Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ginkgoforce Memory & Circulation Ginkgo tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 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 with known effect:

Each tablet contains 12.5 mg soya polysaccharide

For the 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 alleviate age-related memory loss and the symptoms of poor blood flow in conditions such as cold hands and feet. This is exclusively based on long-standing use. Prior to use, other serious conditions should have been ruled out by a medical doctor.

This product is indicated for use in adults and older people.

4.2 Posology and method of administration

Posology
Adults and older people: One tablet twice daily after food

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 2 weeks, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Method of administration
For oral use only.

4.3 Contraindications

Hypersensitivity to Ginkgo preparations or to any of the excipients listed in section 6.1.

Pregnancy (see section 4.6 'Fertility, pregnancy and lactation').

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.

There are rare case reports of spontaneous bleeding in association with the use of products containing *Ginkgo biloba* extracts. Although no exact causal link has been established, care should be taken by patients who are at an increased risk of bleeding such as those with bleeding disorders or those being treated with anti-platelet agents or anticoagulants. It is advisable that Ginkgoforce tablets are discontinued at least 2 weeks prior to surgery.

In patients with epilepsy, onset of further seizures – promoted by intake of Ginkgo preparations – cannot be excluded.

Concomitant use of *Ginkgo biloba* containing products and efavirenz is not recommended (see section 4.5).

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.
Limited clinical data suggest that *Ginkgo biloba* may raise Nifedipine levels and increase its effects. In some individuals this may result in dizziness and increased severity of hot flushes.

Products containing *Ginkgo biloba* have been observed in some studies to cause moderate induction of drug metabolizing enzymes such as CYP3A4, CYP2C9 and CYP2C19. It cannot be excluded that other enzymes could also be affected. Because induction causes increased synthesis of these enzymes, it can result in a slight to moderate decrease in plasma concentrations of drugs metabolized by these enzymes. Induction generally varies widely among individuals. The results reported from different studies are somewhat contradictory, however. Besides induction, weak inhibition of CYP3A4 has also been observed. Since the enzyme inducing and inhibiting effects of *Ginkgo biloba* are quite small, they are unlikely to be of clinical relevance for most drugs. However, it may be relevant for drugs with a narrow therapeutic index and in certain patients.

Concomitant use of *Ginkgo biloba* preparations and efavirenz is not recommended; plasma concentrations of efavirenz may be decreased because of induction of CYP3A4.

4.6 Fertility, pregnancy and lactation

There are no or limited amount of data from the use of *Ginkgo biloba* in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Ginkgoforce tablets are not recommended during pregnancy and in women of childbearing potential not using contraception.

It is unknown whether *Ginkgo biloba*/active metabolites are excreted in human milk. A risk to newborns/infants cannot be excluded. Ginkgoforce tablets should not be used during breast-feeding.

No studies with *Ginkgo biloba* in humans have been conducted to evaluate the effects on fertility.

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.

Immune system disorders

- Allergy

Nervous system disorders

- Headaches
- Dizziness

Gastrointestinal disorders

- Nausea
- Vomiting
- Diarrhoea
- Abdominal pain

Skin and subcutaneous tissue disorders

- 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 in patients who have been taking preparations containing Ginkgo extract. The causality in these cases is not established.

In patients with epilepsy, onset of further seizures - promoted by the intake of Ginkgo preparations - cannot be excluded.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel +353 1 6764971; Fax + 353 1 6762517. Website: http://www.hpra.ie/; E-mail: medsafety@hpra.ie

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 packed in a cardboard outer.

Pack sizes: 60 tablets

120 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

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9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 23rd of October 2015.

10 DATE OF REVISION OF THE TEXT