Trental®
Pentoxifylline
400mg

SANOFI

Composition
Each film-coated tablet with sustained release contains 400 mg pentoxifylline.

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

Indications
Peripheral occlusive arterial disease and arteriovenous disorders of an arteriosclerotic or diabetic nature (e.g. arteriosclerosis with intermittent claudication or rest pain, diabetic angiopathy) and trophic disturbances (post-thrombotic syndrome, leg ulcer and gangrene).
Vascular disturbances of the eye (acute, sub-acute and chronic impairment of retinal and choroidal perfusion).
Cerebral circulatory disorders (sequelae of cerebral arteriosclerosis such as difficulties in concentration, vertigo, impairment of memory), ischaemic and post-apoplectic states.

Contraindications
Trental 400 mg film-coated tablet must not be administered to patients with hypersensitivity to pentoxifylline, cerebral or extensive retinal haemorrhage, or acute myocardial infarction.
Trental 400 mg film-coated tablet should not be used during pregnancy. Trental should not be administered to patients intolerance to methylxantine derivates such as caffein, theophyllin and theobromine.

Precautions
• Administration to nursing mother is not recommended, or stop nursing if the drug is needed.
• Safety and effectiveness in children below the age of 18 years have not been decided.
• If side effects persist at this lower dosage, the administration of Trental 400 mg film-coated tablet should be discontinued.
• Periodic blood presure monitoring is recommended for patients receiving concomitant antihypertensive therapy.
• At the first signs of an anaphylactic/anaphylactoid reaction, must be discontinued or the infusion be halted immediately, and a physician must be informed.

Particularly careful monitoring is required:
• in hypotensive patients.
• in patients with impaired renal function (creatinine clearance below 30 mL/min)
• in patients treated concomitantly with pentoxifylline and anti-vitamin K or platelet aggregation inhibitors.
• in patients treated concomitantly with pentoxifylline and antidiabetic agents
• in patients treated concomitantly with pentoxifylline and ciprofloxacin.

Adverse reactions
These adverse reactions have been reported in clinical trials or post-marketing. Frequencies are unknown.

System Organ Class	Adverse Reaction
Investigations	**Transaminases increased** (Transaminase elevation), **Blood pressure decreased** (Fall in blood pressure)
Cardiac disorders	**Arrhythmia** (Cardiac arrhythmia), **Tachycardia, Angina Pectoris.**
Blood and lymphatic system disorders	**Thrombocytopenia** (Thrombopenia), **Leucopenia, Neutropenia**
Nervous system disorders	**Dizziness, headache, meningitis aseptic** (Aseptic meningitis)
Gastrointestinal disorders	**Gastrointestinal disorder** (Gastrointestinal complaints), **Epigastric discomfort** (Gastric pressure), **Abdominal distension** (Fullness), **Nausea, Vomiting, Diarrhoea, Constipation Hypersalivation.**
Skin and subcutaneous tissue disorders	**Pruritus, Erythema** (Reddening of the skin), **Urticaria, Rash.**
Vascular disorders	**Hot flush** (Flushes), **Haemorrhage** (Bleedings)
Immune system disorders	**Anaphylactic reaction, Anaphylactoid reaction, Angioedema** (Angioneurotic edema), **Bronchospasm, Anaphylactic shock** (shock)
Hepatobiliary disorders	**Cholestasis** (Intrahepatic cholestasis)
Psychiatric disorders	***Agitation, Sleep disorder*** (Sleep disturbances)

Interactions
The effect of antihypertensives may be potentiated in case of concurrent administration of Trental 400 mg film-coated tablet. In such event, the dosage should be adjusted.

Precautions for use
The blood-sugar lowering effect of insulin or oral antidiabetics may be potentiated. Therefore it is recommended that patients under medication for diabetes mellitus be carefully monitored. Post-marketing cases of increased anti-coagulant activity have been reported in patients concomitantly treated with pentoxifylline and anti-vitamin K. Monitoring of anti-coagulant activity in these patients is recommended when pentoxifylline is introduced or the dose is changed.

Take into account
The blood-pressure-lowering effect of antihypertensive agents and other drugs with blood-pressurelowering potential may be increased by Trental.
Concomitant administration with ciprofloxacin may increase the serum concentration of pentoxifylline in some patients. Therefore, there may be an increase in and intensification of adverse reactions associated with co-administration.
Potential additive effect with platelet aggregation inhibitors: Because of the increased risk of bleeding, the concomitant administration of a platelet aggregation inhibitor (such as clopidogrel, eptifibatide, tirofiban, epoprostenol, iloprost, abciximab, anagrelide, NSAIDs other than selective COX-2 inhibitors, acetylsalicylates [ASA/LAS], ticlopidine, dipyridamole) with pentoxifylline should be undertaken with caution.
Concomitant administration with cimetidine may increase the plasma concentration of pentoxifylline and the active Metabolite I.

Dosage and administration
Unless otherwise prescribed, the usual dose is one film coated tablet Trental 400 mg film-coated tablet two or three times daily after meals, to be swallowed whole with some liquid.
In patients with low or labile blood pressure or with pronounced renal dysfunction, individual dosage adjustment is required.

Keep medicine out of the reach of children.

Storage :
Store below 30°C.

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

This package insert is continually updated: Please read carefully before using a new pack.

Presentation
10 Blisters x 10 Film Coated Tablets of 400 mg.
Reg.No.DKL0121203317A1

HARUS DENGAN RESEP DOKTER
ON MEDICAL PRESCRIPTION ONLY

Manufactured by:
PT Aventis Pharma
Jakarta, Indonesia.

SA/546571

Based on CCDS v.05-LRC-09-May-2014 and CCDS v.06&07-LRC-02-June-2015

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SAP / ID. number : PACKING INSERT TRENTAL (OM) – 4 / 546571
Version number : 1
Country : Indonesia
Date : 13.11.2018
Dimensions : 105 x 300 mm
Logo version : Version SCV A1 : 28.09.2005
Film code : SA/546571
Min. point size of text : 7 pt
Type of text : Ocean Sans Pro SAN Family
Colour : PMS Pantone Reflex Blue CVC
Type of Prefolded : 3x Horizontal
Dimension after folded : 105 x 37mm
Material : HVS Paper 60 g/m²
Pharmacode : 65711
Position visual codes : 12-13mm,34-35mm
Prepared by : Rahmat Hafid & Azka Afina

546571 - PACKING INSERT TRENTAL (OM) # 4

Plant:	JAKARTA - INDONESIA
Packaging material code:	546571
Packaging material name:	PACKING INSERT TRENTAL (OM) # 4
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VISTAlink folder number:	3990337
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Plant final technical validation	Syandi Hendrakusuma (Jakarta packaging team)	05/07/2019 09:13:44
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