

Ginkgo biloba tablets 40mg

1. Name of the Medicinal Product

Ginkgo biloba tablets 40mg Taj Pharma

2. Qualitative and Quantitative Composition

Each film coated tablet contains:

Dried extract of Ginkgo Biloba BP 40mg
(Contains 9.6mg of Ginkgo Flavones Glycoside)
Colours: Tartrazine and Titanium Dioxide USP.

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Tablet.

4. Clinical Particulars

Therapeutic indications

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

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.

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.

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.

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.

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.

Effects on ability to drive and use machines

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

undertaken.

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.

Overdose

No case of overdose has been reported.

5. Pharmacological properties:

Pharmacodynamic properties

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

Pharmacokinetic properties

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

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. Pharmaceuticals Particulars:

List of excipients: Microcrystalline cellulose, Magnesium stearate, Soya polysaccharide

Incompatibilities

Not applicable.

Shelf life

36 months

Special precautions for storage

Store in the original container.

Nature and contents of container

Aluminium Blister Packs.

Pack Size of: 7, 14, 28, 30, 50, 100 and 500 tablets.

Special precautions for disposal

No special requirements

7. Manufactured In India By:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

Unit No. 214.Old Bake House,

Maharashtra chambers of Commerce Lane,

Fort, Mumbai - 400001

at:Gujarat, INDIA.

Customer Service and Product Inquiries:

1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)

Monday through Saturday 9:00 a.m. to 7:00 p.m. EST

E-mail: tajgroup@tajpharma.com