

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ginkgo-Biloba Pharma Nord® film-coated tablets

Ginkgo dry extract

Read all of this leaflet carefully before you start taking this traditional herbal medicine because it contains important information for you.

Always take this product exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

What is in this leaflet

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2. What you need to know before you take Ginkgo-Biloba Pharma Nord
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1. What Ginkgo-Biloba Pharma Nord is and what it is used for

Ginkgo-Biloba Pharma Nord is a traditional herbal medicine containing an extract obtained from leaves of the *Ginkgo biloba* tree.

It is used to relieve 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.

Ginkgo-Biloba Pharma Nord is for use in adults.

2. What you need to know before you take Ginkgo-Biloba Pharma Nord

Do not take Ginkgo-Biloba Pharma Nord

- If you are allergic (hypersensitive) to Ginkgo biloba or any of the other ingredients in this product (listed in section 6).
- If you are pregnant, may become pregnant or if you are breastfeeding

Warnings and precautions

Before taking this product

- Check with your doctor that your symptoms are not caused by any serious underlying condition.
- Talk to your doctor or pharmacist if you have a condition that causes you to bleed for longer than is normal. This product may not be suitable for you.

If you suffer from epilepsy Ginkgo may increase the risk of you having a seizure.

Stop taking this product 2 weeks before any planned surgery.

Talk to your doctor or pharmacist if your symptoms worsen or do not improve within 2 weeks.

Children and adolescents

Do not give this product to children or adolescents under 18 years of age.

Other medicines and Ginkgo-Biloba Pharma Nord

Do not take this product if you are taking any of the following medicines

- nifedipine
- efavirenz

If you are taking aspirin, warfarin or any other medicines that may increase your risk of bleeding talk to your doctor or pharmacist before taking Ginkgo-Biloba Pharma Nord as it may not be suitable for you.

If you are speaking to your doctor, pharmacist or nurse always remember to tell them about any medicines you are taking, or have recently taken, including herbal remedies such as Ginkgo-Biloba Pharma Nord.

Interactions with food and drink

Ginkgo-Biloba Pharma Nord can be taken with food (see section 3).

Pregnancy, breast-feeding and fertility

Do not take this product if you are pregnant, may become pregnant or if you are breast-feeding.

Driving and using machines

It is not known if Ginkgo-Biloba Pharma Nord can affect the ability to drive and use machines. Make sure you know how this product affects you before you drive or use machinery.

3. How to take Ginkgo-Biloba Pharma Nord

Always take this product exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Recommended dose

- **Adults and older people:** Take 1 tablet twice daily after food. Do not take more than the recommended dose
- Tablets should be swallowed whole with a glass of water.
- For oral use only.

If you take more Ginkgo-Biloba Pharma Nord than you should

If you accidentally take too much of this traditional herbal medicine and feel ill, talk to your doctor, pharmacist or nurse. Have this leaflet at hand.

If you forget to take Ginkgo-Biloba Pharma Nord

- Do not worry about a missed a dose. Take the next dose at the usual time.
- Do not take a double dose to make up for a missed dose.

If you have any further questions about taking this product talk to your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this traditional herbal medicine can cause side effects, although not everybody gets them.

Side effects

Digestive symptoms

- Feeling sick (nausea)
- Digestive upsets such as sickness or diarrhoea
- Stomach discomfort

These are often short-lived and should get better on their own. However if they persist, talk to your doctor or pharmacist.

Skin reactions

- Itching
- Rash

Other side effects

- Allergic reactions
- Headache
- Dizziness

Stop taking this product if any of these occur.

These side effects are rare and likely to affect less than 1 in every 1,000 people.

There have been very rare reports of the following occurring after the use of Ginkgo extracts:

- Blistering of the skin, mouth, eyes or groin (Stevens-Johnson syndrome)
- Bleeding

It is not known if these were caused by Ginkgo. If either occurs seek medical advice *immediately* and take this leaflet with you.

If you suffer from epilepsy Ginkgo may increase the risk of you having a seizure.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ginkgo-Biloba Pharma Nord

- Keep this product out of the sight and reach of children.
- Do not use this product after the expiry date which is stated on the blisters and carton. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package to protect from moisture.
- Do not use this product if you notice a change in colour. The tablets should be white in colour.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ginkgo-Biloba Pharma Nord contains

- The active ingredient in each tablet is 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.
- Other ingredients in the tablet core are microcrystalline cellulose, colloidal anhydrous silica, talc and magnesium stearate. The film-coating contains hypromellose, talc and titanium dioxide (E171).

What Ginkgo-Biloba Pharma Nord looks like and contents of the pack

- Ginkgo-Biloba Pharma Nord is a white, round, biconvex film-coated tablet.
- Ginkgo-Biloba Pharma Nord is available in blister packs containing 60 or 150 film-coated tablets. Not all pack sizes may be marketed.

Traditional Herbal Registration Holder and Manufacturer

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

Importer and Distributor

Pharma Nord Limited
Pharmapark
Chapelizod
Dublin 20
Ireland

TR: 1242/1/1

What is Ginkgo biloba?

Ginkgo biloba L. is the scientific name for a species of tree commonly called the Ginkgo. An extract of its leaves is the active ingredient in Ginkgo-Biloba Pharma Nord film-coated tablets.

This leaflet was last revised 08/2022