

This medicine can be sold with a physician's prescription only

Oxopurin® 400, Prolonged Release Caplets

Each caplet contains pentoxifylline 400 mg inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

1. What is the medicine intended for?

The medicine is intended for the improvement of blood flow in the peripheral blood vessels.

Therapeutic group: methylxanthine derivative.

The medicine belongs to a group of medicines that dilate peripheral blood vessels. It works by increasing the blood flow to the arms and legs.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (pentoxifylline), to other similar medicines such as theophylline or aminophylline or to any of the other ingredients this medicine contains (see section 6). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue
- You have heart problems or have recently had a heart attack
- You have severe palpitations (very fast and uneven heartbeats)
- You have a stroke accompanied by bleeding in the brain (cerebral hemorrhage)
- You have bleeding in the eye (retinal hemorrhage)

Do not use the medicine if one or more of the conditions listed above apply to you. If you are not sure, consult the doctor or pharmacist before taking Oxopurin.

Special warnings regarding the use of the medicine

Before the treatment with Oxopurin, tell the doctor if:

- You feel dizzy or faint when you stand or sit up too quickly (low blood pressure)

- You have problems with the blood supply to the heart caused by hardening or narrowing of the arteries
 - You have liver or kidney problems
- If you are not sure if one or more of the conditions listed above apply to you, consult the doctor before taking Oxopurin.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. This is because Oxopurin may affect the activity of certain medicines. In addition, certain medicines may affect the activity of Oxopurin.

Especially tell the doctor or pharmacist if you are taking:

Oxopurin may increase the effect of the following medicines:

- Medicines for the treatment of diabetes including oral medicines or insulin
 - Medicines for the treatment of high blood pressure
 - Anticoagulants such as warfarin
- The use of the following medicines in combination with Oxopurin increases the possibility of the appearance of side effects:**

- Ketorolac (for pain relief)
- Theophylline (for the treatment of wheezing or difficulty in breathing)
- Ciprofloxacin (for the treatment of bacterial infections)
- Medicines used to stop blood clots from forming
- Cimetidine (for the treatment of heartburn and stomach ulcers)

Use of this medicine and food

Take Oxopurin with or just after meals.

Pregnancy and breastfeeding

Do not take Oxopurin if you are pregnant. Consult a doctor or pharmacist before taking any medicine.

If you are breastfeeding or planning to breastfeed, consult the doctor or pharmacist before taking Oxopurin. This is because very small amounts may pass into the breast milk.

Driving and using machines

You may feel dizzy while using this medicine. If this happens, do not drive or use tools or machines.

Important information about some of the ingredients of this medicine

This medicine contains lactose. If you have been told in the past by a doctor that you have an intolerance for certain sugars, consult the doctor before beginning treatment.

3. How to use this medicine

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

If you feel the effect of the medicine is too weak or too strong, do not change the dosage yourself, consult the doctor.

The dosage and manner of treatment will be determined by the doctor only. The usual recommended dosage is:

Adults including the elderly: The usual starting dosage is one caplet (400 mg) 3 times a day. Your doctor may reduce the dosage to one caplet twice a day.

Patients with kidney problems: Your doctor may prescribe you a lower dosage. **Children:** Oxopurin is not intended for the treatment of children.

Do not exceed the recommended dose.

Method of administration:

- Swallow the medicine whole with plenty of fluids, with or immediately after a meal.
- The score line on the tablet is not intended for halving. Do not halve, crush or chew the caplet as the medicine is prolonged release.

If you have accidentally taken a higher dosage

If you have taken an overdose, you may suffer from the following effects: low blood pressure, sleepiness, fits or uneven heartbeat. If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, do not take a double dose to make up for a forgotten dose. Continue with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

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

4. Side effects

Like any medicine, the use of Oxopurin 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.

Stop taking this medicine and refer to the doctor or to a hospital immediately with the appearance of:

- An allergic reaction. The signs can include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue
- Bleeding under the skin
- Blood in your vomit or stools
- A condition called aseptic meningitis. The signs include headache, neck stiffness, eye pain or discomfort with exposure to bright light

Refer to a doctor as soon as possible if you suffer from the following side effects:

- You bruise more easily than usual. This could be because of a blood disorder (thrombocytopenia)
- Increased heartbeat or fast heartbeat (tachycardia)
- Chest pain (angina pectoris)
- Irregular heartbeat (palpitations)
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers. These may be signs of a blood problem called leukopenia
- You get more infections than usual. This could be caused by a decrease in the number of white blood cells (neutropenia)

Additional side effects

- Nausea or vomiting, diarrhea
- Headache, dizziness or fainting
- Flushing
- Agitation, sleep problems
- An illness where there is a blockage of the bile ducts in the liver (intrahepatic cholestasis). The signs include jaundice, rash or fever, and the color of the urine becomes darker
- Discomfort or bloating in the abdomen
- Rash
- Constipation
- Producing more saliva than usual

Blood tests

Oxopurin can change the levels of liver enzymes, shown up in blood tests. This condition can indicate problems with your liver function.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health via the link

"דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link:

<https://sideeffects.health.gov.il>

5. How to store the medicine

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants 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 (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.

Storage conditions: Store in a dark place, below 25°C.

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

6. Additional information

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

Lactose monohydrate, hypromellose, magnesium stearate, titanium dioxide (E171), macrogol 400, erythrosine aluminum lake (E127), indigo carmine aluminum lake (E132), quinoline yellow aluminum lake (E104), carnauba wax

What the medicine looks like and what the package contains

A pink caplet, with a score line on both sides. Approved package sizes: 50 or 100 caplets. Not all package sizes may be marketed.

Revised in February 2021 according to MOH guidelines

Drug registration number at the national drug registry of the Ministry of Health: 011-41-23858-00

Oxopurin 400 mg Caps PIL PB0321-10

Manufacturer and registration holder:

Dexcel® Ltd.

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