - effects that occur in more than one user in ten:

- cough
- headache

- mouth and throat pain
- diarrhea
- nausea
- joint pains
- pain in the extremities (arms, legs, hands and feet)
- dizziness
- feeling very tired
- fever
- chills
- itchy eyes
- 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 enzyme (aspartate aminotransferase [AST]).

Common side effects – effects that occur in 1-10 in 100 users:

- anxiety
- depression
- feeling cold
- general unwell feeling
- eye problems including vision problems, blurred vision, clouding of the lens of the eye (cataract), spots or deposits in the 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 or discomfort, swollen stomach, gas, constipation, intestinal motility disturbance that causes constipation, bloating, diarrhea and/or above-mentioned symptoms, changes in stool color
- fainting
- skin problems, including small red or purple spots caused by bleeding into the skin (petechia), rash, itching, hives, skin lesions
- bleeding of the gums
- back pain
- muscle pain
- bone pain
- weakness
- swelling of the lower limbs due to the accumulation of fluids
- abnormal urine color
- interruption in blood supply to the 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 (hypoglycemia)
- increased levels of blood bilirubin (a substance produced by the liver)
- decreased levels of white blood cells.

Side effects of unknown frequency (effects whose frequency has not been determined):

- skin discoloration
- darkening of the skin
- liver injury due to medicine.

If a side effect occurs, if one of the side effects worsens, or if you suffer from side effects not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il. Additionally, you can report to "Unipharm Ltd.".

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place, out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
Storage conditions: Store below 25°C, in a place protected from light.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, Lactose monohydrate, Sodium starch glycolate, Povidone, Brown coating blend (Hypromellose, Titanium dioxide, Talc, Macrogel/PEG 400, Iron oxide yellow, Iron oxide red, Iron oxide black), Magnesium strearate.

Each **Eltop 25** tablet contains 29.75 mg lactose.
Each **Eltop 50** tablet contains 59.5 mg lactose.
Each **Eltop 75** tablet contains 89.25 mg lactose.

What the medicine looks like and the contents of the package:

Eltop 25;50: Round, film-coated, biconvex, brown tablets, with a score line on one side.
Eltop 75: Capsule-shaped, film-coated, biconvex, brown tablets, with a score line on one side.
Package sizes: 28 or 30 tablets (not all package sizes may be marketed).

Registration holder and address: Unipharm Ltd., P.O. Box 16545, Tel Aviv, 6116401.
Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

Revised in November 2025

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Eltop 25: 180 71 38139 99
Eltop 50: 180 72 38140 99

Eltop 75: 180 73 38141 99

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