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

This medicine is dispensed with a doctor's prescription only

Optzuro
Film-coated tablets

Active ingredient:
Each film-coated tablet contains 20 mg avatrombopag as maleate.

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

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Optzuro is used:

- for the treatment of severe thrombocytopenia (low platelet count) in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure.
- for the treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. steroids, immunoglobulins).

Therapeutic group: Antihaemorrhagics, other haemostatics.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient avatrombopag or to any of the other ingredients in this medicine (see section 6 'Additional information').

Special warnings about using this medicine

Before using Optzuro, tell your doctor:

- If you are at risk of blood clot formation in the veins or arteries, or a member of your family has had blood clots.
- If you have another blood disease called myelodysplastic syndrome (MDS); taking Optzuro may worsen this syndrome.

You may be at increased risk of blood clot formation as you get older or if:

- you have had to stay in bed for a long time
- you have cancer
- you are taking contraceptive birth control pill or hormone replacement therapy
- you have recently had surgery or been injured
- you are very overweight
- you smoke
- you have advanced chronic liver disease.

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before taking Optzuro.

Smoking
If you are a smoker, you may be at increased risk of blood clot formation.

Children and adolescents
Optzuro is not intended for children and adolescents below 18 years of age.
There is no information regarding the safety and efficacy of using this medicine in children and adolescents.

Tests and follow-up

Blood tests for platelet count
If you stop taking Optzuro, your platelet count is likely to become low as before treatment or even lower, with a risk of bleeding. This may happen within days. The platelet count will be monitored, and your doctor will discuss appropriate precautions with you.

Bone marrow tests
In people who have problems with the bone marrow, medicines like Optzuro could make them worse. Signs of bone marrow changes may show up as abnormal results in the blood tests.
Your doctor may also carry out a test to directly check the bone marrow during treatment with Optzuro.

Interactions with other medicines
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.
If you are taking other medicines for primary chronic immune thrombocytopenia (ITP), you may need to take a lower dose or to stop taking them while you are taking Optzuro.

Using this medicine and food
Take the medicine with food.

Pregnancy and breastfeeding
Pregnancy
If you are pregnant, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine. Optzuro is not recommended for use in pregnancy and in women who may become pregnant and are not using contraceptives.

Breastfeeding
If you are breastfeeding, ask your doctor or pharmacist for advice before taking Optzuro. It is not known whether this medicine passes into breast milk. The doctor will help you decide whether to stop breastfeeding or to stop using the medicine, considering the benefit of breastfeeding and the benefit of treatment for you.

Driving and using machines
Optzuro is not expected to affect or has a negligible effect on the ability to drive, cycle or use tools or machines.

Important information about some of this medicine's ingredients
Optzuro contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dosage or about how to take this medicine.

If you have chronic liver disease and low platelet count, you should be scheduled to undergo your procedure 5 to 8 days after the last dose of Optzuro.

If you have chronic immune thrombocytopenia, your doctor will tell you how much Optzuro to take and how often to take it.

Only your doctor will determine your dosage and how you should take this medicine.

The recommended dosage is usually:
If you have chronic liver disease and are scheduled for an invasive procedure
- Optzuro is available in 20 mg tablets. The usual recommended dose is either 40 mg (2 tablets) or 60 mg (3 tablets) every day for 5 days in a row.
- The dose will depend on the blood platelet count.
- Your doctor or pharmacist will tell you how many tablets to take and when to take them.

If you have chronic immune thrombocytopenia
- The usual recommended starting dose is 20 mg (1 tablet) a day. If you are taking certain other medicines, you may need a different starting dose.
- Your doctor or pharmacist will tell you how many tablets to take and when to take them.
- Your doctor will monitor your platelet count regularly and will adjust your dose as needed.

Do not exceed the recommended dose.

Method of administration
Swallow the tablets whole with food at the same time on the days of Optzuro intake.
If you have chronic liver disease and low platelet count
- Start taking Optzuro 10 to 13 days before the planned medical procedure.
- Your doctor or pharmacist will tell you how many tablets to take and when to take them.

If you have chronic immune thrombocytopenia
- Your doctor or pharmacist will tell you how many tablets to take and when to take them.

Crushing/splitting/chewing
There is no information regarding crushing/splitting/chewing.

If you have accidentally taken a higher dosage
If you take more Optzuro than you should, contact your doctor or pharmacist immediately. If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine
Take the forgotten dose as soon as you remember, and then take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking this medicine
Take Optzuro for as long as your doctor tells you. Do not stop taking Optzuro unless your doctor tells you to.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Optzuro may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The following side effects have been reported to be associated with treatment with Optzuro in adult patients with chronic liver disease:

Common side effects (affect 1–10 in 100 users)
- tiredness.

Uncommon side effects (affect 1–10 in 1,000 users)
- low red blood cell count (anaemia)
- blood clot in the portal vein (a blood vessel carrying blood from the intestines to the liver), which may cause upper abdominal pain or swelling
- bone pain
- muscle aches
- fever.

Side effects of unknown frequency (the frequency cannot be estimated from the available data)
- allergic reactions including swollen face, swollen tongue, and skin changes such as rash and itching.

The following side effects have been reported to be associated with treatment with Optzuro in adult patients with primary chronic immune thrombocytopenia:

Very common side effects (affect more than one in ten users)
- tiredness
- headache.

Common side effects (affect 1–10 in 100 users)
- back pain, muscle pain, joint pain, pain in arms or legs
- discomfort or pain in bones, muscles, ligaments, tendons and nerves
- nausea, diarrhoea, vomiting, abdominal pain, gas
- dizziness, head discomfort, migraine
- decreased appetite
- weakness
- nosebleeds
- skin rash, itching, acne, red spots on the skin
- feeling of tingling, prickling or numbness (paraesthesia)
- enlarged spleen
- shortness of breath
- high blood pressure
- tendency to bruising/hematomas or bleeding (low platelets).

Common side effects that may appear in blood tests
- increased blood fats (cholesterol, triglycerides)
- increased or decreased blood sugar (glucose)
- increased liver enzyme (alanine aminotransferase)
- increased lactate dehydrogenase
- increased gastrin
- decreased number of red blood cells (anaemia)
- increased or decreased number of platelets.

Uncommon side effects (affect 1–10 in 1,000 users)
- redness, swelling and pain in a vein caused by a blood clot
- pain, swelling and tenderness in one of the legs (usually in the calf) with warm skin in the affected area (signs of a blood clot in a deep vein)
- blood clots in the veins carrying blood from the brain
- narrowing of blood vessels (vasoconstriction)
- 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
- blockage or narrowing of the vein carrying blood to the liver

- stroke or mini-stroke
- heart attack
- irregular heartbeat
- haemorrhoids
- dilation of the rectal veins
- inflammation (swelling) and infection in the nose, sinuses, throat, tonsils or middle ear (upper respiratory tract infection)
- scarring of the bone marrow
- loss of water or body fluids (dehydration)
- increased appetite, hunger
- mood changes
- abnormal thoughts
- changes in sense of taste, smell, hearing, vision
- eye problems including irritation, discomfort, itching, swelling, tearing, sensitivity to light, blurred vision, impaired vision, loss of vision
- ear pain
- increased sensitivity to everyday sounds
- coughing up blood
- nasal congestion
- abdominal pain, discomfort or swelling
- constipation
- belching
- acid reflux
- burning or stinging sensation in the mouth
- numbness in the mouth, swollen tongue, tongue problems
- numbness
- hair loss
- boils (purulent abscess)
- dry skin
- dark purple spots on the skin (blood leakage out of blood vessels, bruising)
- excessive sweating
- changes in skin colour
- itchy rash
- skin irritation
- joint abnormality
- muscle cramps, muscle weakness
- blood in urine
- heavy menstrual bleeding
- nipple pain
- chest pain
- pain
- swelling in legs or arms.

Uncommon side effects that may appear in blood tests
- bacteria in the blood
- increased white blood cells
- decreased iron in blood
- increased liver enzyme (aspartate aminotransferase), abnormal liver test results.

Side effects of unknown frequency (the frequency cannot be estimated from the available data)
- allergic reactions including swollen face, swollen tongue and skin changes such as rash and itching.

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

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

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:
No special storage conditions. Storage at room temperature is recommended.

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

6. Additional information

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

Tablet core
Lactose monohydrate; microcrystalline cellulose; crospovidone type B; magnesium stearate, silica, colloidal anhydrous.

Tablet coating
Poly (vinyl alcohol); titanium dioxide; macrogol 3350; talc; iron oxide yellow.

What the medicine looks like and contents of the pack:
Optzuro film-coated tablets are pale yellow, round, rounded on the upper and lower side, with "AVA" imprinted on one side and "20" on the other.
The tablets are packed in cartons containing one or two aluminium blisters. Each blister contains either 10 or 15 tablets.
Not all pack sizes may be marketed.

Registration holder's name and address:
TrueMed Ltd., 10 Beni Gaon St., Poleg Industrial Park, P.O.B. 8105, Netanya 4250499

Manufacturer's name and address:
Swedish Orphan Biovitrum AB (publ), Stockholm, Sweden

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