This package insert is continually updated:
please read carefully before using a new pack!

Trental® 400

Active ingredient: Pentoxifylline

Composition
Each sugar-coated tablet with controlled release contains, as active ingredient, 400 mg pentoxifylline.
Excipients: Hydroxyethylcellulose, polyvidone 25000, talc, magnesium stearate, sucrose, acacia, titanium dioxide (E 171), macrogol 6000, erythrosine (E 127).

Properties
Trental 400 improves the blood flow properties by influencing pathologically altered red cell deformability, inhibiting platelet aggregation, and reducing increased blood viscosity. Consequently, Trental 400 enhances the nutritive microcirculation in areas with impaired blood flow.
The important feature of Trental 400 is the continuous release of the active ingredient resulting in constant absorption and long-lasting blood levels.
Improvement of symptoms of cerebrovascular disorders has been demonstrated after administration of Trental 400.
Treatment of peripheral arterial occlusive diseases (e.g. intermittent claudication) results in an increase in walking distance and relief of nocturnal calf cramps and rest pain.

Indications
Peripheral arterial occlusive disease and arteriovenous disorders of an arteriosclerotic or diabetic nature (e.g. intermittent claudication or rest pain) and trophic disturbances (e.g. leg ulcers and gangrene).
Cerebral circulatory disorders (sequelae of cerebral arteriosclerosis such as difficulties in concentration, vertigo, impairment of memory), ischaemic and post-apoplectic states.
Circulatory disturbances of the eye or internal ear, associated with degenerative vascular processes and impaired sight or hearing.

Contraindications
Trental 400 must not be used in patients with
- hypersensitivity to pentoxifylline, other methylxanthines or any of the excipients (see under "Composition").
- massive bleeding (risk of increased bleeding).
- extensive retinal bleeding (risk of increased bleeding).

Pregnancy and lactation
Insufficient experience has been gained concerning use in pregnancy. Therefore, Trental 400 should not be used during pregnancy.
Pentoxifylline passes into breast milk in minute quantities. Because insufficient experience has been gained, the physician must carefully weigh the possible risks and benefits before administering Trental 400 in breast-feeding women.

Special warnings and precautions
Particularly careful monitoring is required in patients
- with severe cardiac arrhythmias (risk of deterioration of arrhythmias).
- with myocardial infarction (increase of pre-existing risk of cardiac arrhythmias and fall in blood pressure).
- with hypotension (risk of further blood pressure reduction; see also under "Dosage and administration").
- with severely impaired renal function (creatinine clearance below 10 ml/min) (risk of accumulation and increased risk of adverse reactions; see also under "Dosage and administration").
- with severely impaired liver function (risk of accumulation and increased risk of adverse reactions; see also under "Dosage and administration").
- with increased bleeding tendency due to e.g. anticoagulant medication or coagulation disorders (risk of more severe bleedings). Concerning bleeding see also under "Contraindications".

No experience is available on the use of Trental 400 in children.

Adverse effects
Particularly when Trental 400 is taken in high doses, flushes (reddening of the skin with a sensation of heat), gastrointestinal complaints such as gastric pressure, fullness, nausea, vomiting or diarrhoea may frequently occur as may, occasionally, cardiac arrhythmias (e.g. tachycardia).
Pruritus, reddening of the skin and urticaria may occasionally develop, as may, in isolated cases, severe anaphylactic/anaphylactoid reactions accompanied by, e.g., angioneurotic oedema, bronchospasm, and sometimes even circulatory failure (shock). At the first signs of an anaphylactic/anaphylactoid reaction Trental 400 must be discontinued immediately, and a physician must be informed.
Dizziness, headache, agitation and sleep disturbances may occasionally occur, as may, in isolated cases, intrahepatic cholestasis and transaminase elevation.
Rarely, angina pectoris, a fall in blood pressure, and – especially in patients with increased bleeding tendency – bleedings (e.g. on the skin and/or mucosae, in the stomach and/or intestine) may develop, as may – in isolated cases – thrombopenia.
Please consult a physician if you notice any of the adverse effects listed in this package insert or any other undesired effects or unexpected changes.
Since some adverse drug effects (e.g. severe anaphylactic or anaphylactoid reactions) may under certain circumstances become life-threatening, it is essential that you inform a physician immediately if sudden or severe reactions occur, and on no account continue taking the drug without a physician's express guidance.

Interactions
The blood-pressure-lowering effect of antihypertensive agents (e.g. ACE inhibitors) and other drugs with blood-pressure-lowering potential (e.g. nitrates) may be increased by Trental 400.
The blood-sugar-lowering effect of insulin or oral antidiabetics may be potentiated (increased risk of hypoglycaemia). Therefore, patients under medication for diabetes mellitus should be carefully monitored.
In some patients, concomitant administration of pentoxifylline and theophylline may increase theophylline levels. This may lead to an increase in or intensification of adverse effects associated with theophylline.

Dosage and administration
In principle, dosage and mode of administration is based on the type and severity of the circulatory disorder and on how the individual patient tolerates the drug. Dosage is generally based on the following guidelines and is determined by the physician in accordance with individual requirements:
The usual dose is one sugar-coated tablet [illegible] two or three times daily. The tablets are to be swallowed whole during or shortly after a meal with sufficient amounts of liquid (approx. ½ glass).
In patients with marked impairment of renal function (creatinine clearance below 10 ml/min), it may be necessary to reduce the dose to 2 or 1 sugar-coated tablet daily. The precise reduction implemented will vary depending on how the patient tolerates the drug.
A dose reduction, guided by individual tolerance, is necessary in patients with severely impaired liver function.
Treatment must be started with low doses in hypotensive patients or patients whose circulation is unstable as well as in patients who would be at particular risk from a reduction in blood pressure (e.g. patients with severe coronary heart disease or relevant stenoses of blood vessels supplying the brain); in such cases, the dose must be increased only gradually.

Expiry date
Do not use later than the date of expiry.

Keep medicines out of the reach of children.

Presentation
20, 50, and 100 sugar-coated tablets

This is a medicament
- 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.

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

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Hoechst

إن هذا دواء

- الدواء مستحضر يؤثر على صحتك واستعماله خلافا للتعليمات يعرضك للخطر
- إتبع بدقة وصفة الطبيب وطريقة الإستعمال المنصوص عليها وتعليمات الصيدلاني الذي صرفها لك
- فالطبيب والصيدلاني هما الخبيران بالدواء وبنفعه وضرره
- لا تقطع مدة العلاج المحددة لك من تلقاء نفسك
- لا تكرر صرف الدواء بدون وصفة طبية

لا تترك الأدوية في متناول أيدي الأطفال

مجلس وزراء الصحة العرب
وإتحاد الصيادلة العرب

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