

PATIENT INFORMATION LEAFLET

TRENTILIN® Ampoule 100 mg Intravenous administration

- **Drug Substance:** Pentoxifylline 100 mg
- **Excipients:** Sodium monohydrogen phosphate, potassium dihydrogen phosphate, sodium chloride, hydrochloric acid, water for injection

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this product, tell your doctor that you use this medicinal product.*
- *Strictly follow these instructions. Do not take **lower or higher** doses than the recommended dose.*

In this leaflet:

1. **What TRENTILIN® is and what it is used for?**
2. **What you need to know before you use TRENTILIN®**
3. **How to use TRENTILIN®?**
4. **Possible side effects**
5. **How to store TRENTILIN®?**

1. What TRENTILIN® is and what it is used for?

TRENTILIN® contains the active substance pentoxifylline. It is administered intravenously. 1 ampoule for infusion contains 5 ml of solution and 100 mg of pentoxifylline in total. It is available in packaging containing 5 ampoules for infusion.

TRENTILIN® is also available as retard film tablet on the market other than the ampoule form.

TRENTILIN® is a drug that enlarges the blood vessels to the extremities of the body, that is, the arms and legs, and increases blood flow to these areas.

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

- Treatment of your complaints such as intermittent claudication and resting pain due to circulatory disorders caused by peripheral arterial occlusive disorders, vessel stiffness (arteriosclerosis) or diabetes.
- Treatment of disorders resulting from the interruption of nervous system, such as leg ulcers and gangrene
- Treatment of circulatory disorders of the brain
- Treatment of circulatory disorders with destruction of eye vessels

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

Do not use TRENTILIN® if you have the following:

- If you are allergic to the active substance pentoxifylline, to other drugs from the same therapeutic class or any of the other ingredients of the medicinal product
- If you are experiencing brain hemorrhage (symptoms such as nausea, vomiting, headache, numbness, loss of consciousness, dizziness, facial distortion, speech impairment)
- If you have an extensive bleeding in the retina of your eye
- If you had a heart attack (acute myocardial infarction)
- If your heart rate is irregular
- If you have a bleeding disorder
- If you have a stomach or intestinal ulcer

Take special care with TRENTILIN® if you have the following:

- Low blood pressure
- Severe cardiovascular disease (coronary artery disease)
- Renal dysfunction (if your creatinine level is less than 30 ml per minute in the blood test)
- Severe liver dysfunction
- Coagulation disorders or increased tendency to bleeding due to anticoagulant medication (for ex. Vitamin K affecting drugs or low molecular weight heparin)
- Concomitant use of TRENTILIN® with drugs used for the treatment of diabetes
- Patients at risk of decrease in blood pressure (For ex. patients with severe coronary heart disease or obstruction of blood vessels that supply blood to the brain)
- If you have a disease that affects connective tissue, such as systemic lupus erythematosus or mixed connective tissue disease
- Anemia due to the deterioration of blood cell production (anemia due to deterioration of blood cells during treatment with TRENTILIN® may develop, your doctor will follow your blood table)

It is not recommended for use in children as there is not enough experience with the use of TRENTILIN® in children.

Please consult your doctor even if these warnings apply to you at any time in the past.

Taking TRENTILIN® with food and drink

TRENTILIN® is for intravenous administration only.

Pregnancy

Before using this medicine consult your doctor or pharmacist.

There is no adequate experience with the use of TRENTILIN® in pregnancy. You should therefore not take TRENTILIN® if you are pregnant.

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

Breastfeeding

Before using this medicine consult your doctor or pharmacist.

Pentoxifylline passes into breast milk in small amounts. You should therefore not use TRENTILIN[®] while breastfeeding.

Driving and using machinery

There is no known side effect of TRENTILIN[®] on the ability to drive and use machines. If you feel dizzy, do not drive or use machines.

Important information on some excipients present in TRENTILIN[®]

TRENTILIN[®] contains less than 1 mmol (39 mg) of potassium (0.01 mmol) per ampoule; i.e. it is "potassium free".

TRENTILIN[®] contains less than 1 mmol (23 mg) of sodium (0.72 mmol) per ampoule; i.e. it is "sodium free".

Taking with other medicines

If you are taking insulin or oral medicines for the treatment of diabetes, your doctor will want to follow you closely.

If you started taking TRENTILIN[®] with anticoagulant drugs such as vitamin K antagonists and heparin, or if you changed their dosage, your doctor will want to follow you closely because of the potential for increased anticoagulant activity (which prevents blood clotting).

Concomitant use of TRENTILIN[®] with antihypertensive drugs may increase the effectiveness of these drugs.

Concomitant use of theophylline with TRENTILIN[®] may increase the effect of theophylline used in respiratory diseases and therefore the risk of theophylline-related side effects may increase.

Concomitant use of TRENTILIN[®] with cimetidine (used in the treatment of ulcers), ciprofloxacin (antibiotic), ketorolac (pain reliever) may increase the activity of TRENTILIN[®].

If you are taking or have recently taken any other medicines, with or without a prescription, tell your doctor or pharmacist.

3. How to use TRENTILIN[®]?

Instructions for proper use and dosage/administration frequency:

Your doctor will determine the dosage of your drug depending on your disease and will apply to you.

Route and method of administration:

TRENTILIN[®] ampoule is administered by a healthcare professional trained on vascular and intramuscular drug administration.

Opening the ampoule



Hold the ampoule pointing upwards. If there is some liquid in the neck of the ampoule, gently tap the neck or shake the ampoule



Hold the ampoule upright and snap off the top of the ampoule by pulling the tip of the ampoule downward to drain the

Different age groups:

Use in children:

It is not recommended for use in children as there is not enough experience with the use of TRENTILIN® in children.

Use in elderly:

In elderly patients treatment should be started with low doses. Your doctor will determine the most suitable dose for you.

Special populations:

Renal/Hepatic Failure:

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

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

If you use more TRENTILIN® than you should

Because TRENTILIN® is administered only in a hospital, your doctor will take preventive measures to prevent this to occur. In case it happens, an appropriate treatment will be applied to you.

If you forget to take TRENTILIN®

Because TRENTILIN® is administered only in a hospital, your doctor will take preventive measures to prevent this to occur.

Effects that may occur if you stop taking TRENTILIN®

Because TRENTILIN® is administered only in a hospital and under the supervision of your doctor, it is not possible to discontinue treatment without your doctor's approval.

4. Possible side effects

Like all medicines, TRENTILIN® may cause side effects in patients sensitive to its ingredients.

If any of the following occur, stop using TRENTILIN® and report to your doctor or contact the emergency department of your nearest hospital:

- Severe heart rhythm disturbances
- Swelling in the face and throat, difficulty in breathing and sometime shocks due to allergy
- If you have a tendency to bleed, bleeding (skin and / or mucosa, stomach and / or intestine)

These are all very serious side effects.

You may need urgent medical attention or to be admitted to a hospital.

Common	: in less than 1 of 10 patients and more than 1 of 100 patients.
Uncommon	: in less than 1 of 100 patients but, more than 1 of 1000 patients.
Rare	: in less than 1 of 1000 patients but more than 1 of 10.000 patients.
Very rare	: in less than 1 of 10.000 patients.
Unknown	: Cannot be estimated based on available data

Other side effects:**Common:**

- Hot flushes with reddening of the face and neck
- Gastrointestinal disturbances such as nausea, vomiting, flatulation, abdominal discomfort, diarrhea

Uncommon:

- Hypersensitivity reactions of the skin.
- Hyperactivity (agitation), sleep disorders
- Dizziness, chills, headache
- Blurred vision, conjunctivitis
- Heart rhythm disorders (increased heart rate)
- Pruritus, erythema, urticaria
- Fever

Rare:

- Chest pain, respiratory distress
- Bleeding in the stomach and intestines
- Bleeding in skin and mucous membranes
- Urinary tract bleeding
- Decrease in blood pressure
- Swelling in the arms and legs

Very rare:

- Bleeding foci on the skin with a decrease in the number of blood platelets
- Anemia due to impairment in the construction of red blood cells which can be fatal
- Allergic reactions developing within minutes after application (swelling in face, tongue and throat, constriction in bronchi and shock)
- Numbness, epileptic seizures, intracranial hemorrhage and cerebral infarction (seen in those with connective tissue disease)
- Bleeding in the eye and detachment in the intraocular layer
- Obstruction of liver bile ducts, increase in liver enzymes
- Tissue death in the uppermost layer of skin, skin rash, severe skin disease characterized by scaling, sweating
- Increase in blood pressure

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.

Reporting side effects

Please inform your doctor, pharmacist or nurse if you get any side effect whether or not included in this leaflet. You can also report side effects directly via clicking “Reporting of Drug Side Effects” icon on the website www.titck.gov.tr or Turkish Pharmacovigilance Center (TUFAM) by calling the phone number 0 800 314 00 08 for side effects reporting line. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store TRENTILIN®

Keep TRENTILIN® out of the reach and sight of children.

Store in room temperature below 25°C and in the original packaging.

Use in accordance with expiry date.

Do not use TRENTILIN® after the expiry date which is stated on the packaging.

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This patient leaflet was approved on 05/12/2014.

THE FOLLOWING INFORMATION IS FOR HEALTH PERSONNEL WHO WILL ADMINISTER THIS MEDICATION.

The infusion time must be at least 60 minutes for 100 mg of pentoxifylline. Administration duration is at least 180 minutes for 300 mg.

TRENTILIN® should be given as an intravenous infusion after being diluted with an appropriate fluid.

Physiological saline, Ringer solution can be used as the infusion solution. Compatibility with the solution to be used should be tested before each case. Only clear solutions should be infused.

Depending on the comorbid disease (such as congestive heart failure), it may be necessary to keep the amount of infusion low. Especially in such cases, it may be useful to use a volume controlled infusion pump.