Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Trilobal Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Trilobal tablet contains 40mg of ginkgo biloba extract (standardised to 24% (9.6mg) ginkgo-heterosides and 6% (2.4mg) ginkgolide and bilobalide).

Each tablet also contains 82.5mg lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet

Round, brick red coloured biconvex film-coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The symptomatic treatment of peripheral arterial occlusive disease (POAD) of the lower limbs.

4.2 Posology and method of administration

One Trilobal 40mg tablet three times daily with meals.

After three months of treatment, the justification for continuing use should be reviewed.

Use in children:
Trilobal should not be used in children under 12 years of age.

4.3 Contraindications

Hepatic insufficiency or inflammation of the gastrointestinal tract.

Hypersensitivity to Ginkgo biloba extracts.

4.4 Special warnings and precautions for use

The product should be used with caution in patients with hepatic or gastrointestinal dysfunction. Steatorrhoea may affect absorption.

This product is not an antihypertensive and cannot replace medication prescribed for the treatment of arterial hypertension.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose – galactose malabsorption should not take this medication.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration of antibiotics may alter the absorption and activity of this substance through effects on intestinal flora.

4.6 Fertility, pregnancy and lactation

Results of animal experimental studies did not show any evidence of teratogenic effect. No studies have been conducted in humans during pregnancy and no precise epidemiological data are available. However, to date no birth abnormalities have been reported. Trilobal should not be used in pregnancy unless the benefits to the mother outweigh the risks to the unborn child.

It is not known whether Trilobal is excreted in human milk. Trilobal should not be taken while breast-feeding.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Adverse drug reactions include cutaneous hypersensitivity reactions (pruritus, urticaria, allergic dermatitis, rash), minor gastrointestinal disturbances (nausea, vomiting, abdominal pain and diarrhoea). Orthostatic hypotension, headaches and dizziness may occur particularly in the elderly.

4.9 Overdose

There is no human experience of overdose.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The substance appears to reduce capillary permeability, assist in the maintenance of tissue perfusion pressure and protect against platelet aggregation.

5.2 Pharmacokinetic properties

None supplied.

5.3 Preclinical safety data

None supplied.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core
Lactose monohydrate
Microcrystalline cellulose
Maize starch
Colloidal Anhydrous Silica
Talc
Magnesium stearate

Coating
Macrogol 400
Macrogol 6000
Hypromellose
Titanium dioxide (E171)
Red iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

A transparent, colourless PVC/Aluminium blister pack containing 20 tablets per blister and 3 blisters (60 tablets) per box.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Intersan GmbH
Einsteinstrasse 30-32
D-76275 Ettlingen
Germany

8 MARKETING AUTHORISATION NUMBER

PA 414/1/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12 December 1984

Date of last renewal: 12 December 2009

10 DATE OF REVISION OF THE TEXT

November 2011