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Product : T-TRENLIN 400MG SR TABLET SAP No. : Date : 24 February 2025	☐ Unit Box ☑ Leaflet ☐ Aluminium Foil ☐ Generic Box ☐ Outer Box ☐ Fix-A-Form ☐ Sachet ☐ Label ☐ Shipper Carton ☐ Others : _____	

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Remarks	Colour
1. Font : Archivo Regular (Spacing -5pt / Size - 5pt) 2. Dimension : 194mm(w) x 130mm(h)	Black Colours shown on this proof are to indicate correct colour separations.

Trenlin™ 400

S. R. Tablet

PRODUCT
Trenlin SR Tablet 400mg

DESCRIPTION
Pink, caplet shaped, film coated tablet, plain on both sides.

NAME(S) AND STRENGTH(S) OF ACTIVE INGREDIENT (S)
Active Ingredient: Pentoxifylline 400mg
Preservatives: None

PHARMACODYNAMICS
Pentoxifylline is 3,7-dimethyl-1-(5-oxo-hexyl)xanthine. It is a water-and lipid-soluble xanthine derivative. It reduces blood viscosity and improves erythrocyte flexibility and tissue oxygen concentrations. Improvement in erythrocyte flexibility appears to be due to inhibition of phosphodiesterase and a resultant increased in cyclic AMP in red blood cells. Reduction of blood viscosity may be the result of decreased plasma fibrinogen concentrations and inhibition of red blood cell and platelet aggregation. One important feature of Trenlin is the continuous release of the active substance resulting in constant absorption and long lasting blood level.

PHARMACOKINETICS
Pentoxifylline is readily absorbed from the gastro-intestinal tract but undergoes extensive first-pass hepatic metabolism. Pentoxifylline is metabolised by erythrocytes and in the liver. The 5-hydroxy-methyl metabolite and 3-carboxypropyl metabolite are active. The apparent plasma half-life of pentoxifylline is reported to be 0.4 to 0.8 hours; that of the metabolites varies from 1.0 to 1.6 hours. In 24 hours most of the dose is excreted in the urine mainly as metabolites and less than 4% is recovered in the faeces. Elimination of pentoxifylline is decreased in elderly patients and patients with hepatic disease. Pentoxifylline and its metabolites cross into breast milk.

INDICATIONS
Pentoxifylline is used in the treatment of peripheral occlusive arterial disease and arteriovenous disorders (e.g. intermittent claudication or rest pain) and trophic disturbances (e.g. gangrene and leg ulcers.) It is also used in cerebrovascular disorders (sequel to cerebral arteriosclerosis such as difficulties in concentration, vertigo, impairment of memory.)

CONTRAINDICATIONS
Trenlin 400 should be avoided in patients who are hypersensitive or intolerant to the active ingredient, pentoxifylline and other xanthine derivatives such as caffeine, theophylline or theobromine.

Pentoxifylline is also contraindicated in cases where patients suffer from acute myocardial infarction.

Risk-benefit should be considered when there is a risk of bleeding, especially recent cerebral or retinal hemorrhage or active bleeding (may cause or exacerbate bleeding).

In accordance with general principle, pentoxifylline should not be given during pregnancy.

DRUG INTERACTIONS
Concurrent use of anticoagulants, platelet aggregation inhibitors and thrombolytic agents may increase the risk of bleeding because of additive interference with blood clotting. Antihypertensive effects may be potentiated when antihypertensive medications are used concurrently with pentoxifylline.

Smoking may interfere with the therapeutic effect because nicotine constricts blood vessels, which may worsen the condition for which pentoxifylline is being used.

High parenteral doses of pentoxifylline, in rare cases, have been shown to enhance the hypoglycaemic action or insulin and oral antidiabetic drugs.

Ketorolac and pentoxifylline should not be given concomitantly as there is increased risk of bleeding and/or prolongation of prothrombin time.

SIDE EFFECTS/ADVERSE REACTIONS
Pentoxifylline can cause nausea, gastro-intestinal disturbances, dizziness and headache. Flushing, angina, palpitation, cardiac arrhythmia and hypersensitivity reaction may also occur, particularly under high doses of pentoxifylline. In such cases, a reduction of the daily dosage or a discontinuation of the preparation is to be considered.

PRECAUTIONS/WARNINGS
Pentoxifylline should be used with caution in patients with severe coronary artery disease or hypotension, cerebrovascular disease, hepatic function impairment or renal function impairment.

It has been used safely for treatment of peripheral arterial disease in patients with concurrent coronary artery and cerebrovascular disease but there have been occasional reports of angina, hypotension and anhythmia.

When concomitantly administered with antihypertensive agents, dosage adjustment is required.

Avoidance of smoking is recommended.

Nursing mother: Pentoxifylline and its metabolites are distributed into breast milk. The use of pentoxifylline during breast-feeding is not recommended due to lack of information.

Paediatric use: Safety and effectiveness in children below the age of 18 years have not been established.

Geriatrics: Bioavailability of pentoxifylline may be increased due to decrease in excretion as well as age-related renal function impairment in the elderly. This may result in increased potential for toxicity.

Pregnancy and Lactation
In accordance with general principle, pentoxifylline should not be given during pregnancy.

RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION
Usual dose is one tablet two or three times daily with meals and swallow whole with some liquid.
Impaired renal function creatinine clearance below 10ml/min, may be necessary to reduce the dose to 800mg or 400mg daily.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE AND ANTIDOTE(S)
The signs of overdosage include flushing, loss of consciousness, "coffee-ground" vomit, absent reflexes, tonic-clonic convulsions. Recommended treatment consists of the following:

- Immediate evacuation of the stomach.
- Symptomatic and supportive treatment, including respiratory support, maintenance of blood pressure, and control of convulsions.

PACKING/PACK SIZE
Packed in a well-closed, amber glass bottle.
Pack sizes: 90's and 100's tablets.

STORAGE CONDITIONS, USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS
Keep container tightly closed.
Store in a dry place below 25° C.
Keep medicines out of reach of children.
Jauhi ubat-ubatan daripada kanak-kanak.
Route of administration: Oral

SHELF LIFE
Please refer to label or unit carton.

PRODUCT REGISTRATION HOLDER:
Duopharma Manufacturing (Bangi) Sdn. Bhd.
Lot No. 2, 4, 6, 8 & 10 Jalan P7, Section 13, Bangi Industrial Estate,
43650 Bandar Baru Bangi, Selangor, Malaysia.

MANUFACTURED BY:
Duopharma Manufacturing (Bangi) Sdn. Bhd.
Lot No. 2 & 4, Jalan P7, Section 13, Bangi Industrial Estate,
43650 Bandar Baru Bangi, Selangor, Malaysia.

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