

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ginkgoforce Ginkgo biloba tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains 90 mg of extract (as dry extract) from *Ginkgo biloba* L. fresh leaf (3-5:1). Extraction solvent: Ethanol 60% m/m.

Excipients:

One tablet contains 12.5 mg soya polysaccharide

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet.

It is a brown speckled, round, biconvex, bevelled tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used to relieve the symptoms of Raynaud's syndrome and tinnitus, based on traditional use only.

4.2 Posology and method of administration

Adults and the elderly: One tablet twice daily after food increasing to two tablets twice daily if necessary.

Children and adolescents less than 18 years old:

The use in children and adolescents under 18 years of age is not recommended (see Section 4.4).

Duration of use:

If the symptoms worsen or persist for more than 4 weeks a doctor or a qualified healthcare practitioner should be consulted.

For oral use only.

4.3 Contraindications

Do not use in cases of known hypersensitivity to Ginkgo preparations or to any of the excipients.

This product contains soya polysaccharide. If you are allergic to peanut or soya, do not take this product. Refer to Section 2, for soya polysaccharide content.

4.4 **Special warnings and precautions for use**

The use in children and adolescents under 18 years of age is not recommended because data are not sufficient and medical advice should be sought.

Keep out of the reach and sight of children.

There are rare case reports of spontaneous bleeding in association with the use of products containing *Ginkgo* extracts. Although no causal link has been established care should be taken by patients who have a pre-existing bleeding disorder. It is advisable that Ginkgoforce tablets are discontinued at least 2 weeks prior to surgery or that clotting parameters are assessed prior to surgery.

4.5 **Interaction with other medicinal products and other forms of interaction**

Appropriate studies have not been conducted to determine whether drug interactions occur with Ginkgoforce and its active constituents.

4.6 **Pregnancy and lactation**

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

4.7 **Effects on ability to drive and use machines**

No studies on the effects on the ability to drive and use machines have been undertaken.

4.8 **Undesirable effects**

The following adverse reactions have rarely been reported in association with the use of products containing *Ginkgo* extract.

Body as a whole – general disorders

- Allergy

Central and peripheral nervous system disorders

- Headache

Gastrointestinal system disorders

- Nausea
- Vomiting
- Diarrhoea

Skin and appendages

- Pruritis
- Rash

There have been very rare case reports of Stevens-Johnson syndrome associated with the use of *Ginkgo* extract.

There are sporadic case reports of bleeding disorders in patients who have been taking preparations containing *Ginkgo* extract. The causality in these cases is not established.

- 4.9 Overdose**
No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

- 5.1 Pharmacodynamic properties**
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

- 5.2 Pharmacokinetic properties**
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

- 5.3 Preclinical safety data**
The preclinical toxicology data available are limited.

An *in vitro* study has shown the aqueous ethanolic *Ginkgo* extract used in this product to be non-mutagenic in the *Salmonella typhimurium* reverse mutation assay up to the dose of 5,000 µg/plate.

Tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

- 6.1 List of excipients**
Microcrystalline cellulose
Magnesium stearate
Soya polysaccharide

- 6.2 Incompatibilities**
Not applicable.

- 6.3 Shelf life**
36 months

- 6.4 Special precautions for storage**
Store in the original container.

- 6.5 Nature and contents of container**
Amber glass bottles (type III) with aluminium pilfer proof closure fitted with a polyethylene liner.

Pack sizes: 60 tablets
120 tablets

Not all pack sizes may be marketed.

- 6.6 Special precautions for disposal**
No special requirements

- 7 MARKETING AUTHORISATION HOLDER**
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