

PATIENT INFORMATION LEAFLET

TRENTİLİN® retard 400 mg film-coated tablet For oral use

- **Active substance:** Pentoxifylline 400 mg
- **Excipients:** Bovine-derived lactose monohydrate, copovidone (VA64), hydroxypropyl methylcellulose, magnesium stearate, titanium dioxide, talc, polyethylene glycol, and hydroxypropyl methylcellulose E15.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start taking this medicine, because it contains important information for you.

- *Keep this leaflet because you may need to read it again.*
- *If you have any further questions or are not sure about anything, please ask your doctor or your pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others as it may harm them, even if their symptoms are the same as yours.*
- *Tell your doctor or pharmacist that you use this medicine if you visit your doctor or go to the hospital*
- *Strictly follow these instructions. Do not take **lower or higher** doses than the recommended dose.*

In this patient information leaflet:

- 1. What TRENTİLİN® is and what it is used for?**
- 2. What you need to know before you use TRENTİLİN®**
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1. What TRENTİLİN® is and what it is used for?

TRENTİLİN® contains pentoxifylline active substance. 1 sustained release tablet contains 400 mg of pentoxifylline. It is available in blister packaging that contains retard 20 tablets.

Except TRENTİLİN®'s retard tablet form, ampul and retard film tablet forms are also available.

TRENTİLİN® is a drug which extends blood vessels leading to the arms and legs, namely end portions of the body and increases blood flow to these areas.

TRENTİLİN® contains lactose monohydrate of bovine origin.

Your doctor may have prescribed you TRENTİLİN® due to one or more of the following reasons:

- Peripheral (at the end of the body) of arterial occlusive disease, hardening of the arteries (arteriosclerosis) or diabetes due to occurring due to circulatory disorders such as intermittent claudication and rest pain treatment of your complaint
- Treatment of disorders arising from the disruption of neural features such as leg ulcers and gangrene
- The treatment of circulatory disorders in the brain

- The treatment of circulatory disorders characterized by destruction of blood vessels of the eye

2. What you need to know before you use TRENTİLİN®

DO NOT USE TRENTİLİN® in the following cases

- If you are allergic to another drugs from the same class or any other substances contained by the drug or the active substance pentoxifylline,
- If you are having a brain hemorrhage (nausea, vomiting, headache, drowsiness, unconsciousness, somnolence, warping in the face, slurred speech occur)
- If you have severe hemorrhage in the retina of your eye
- If you had heart attack (acute myocardial infarction)
- If you have irregular heartbeat
- If you have a bleeding disorder
- If you have stomach or intestinal ulcers

Take special care with TRENTİLİN® if you have any of the following

- If you have low blood pressure
- If you have severe cardiovascular disease (coronary artery disease)
- If you have kidney function disorder (if your blood creatinine level is under 30 ml in a minute which is measured as a result of a blood test by your doctor).
- If you have severe disorders of the liver function
- If you have a disease that disrupts blood clotting or clotting ability or if you have an increased tendency for bleeding due to having any medication preventing the blood clotting (for example; drugs affecting K vitamin or low molecular heparin).
- If you use medicines used to treat diabetes with TRENTİLİN®
- The ones that have risk of fall in blood pressure (for example: patients that have severe coronary heart disease or having blockages in the arteries that supply blood to the brain)
- If you have a disorder that affects the connective tissue such as systemic lupus erythematosus or mixed connective tissue disease
- If you have anemia due to impaired production of blood cells (During the treatment, anemia can develop due to the deterioration in the production of blood cells along with TRENTİLİN®, your doctor will monitor your blood table).

Due to the limited experience of use TRENTİLİN® in children, it is not recommended for use in children.

If these warnings are true for you at any time in the past, please consult your doctor.

Using TRENTİLİN® with food and beverages

The nutrients do not affect the absorption of TRENTİLİN®. Tablets are ingested with the help of some liquid (about 1/2 cup) without chewing, after meals or along with meals.

Pregnancy

Before using this medicine consult your doctor or pharmacist.

There is not enough experience on the use of TRENTİLİN® during pregnancy, therefore if you are pregnant; you should not use TRENTİLİN®.

If you notice that you have been pregnant during treatment, consult immediately your doctor or pharmacist.

Lactation

Before using this medicine, consult your doctor or pharmacist.

Pentoxifylline passes into breast milk in small accounts. Therefore, you should not use TRENTİLİN® during lactation.

Driving and using machinery

TRENTİLİN® has no known effect on your ability to drive or use machines. If dizziness occurs, do not drive or use machinery.

Important information on some excipients present in TRENTİLİN®**If you have intolerance to lactose or any other sugars, tell your doctor.**

TRENTİLİN® contains lactose monohydrate. If you know that you have intolerance to lactose or if you have been told that you have intolerance to any other drugs, talk to your doctor before taking this medicine.

Taking with other medicines

- If you take insulin or oral medications for the treatment of diabetes, your doctor will want to follow you closely.
- If you began to get K antagonists and medications preventing clotting with TRENTİLİN® or if you changed the doze, your doctor will want to follow you closely due to anticoagulants (preventing blood clotting) having the possibility to increase in activity.
- The use of TRENTİLİN® along with medications taken to treat high blood pressure can increase the effects of these drugs.
- The use of theophylline with TRENTİLİN® may increase the effects of theophylline used in respiratory diseases and thus may increase the risk of side effects induced by theophylline.
- The use of TRENTİLİN® with cimetidine (used to treat ulcers), ciprofloxacin (antibiotics), ketorolac (analgetic) may increase the effect of TRENTİLİN®.

If you use any prescribed or non-prescribed medications currently or if you have used recently, please inform your doctor or pharmacist about them.

3. How to use TRENTİLİN®?**Instructions for proper use and dosage/administration frequency**

In principle, the dosage and mode of administration (orally or intravenously) depends on the type of circulatory disorders, weight and the patient's susceptibility to the drug. The dosage is usually as follows:

As long as your doctor recommends no other, 2 or 3 times in a day 1 tablet of TRENTİLİN® should be taken.

Route and method of administration:

TRENTİLİN® is taken orally.

Different age groups:**Use in children:**

There is not enough experience about the use of TRENTILIN® in children, it is not recommended to use it in children.

In elderly people:

In elderly patients, the treatment should be started with low doses. Your doctor will determine the optimal dosage for you.

Special conditions of use:**Kidney / liver failure**

Your doctor will determine the appropriate treatment dose for you. In both cases, the dose reduction is required.

If you have the impression that the effect of TRENTILIN® is too strong or too weak, please talk to your doctor or pharmacist.

If you use more TRENTILIN® than you should

If you use more TRENTILIN® than was prescribed, tell your doctor or pharmacist immediately.

A sudden overdose may reveal itself by nausea, dizziness, excessive increase in heart rate, blood pressure fall. If you see these symptoms in yourself, tell your doctor immediately.

If you forget to use TRENTILIN®

If you forget to use TRENTILIN® at the right time, use it as soon as you remember, then carry on as before.

Do not take double dose to make up the dose you have missed.

Effects that may occur if you stop taking TRENTILIN®

If you leave the treatment of TRENTILIN® without the consent of your doctor, your complaints due to circulatory disorder may occur again.

4. Possible side effects?

Like all medicines, there may be side effects for people who are sensitive to the substances contained in TRENTILIN®.

If any of the following occurs, please stop using TRENTILIN® and tell your doctor IMMEDIATELY or refer to the nearest hospital's emergency department.

- Serious disturbances in heart rhythm
- As a result of allergy, difficulty breathing and swelling of the throat or face and sometimes there are situations that can shock
- If you have a bleeding tendency, the bleedings (skin and / or mucous membranes of the stomach and / or intestines).

These are all very serious side effects.
You may need urgent medical attention or hospitalization.

Common: It can be seen at least one of 10 patients, but more than one in 100 patients.

Uncommon: It can be seen at least one of 100 patients but more than one in 1000 patients.

Rare: It can be seen less than one in 1000 patients but more than one in 10000 patients.

Very rare: It can be seen less than one in 10.000 patients.

Not known (it cannot be estimated from the available data).

Other side effects:

Common:

- Hot flashes associated with flushing of face and neck.
- Gastrointestinal complaints such as nausea, vomiting, flatulence, stomach pressure, diarrhea

Uncommon:

- Hypersensitivity reactions of the skin
- Excessive movement (agitation), sleep disorders
- Dizziness, chills, headache
- Blurred vision, conjunctivitis
- Heart rhythm disorders (increased heart rate)
- Itching of the skin, redness, hives
- Fever

Rare:

- Chest pain, difficulty breathing
- Bleeding in the stomach and intestines
- Bleeding in the skin and mucous membranes
- Urinary tract bleeding
- A decrease in blood pressure
- Swelling in the arms and legs

Very rare:

- Haemorrhages in the skin with a reduced number of blood platelets
- Anemia that can be fatal disorder in the production of red blood cells
- Allergic reaction that develops within minutes after application (swelling in the face, tongue and throat and contraction of the bronchi and shock)
- Numbness, seizure, bleeding and symptoms of inflammation of the lining of the brain within the head (as seen in patients with connective tissue disease)
- Separation of the layers of the eye and intraocular hemorrhage
- Liver bile duct obstruction, increase in liver enzymes
- Deep tissue death in the upper layer, skin rash, severe skin disease characterized by scaling and sweating
- Rise in blood pressure

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting the side effects

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

5. How to store TRENTİLİN®?

Store TRENTİLİN® in its original packaging and keep out of the reach and sight of children. Store at room temperature, below 25°C.

Use in accordance with expiry date.

Do not use TRENTİLİN® after the expiration date on the packaging.

Marketing Authorization Holder:

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This leaflet has been approved <{DD month YYYY}>. [To be completed nationally]