Trental® 400mg

pentoxifylline

Prolonged-release tablets

sanofi aventis

Composition

Active ingredient

1 prolonged-release tablet contains 400 mg of pentoxifylline.

Other ingredients

Hydroxyethylcellullose, povidone K 25, talc, magnesium stearate [vegetable origin], hypromellose, titanium dioxide (E 171), erythrosine (E 127), macrogol 8000.

Pharmaceutical form and content

Trental® 400 mg prolonged-release tablet is available in packs of 20 and 100 prolonged-release tablets.

Mechanism of action

Medicine for the treatment of peripheral circulatory disorders.

WHEN THIS MEDECINE SHOULD BE USED

- Prolong the walking distance in patients with chronic peripheral arterial occlusive disease of Fontaine's stage IIb (intermittent claudication) if other therapeutic procedures such as walking training, vessel lumen-widening and/or reconstructive procedures cannot be performed or are not indicated.
- Inner ear circulatory function disorders (such as difficulty hearing, hearing loss).

ATTENTION!

WHEN THIS MEDECINE SHOULD NOT BE USED

– if you are allergic to pentoxifylline, other methylxanthines or any of the other ingredients
– if you have had an acute heart attack
– if you have had bleeding in the brain or other clinically relevant bleeding
– if you suffer from ulcers in the stomach and/or intestinal region
– if you have hemorrhagic diathesis (a condition involving an increased tendency to bleeding)
– if you have retinal bleeding.

If retinal bleeding occurs during treatment with pentoxifylline, treatment must be stopped immediately.

WHAT YOU SHOULD KNOW BEFORE YOU USE TRENTAL® 400 mg PROLONGED-RELEASE TABLET

In what circumstances should you take Trental® 400 mg prolonged-release tablet only after consulting your doctor?

Special precautions for use

Below you will find information about when to take Trental® 400 mg prolonged-release tablet only in certain circumstances and with special care. Please ask your doctor about this. This is also true if these recommendations have already applied to you.

Particularly careful medical supervision is necessary in patients with heart rythm disorders, hypotension (low blood pressure), coronary sclerosis (narrowing or obstruction of the coronary vessels of the heart), following a heart attack or postoperatively following surgical procedures.

Trental® 400 mg prolonged-release tablet should be used with particular care and under medical supervision in patients with certain autoimmune diseases (systemic lupus erythematosus and mixed connective tissue diseases).

In patients with impaired kidney function (creatinine clearance less than 30 ml/min) or with severe liver function disorders, elimination of pentoxifylline may be delayed. In such cases a dose reduction and appropriate monitoring is necessary.

Pregnancy and breast-feeding

Trental® 400 mg prolonged-release tablet should not be used during pregnancy as there is insufficient experience in pregnant women.

Pentoxifylline passes into breast milk during breast-feeding, but the infant receives only extremely small quantities of substance, so that no effects on the infant are to be expected during breast-feeding in justified cases.

Warnings and precautions for use

What precautions for use should you take into consideration?

When Trental® 400 mg prolonged-release tablet is used simultaneously with blood-thinning medicines (oral anticoagulants), careful supervision and frequent monitoring of coagulation values (INR) are necessary because of the risk of bleeding.

The blood count should be monitored regularly during treatment with Trental® 400 mg prolonged-release tablet.

Taking other medicines

IN ORDER TO PREVENT POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDECINE, YOU MUST SYSTEMATICALLY INFORM YOUR DOCTOR OR PHARMACIST IF YOU ARE TAKING ANY OTHER MEDECINES

Blood pressure-lowering medicines *(antihypertensives)*:

Trental® 400 mg prolonged-release tablet can exaggerate the effect of blood-pressure lowering medicines and an exaggerated reduction in blood pressure is possible.

Medicines for thinning the blood (anticoagulants):

Trental® 400 mg prolonged-release tablet can exaggerate the effect of anticoagulants. In patients with an increased tendency to bleeding, for example because of the simultaneous administration of blood-thinning medicines, particularly careful surveillance (e.g. regular monitoring of INR) is necessary since any bleeding that occurs may be exaggerated.

Oral antidiabetics (medicines for treating diabetes), insulin:

An exaggeration of the blood sugar-lowering effect can occur (hypoglycemic reactions). The control of blood sugar should be monitored at individually defined intervals.

Theophylline (drug for treating airway diseases):

Increased blood levels of theophylline are possible and consequently the side effects of theophylline may be exaggerated in the treatment of airway diseases.

Cimetidine (gastric acid-reducing drug):

An increase in pentoxifylline plasma levels and an exaggerated effect of Trental® 400 mg prolonged-release tablet are possible.

HOW TO USE TRENTAL® 400 mg PROLONGED-RELEASE TABLET

The following information is applicable, provided Trental® 400 mg prolonged-release tablet has not been otherwise prescribed by your doctor. Please follow the instructions for use, or Trental® 400 mg prolonged-release tablet may not work properly.

Dosage

The following dosage recommendations apply:

Chronic peripheral arterial occlusive disease of Fontaine's stage IIb (intermittent claudication)

Unless otherwise prescribed, you should take 1 x Trental® 400 mg prolonged-release tablet 3 times daily (equivalent to 1 200 mg of pentoxifylline daily).

Specific dosage instructions may be necessary in patients with low or fluctuating blood pressure values.

The dose should be adjusted in patients with impaired kidney function (creatinine clearance less than 30 ml/min) according to individual tolerability.

A dose reduction is required in patients with severe liver function disorders, which should be decided by the doctor on an individual basis according to the severity of the illness and the tolerability.

Inner ear circulatory function disorders (such as difficulty hearing, hearing loss).

Unless your doctor prescribes otherwise, 1 x Trental® 400 mg prolonged-release tablet should be taken 2 to 3 times per day.

Specific dosage instructions may be necessary in patients with low or fluctuating blood pressure values.

In patients with impaired kidney function (creatinine clearance less than 30 ml/min), the dose should be adjusted to 50% to 70% of the usual dose, according to individual tolerability, for example by taking 2 instead of 3 x Trental® 400 mg prolonged-release tablets per day.

A dose reduction is required in patients with severe liver function disorders, which should be decided by the doctor on an individual basis according to the severity of the illness and the tolerability.

METHOD AND ROUTE OF ADMINISTRATION

Swallow the prolonged-release tablets whole after meals with a large amount of liquid.

Note:

In the case of accelerated gastrointestinal transit (laxative, diarrhea, surgical shortening of the bowel, etc.), tablet residues may be passed out in isolated cases. Consult your doctor in this event.

Treatment duration

Your doctor will decide on the duration of treatment.

Overdose and other errors in use

What should you do if you take more Trental® 400 mg prolonged-release tablet than you should?

If you suspect an overdose with Trental® 400 mg prolonged-release tablet, inform your doctor, who will decide on the measures that may need to be taken depending on your symptoms. If poisoning occurs, medical help must be sought immediately so that you can be admitted to a hospital and receive the relevant treatment.

Symptoms of overdose

Dizziness, nausea, fall in blood pressure, tachycardia (accelerated heart rate), flushing (redness of the face with a sensation of heat), loss of consciousness, fever, agitation (restlessness), areflexia (absence of reflexes), tonic-clonic seizures, coffee ground vomit and arrhythmias (heart rhythm disorders) may occur following an overdose of Trental® 400 mg prolonged-release tablet.

Treatment measures (medical care) following overdose

If not much time has passed since the overdose, your stomach may be pumped or further absorption of the active substance may be delayed by activated charcoal. Subsequent measures depend on the symptoms. Close medical monitoring (especially of blood pressure and breathing) may be necessary to avoid complications.

What should you do if you do not take enough Trental® 400 mg prolonged-release tablet or forget to take a dose?

Do not take a double dose the next time, but continue to take the tablets as prescribed.

What should you do if you interrupt or prematurely stop your treatment with Trental® 400 mg prolonged-release tablet?

Do not interrupt or stop your treatment with Trental® 400 mg prolonged-release tablet without first consulting your doctor.

POSSIBLE SIDE EFFECTS

The frequency of side effects is classified as follows:

Very common: more than 1 in 10 treated patients	**Common:** fewer than 1 in 10 but more than 1 in 100 treated patients
Occasional: fewer than 1 in 100 but more than 1 in 1000 treated patients	**Rare:** fewer than 1 in 1000 but more than 1 in 10000 treated patients
Very rare: fewer than 1 in 10000 treated patients, and isolated cases	

Gastrointestinal tract / liver / bile

Gastrointestinal disorders such as nausea, vomiting, feeling of fullness, heaviness in the stomach or diarrhea may commonly occur.

Very rarely, bile obstruction (intrahepatic cholestasis) and an increase in liver enzymes (transaminases, alkaline phosphatase) may occur.

Heart and blood vessels

Flushing (redness of the face with a sensation of heat) is common; heart rhythm disorders (such as tachycardia) may occur occasionally; and a decrease in blood pressure, angina pectoris, breathlessness (dyspnea) or accumulation of fluid in tissues (peripheral edema/angio-edema) may occur rarely. In very rare cases, there may be an increase in blood pressure.

Allergic reactions

Occasionally, hypersensitivity reactions with itching, redness of the skin and urticaria (wheals with itching) may occur.

In very rare cases, serious hypersensitivity reactions occurring within minutes of administration (angioedema, spasm of the bronchial muscles, anaphylactic shock) may be observed.

On the first signs of a hypersensitivity reaction, stop the treatment with the drug immediately and inform the doctor.

Blood and blood cells

Under treatment with Trental® 400 mg prolonged-release tablet, bleeding (such as on the skin and mucous membranes, and in the stomach, intestine and urogenital region) has been reported in rare cases, and intracranial bleeding (bleeding inside the skull) as well as retinal bleeding and retinal detachment have been reported in very rare cases.

There have been very rare reports of thrombocytopenia (reduced platelet count) with bleeding into the skin (thrombocytopenic purpura) and sometimes fatal aplastic anemia (a reduction in or absence of production of all blood cells, pancytopenia). Regular blood counts should therefore be performed.

Other

Occasionally dizziness, trembling (tremor), headache and fever may occur. Restlessness, and sleep disorders may also occur occasionally, and in very rare cases there may be excessive sweating, sensory disorders (paresthesia), visual disorders, inflammation of the conjunctiva (conjunctivitis), seizures (convulsions) and serious skin reactions (epidermal necrolysis and Stevens-Johnson syndrome). In very rare cases, symptoms of aseptic meningitis may be observed under treatment with Trental® 400 mg prolonged-release tablet. Patients with autoimmune diseases appear to be particularly susceptible (systemic lupus erythematosus and mixed connective tissue diseases). In all observed cases the symptoms disappear after the withdrawal of Trental® 400 mg prolonged-release tablet.

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

What measures are to be taken against side effects?

Breathlessness, vomiting, sweating and dizziness can be early signs of severe hypersensitivity reactions. In these cases stop taking the medicine immediately and contact a doctor.

If retinal bleeding is observed during treatment, Trental® 400 mg prolonged-release tablet must be stopped immediately.

STORING TRENTAL® 400 mg PROLONGED-RELEASE TABLET

The expiry date of this medicine is stated on the box. Do not use the medicine after this date.

Store at a temperature not exceeding 25°C. Protect from moisture

Keep medicines out of the reach of children.

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Packed by
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BPI

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Germany

This is a medicament
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists