Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ginkgo-Biloba Pharma Nord film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100 mg of extract (as dry extract, refined) from *Ginkgo biloba* L., folium (Ginkgo leaf) (35-67:1), corresponding to:

22.0-27.0 mg of flavonoids expressed as flavone glycosides
2.8-3.4 mg of ginkgolides A, B and C
2.6-3.2 mg of bilobalide.

First extraction solvent: acetone 60 % w/w

For full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet (tablet).
White, round (12 mm diameter), biconvex film coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used to alleviate 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: One tablet to be taken twice daily, after food. Tablets should be swallowed whole with a glass of water.

Elderly: No adjustment of dose is required for the treatment of elderly patients.

Children and Adolescents: This product is not indicated or recommended for use in children or adolescents less than 18 years old (see section 4.4).

Duration of use

If symptoms worsen or persist for more than 2 weeks, a qualified healthcare professional (e.g. a doctor or a 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 and Lactation (see section 4.6 'Fertility, pregnancy and lactation').

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 cases of spontaneous bleeding in association with 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 Ginkgo-Biloba Pharma Nord is 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 Ginkgo-Biloba Pharma Nord and its active constituents.

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 may not be excluded that other enzymes may be induced as well. Because induction causes increased synthesis of these enzymes, it can result in slight to moderate decreases 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.

Available studies with warfarin do not indicate that there is an interaction between warfarin and Ginkgo biloba products, but adequate monitoring is advised when starting Ginkgo biloba, when changing Ginkgo biloba dose, when ending Ginkgo biloba intake or if changing product.

An interaction study with talinolol indicates that Ginkgo biloba may inhibit P-glycoprotein at the intestinal level. This may give rise to increased exposure of drugs markedly affected by P-glycoprotein in the intestine such as dabigatran etexilate. Caution is advised if combining Ginkgo biloba and dabigatran.

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.

4.6 Fertility, pregnancy and lactation

Pregnancy

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). Ginkgo-Biloba Pharma Nord should not be used during pregnancy and in women of childbearing potential not using contraception.

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

Fertility
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

Specific studies to determine the potential effect of Ginkgo biloba extract on the ability to drive or operate machinery have not been carried out.

4.8 Undesirable effects

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

Immune system disorders

- Allergy Nervous system disorders

- Headache
- Dizziness Gastrointestinal system disorders

- Nausea
- Vomiting
- Diarrhoea
- Abdominal pain Skin and subcutaneous tissue disorders

- Pruritus
- Rash

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

There are sporadic case reports of bleeding disorders in patients who have been taking preparations containing Ginkgo biloba extract; the causality has not been 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 suspected adverse reactions after authorisation of the medicinal product 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 Website: www.hpra.ie.

4.9 Overdose

There have been no reports of overdose with Ginkgo biloba extract.

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

Adequate tests on reproductive toxicity and tests on genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Microcrystalline cellulose
Colloidal anhydrous silica
Talc
Magnesium stearate

Film coating
Hypromellose
Talc
Titanium Dioxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25 ºC. Store in the original package to protect from moisture.

6.5 Nature and contents of container

PVC/PVDC blisters with aluminium foil backing in a cardboard carton.
Each pack contains 60 or 150 tablets in 30 tablet blister trays.

Not all packs sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

Pharma Nord ApS
Tinglykke 4-6
DK-6500 Vojens
Denmark

8 REGISTRATION NUMBER(S)

TR1242/001/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of First Registration: 16th March 2018
Date of last renewal: 15th March 2023

10 DATE OF REVISION OF THE TEXT

September 2022