

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Trilobal Drops Concentrate for Oral Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Trilobal oral solution contains 40 mg per ml extract of Ginkgo biloba (standardised to 24% ginkgo-heterosides and 6% ginkgolide and bilobalide).

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Concentrate for oral solution.

An orange brown solution.

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 1ml dose (40mg) of Trilobal oral solution should be diluted in a glass of water and taken 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.

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 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

Saccharin sodium
Soluble orange essence
Soluble lemon essence
Ethanol (96%)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

4 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

30ml brown type III glass bottle with a polyethylene screw cap with a PVDC film.

Pack content: one bottle and one volumetric dose graduated dropper.

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

The volumetric dose graduated dropper should be used to remove the appropriate dose of Trilobal drops. Trilobal should be diluted in a glass of water for oral use.

7 MARKETING AUTHORISATION HOLDER

Intersan GmbH
Einsteinstrasse 30-32
D-76275 Ettlingen
Germany

8 MARKETING AUTHORISATION NUMBER

PA 414/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 12 December 2004

10 DATE OF REVISION OF THE TEXT

April 2006