

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

The medicine is dispensed with a doctor's prescription only

TRENTAL 400 - SANOFI

Film-coated, prolonged-release tablets

Active ingredient and its amount:
Each film-coated tablet contains:
Pentoxifylline 400 mg
Inactive ingredients: See section 6.

Read this leaflet carefully in its entirety before using the medicine.

Keep this leaflet. You may need to read it again.

This leaflet contains concise information about the medicine.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

If a side effect worsens or if a side effect not mentioned in this leaflet appears, please refer to the doctor or pharmacist. If you have further questions, refer to the doctor or pharmacist.

1. WHAT IS THE MEDICINE INTENDED FOR?

Trental 400 is used to improve blood flow in the peripheral blood vessels.

Therapeutic group: Methylxanthine derivative. The medicine belongs to the group of medicines known as peripheral vasodilators.

2. BEFORE USING THE MEDICINE

Do not use the preparation if:

- You are allergic (hypersensitivity) to pentoxifylline or to other methylxanthines such as theophylline, caffeine, theobromine or aminophylline or to any of the other ingredients contained in the medicine (see section 6 - Further Information).
Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of lips, face, throat or tongue.
- You are suffering from heart problems or have recently experienced a heart attack.
- You suffer from a very fast and irregular heartbeat.
- You are suffering, or have recently suffered, from bleeding in the brain and/or in the eye (cerebral/retinal hemorrhage) or from any other severe bleeding.
- You have experienced a stroke accompanied by bleeding in the brain.
- You suffer from gastric or digestive system ulcers.
- You suffer from a tendency to bleed.

Special warnings regarding use of the medicine:

Before treatment with Trental 400, tell your doctor if:

- You feel dizzy, light-headed or faint when you stand or sit too quickly (decrease in blood pressure).
- You suffer from problems with blood supply to the heart caused by hardening or narrowing of the arteries.
- You suffer from liver or kidney/urinary system problems.
- You are suffering, or have suffered in the past, from impaired function of the heart and/or vascular system (such as: severe heart rate disturbances, heart attack, low blood pressure).
- You are suffering, or have suffered in the past, from coagulation disorders.
- You are suffering, or have suffered in the past, from diabetes.
- You are suffering, or have suffered in the past, from lupus.
- You are suffering, or have suffered in the past, from impaired function of the digestive system.

If you are not sure if any of the conditions detailed above apply to you, consult the doctor or pharmacist before taking Trental 400.

Warnings:

- At the first signs of an allergic reaction, immediately stop taking the medicine and refer to the doctor at once.
- If you suffer from cardiac arrhythmias, low blood pressure, calcification of blood vessels, or if you have recently had a heart attack or undergone heart surgery - you should be under medical supervision.
- Blood coagulation tests (INR) should be carried out when Trental 400 is given with oral anticoagulants (such as vitamin K antagonists or platelet aggregation inhibitors).
- Blood sugar levels should be monitored when Trental 400 is given with oral medicines for diabetes or insulin.
- During treatment with Trental 400 blood counts should be monitored regularly.
- If ocular bleeding occurs during treatment with the medicine, immediately stop taking the medicine and consult the doctor at once.
- If you are sensitive to any type of food or medicine, inform the doctor before taking the medicine.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking:

The use of the following medicines in combination with Trental 400 may increase their effect:

- Oral medicines for diabetes or insulin.
- Medicines for high blood pressure.
- Anticoagulants (e.g., aspirin, clopidogrel, medicines of the NSAID group, warfarin, platelet aggregation inhibitors, vitamin K antagonists).
- Cimetidine (for treating heartburn).

The use of the following medicines in combination with Trental 400 will increase the risk for side effects:

- Theophylline (for treating breathing problems).
- Ketorolac (for pain relief).
- Ciprofloxacin (an antibiotic for the treatment of infections).

Use of the medicine and food:

Take Trental 400 with or immediately after eating.

Pregnancy and breastfeeding:

Do not use this medicine if you are pregnant, since there are insufficient data regarding its use in this population. If you are breastfeeding or planning to breastfeed, consult the doctor or pharmacist before taking Trental 400. This is because small amounts of medicine may pass into the mother's milk.

Driving and use of machines:

You may feel dizzy while taking this medicine. If this happens, do not drive or operate dangerous machines.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

If you feel that the effect of the medicine is too strong or too weak, do not change the dosage yourself, consult the doctor. Do not chew! Swallow the medicine whole, with or just after a meal, with a large amount of liquid.

The dosage and treatment regimen will be determined by the doctor only. **Do not exceed the recommended dose.** The effect of the medicine will be felt 2-4 weeks after beginning the treatment.

Recommended dosage in adults including the elderly:

The usual starting dosage is 1 tablet (400 mg) 3 times a day. Your doctor may lower your dosage to 1 tablet twice a day.

Patients with kidney problems:

Your doctor may prescribe you a lower dosage.

Children:

Trental 400 is not suitable for use in children.

If you accidentally took too high a dosage, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. You may suffer from the following effects: low blood pressure, feeling sleepy, convulsions or uneven heartbeat.

If you forget to take the medicine at the required time, do not take a double dose.

Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor or pharmacist.

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 Trental 400 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 the treatment and refer to the doctor immediately if you suffer from the following effects:

- An allergic reaction. The signs may include: itching, redness, rash, necrosis and peeling of the epidermis (epidermal necrolysis), sweating, swallowing or breathing problems, swelling of lips, face, throat or tongue.
- Bleeding under the skin.
- Blood in the vomit or stools (black stools).
- If you suffer from symptoms of aseptic meningitis. Signs include headache, neck stiffness, eye pain or discomfort in bright light.
- Ocular bleeding.

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

- You bruise more easily than usual (this may indicate a blood system disorder [thrombocytopenia]).
- Increased or rapid heartbeat (tachycardia).
- Chest pain (angina pectoris).
- Irregular heartbeat (palpitations).
- Tremor, tingling sensation, convulsions, cerebral bleeding.
- Vision disturbances, conjunctivitis, detached retina.
- Urogenital bleeding.
- Decrease or increase in blood pressure.
- Fever, peripheral edema.

Additional side effects:

- Nausea, vomiting, diarrhea.
- Headache, feeling dizzy, or faint.
- Flushing.
- Feeling agitated, sleep problems.
- A disease which involves a biliary tract obstruction (intrahepatic cholestasis). Signs include jaundice, rash or fever, the color of your urine becomes darker.
- Discomfort or bloating in the abdomen, constipation, increased salivation.
- Decreased level of white blood cells (leukopenia, neutropenia).

Blood tests

Trental 400 can cause changes in the levels of liver enzymes that can be identified in blood tests. This situation can indicate liver function problems.

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

Side effects can be reported to the Ministry of Health by clicking on the "Reporting side effects following drug treatment" link found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects or through the following link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach 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: Do not store at a temperature above 25°C. Store in the original package in order to protect from moisture.

Do not use the medicine if you notice that the tablets are crumbling, broken or discolored.

6. FURTHER INFORMATION

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

Hydroxyethylcellulose, talc, hypromellose, povidone, titanium dioxide E171, magnesium stearate, macrogol 8000, erythrosine E127.

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

The tablets are oblong in shape and pink-colored, with "ATA" stamped on one side. The tablets are packaged in a tray (blister) of 50/100 tablets. Not all package sizes may be marketed.

Registration holder: sanofi-aventis Israel Ltd., Address: Beni Gaon 10, P.O.B. 8090, Netanya 4250499.

Manufacturer: Sanofi S.p.A., Italy.

This leaflet was checked and approved by the Ministry of Health in February 2016.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 363720548

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, please ask your doctor.