For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information
TRENTAL®

Pentoxifylline Prolonged Release Tablets I.P.

COMPOSITION
Trental Tablets : Each sustained release film coated tablet contains Pentoxifylline B.P. 400 mg.
THERAPEUTIC INDICATIONS
Peripheral arterial occlusive disease (PAOD) of arteriosclerotic or diabetic origin (e.g. with intermittent claudication and rest pain); Trophic lesions (e.g. leg ulcers and gangrene); Cerebral vascular disease; Circulatory disturbances of the eye in conjunction with degenerative vascular disorders.
DOSAGE AND ADMINISTRATION
Usually dosage is 400 mg pentoxifylline 2 to 3 times daily. Tablets are to be swallowed whole during or shortly after meal with sufficient amounts of liquid (approx ½ glass).
PAOD Stage II (intermittent claudication) and circulatory disturbances of the eye; to start treatment or in support of oral therapy : recommended that an infusion of 100 to 600 mg pentoxifylline be given once or twice daily. When low dose infusion therapy is combined with oral therapy, the recommended total daily dose is 1200mg pentoxifylline (intravenous plus oral).
PAOD Stages III and IV : Total daily dose of 1200mg administered in suitable carrier solution as continuous infusion over a period of 24 hours or as an infusion of 600mg each given twice daily over periods of at least six hours.
Therapy to be continued with oral pentoxifylline alone.
SAFETY RELATED INFORMATION
CONTRAINDICATIONS: Contraindicated in patients with hypersensitivity to pentoxifylline, other methylxanthines or any of the excipients, in patients with massive bleeding (risk of increased bleeding) and in patients with extensive retinal bleeding (risk of increased bleeding).
PRECAUTIONS : Should be discontinued or the infusion be halted immediately, and a physician must be informed if signs of an anaphylactic/anaphylactoid reaction occur. Careful monitoring is required in patients with severe cardiac arrhythmias, myocardial infarction, hypotensive patients, in patients with impaired renal function (creatinine clearance below 30 ml/min), severely impaired liver function, increased bleeding, in patients treated concomitantly with pentoxifylline and anti-vitamin K , or platelet aggregation inhibitors; in patients treated concomitantly with pentoxifylline and anti-diabetic agents, 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 patients treated concomitantly with pentoxifylline and ciprofloxacin, • in patients treated concomitantly with pentoxifylline and theophylline
PREGNANCY : Not recommended.
LACTATION : Pentoxifylline passes into breast milk in minute quantities, hence physician must carefully weigh the possible risks and benefits before administering in breast-feeding women. No experience is available concerning the use of pentoxifylline in children.
ADVERSE REACTIONS: Transaminases increased, blood pressure decreased, cardiac arrhythmia, tachycardia, angina pectoris, thrombocytopenia, **Leucopenia/neutropenia,** dizziness, headache, meningitis aseptic, gastrointestinal disorder, epigastric discomfort, abdominal distension, nausea, vomiting, diarrhea, Constipation, Hypersalivation,pruritus, erythema, urticaria, **Rash,** hot flush, haemorrhage, anaphylactic reaction, anaphylactoid reaction, angioedema, bronchospasm, anaphylactic shock, cholestasis, agitation and sleep disorder.
For full prescribing information, please contact Sanofi India ltd, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

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