

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### BILOBIL FORTE

50 mg hard capsules

GINKGO BILOBAE FOLII EXTRACTUM SICCUM

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What BILOBIL FORTE is and what it is used for
2. Before you take BILOBIL FORTE
3. How to take BILOBIL FORTE
4. Possible side effects
5. How to store BILOBIL FORTE
6. Further information

#### 1. WHAT BILOBIL FORTE IS AND WHAT IS IT USED FOR

BILOBIL FORTE capsules contain dry extract of ginkgo leaves (refined and quantified).

Ginkgo leaf extract is recommended for relieving the symptoms that occur as a result of circulatory disturbances of the brain and limbs.

BILOBIL FORTE capsules improve cerebral blood flow and metabolism and preserve intellectual capabilities. In circulatory disturbances of the limbs, the product relieves the feeling of cold, tingling, numbness and pain when walking.

Bilobil capsules are herbal medicine, which is recommended for the relief of symptoms:

- Reduction of intellectual abilities and memory,
- Dizziness,
- Noise in the ears,
- Reluctance / indisposition,
- Headaches and sleep disorders,
- and in the initial circulatory disturbances of the limbs.

Before starting treatment with this medicine it is necessary to clearly confirm that symptoms are not due to a disease that requires specific treatment.

Bilobil capsules are not intended for use in children and adolescents under 18 years, pregnant women and before surgery.

## **2. BEFORE YOU TAKE BILOBIL FORTE**

### **Do not use BILOBIL FORTE**

- If you are allergic (hypersensitive) to one of the active substances or any other ingredient of this medicine.
- If you are pregnant.

### **Take special care with BILOBIL FORTE if you**

Before starting treatment with this medicine it is necessary to clearly confirm that symptoms are not due to a disease that requires specific treatment.

If you have an increased tendency to bleed (hemorrhagic diathesis) or are being treated with medicines that prevent blood clotting, you can take BILOBIL FORTE only after consulting with your doctor.

In case of a hypersensitivity reaction, stop taking these capsules.

If you are planning surgery, tell your doctor that you are taking BILOBIL FORTE.

If you suffer from epilepsy, consult your doctor before taking BILOBIL FORTE since medicines containing ginkgo can trigger the occurrence of seizures.

Do not take higher doses than recommended.

### **Children and adolescents**

Since there is no indication for the use of Bilobil capsules in children and adolescents under 18 years and due to limited data on safety and efficacy in this age group, this medicine should not be used in children and adolescents under the age of 18.

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription.

If BILOBIL FORTE is used simultaneously with medicines that prevent blood clotting (such as coumarin anticoagulants, clopidogrel, aspirin and other nonsteroidal anti-inflammatory medicines) that can affect their effect. Consult your doctor before starting treatment.

If you are taking medicines to treat epilepsy (eg, valproate, phenytoin), consult your doctor before taking BILOBIL FORTE since medicines containing ginkgo can trigger the occurrence of seizures.

### **Taking Bilobil with food and drink**

Bilobil capsules can be taken independently of meals. Taking the capsules with alcoholic beverages is not recommended.

**Pregnancy and breastfeeding**

If you are pregnant or are breastfeeding, think you may be pregnant or planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

This medicine should not be used during pregnancy and breastfeeding due to lack of data on safety during pregnancy and breastfeeding.

### **Driving and using machines**

BILOBIL FORTE should not affect your ability to drive and use machines.

BILOBIL FORTE contains azorubine.

Azorubine may cause allergic-type reactions.

The medicine contains lactose and glucose.

In case of intolerance to some sugars, contact your doctor before using this medicine.

### 3. HOW TO TAKE BILOBIL FORTE

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Use in children and adolescents

Bilobil capsules are not intended for use in children and adolescents under 18 years.

The usual adult dose is:

- Disorders of the circulatory system and brain function: 1 capsule 2 to 3 times daily
- Dizziness and tinnitus: 2 capsules a day, morning and evening,
- Disorders of blood circulation in the extremities: 2 capsules a day, morning and evening.

Swallow the capsule with a liquid. The medicine can be taken independently of meals.

The first signs of improvement are usually noticed after a month. To achieve a longer effect, it is recommended, especially in the elderly, to take capsules for at least three months. After three months, consult your doctor or pharmacist to discuss the justification of further administration of the medicine.

If you feel that the effect of capsule Bilobil is too strong or too weak, talk to your doctor or pharmacist.

#### ***If you take more BILOBIL FORTE than you should***

If you take more medicine than you should, contact your doctor or pharmacist. To date, no cases of poisoning have been reported with ginkgo extract.

#### ***If you forget to take BILOBIL FORTE***

Do not take a double dose to make up for the forgotten tablet.

If you miss a dose, take the next dose at the usual time and continue to use the medicine as instructed by a doctor.

Talk to your doctor or pharmacist if you have any additional questions.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, **BILOBIL FORTE** can cause side effects, although not everybody gets them.

Side effects are listed according to the following categories of frequency:

**Very common:** more than 1 treated person of 10

**Common:** 1 to 10 treated persons of 100

**Uncommon:** 1 to 10 treated persons of 1000

**Rare:** 1 to 10 treated persons of 10000

**Very rare:** less than 1 treated person of 10000

**Not known:** frequency cannot be estimated from the available data

#### **Very rare:**

- Mild digestive disorders (nausea, vomiting and diarrhea),
- Headache,
- Hypersensitivity reaction on the skin (itching, redness, swelling)
- Bleeding in certain organs (brain, gastrointestinal tract, the eyes), especially when administered simultaneously with medicines that prevent blood clotting.

#### ***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.

### 5. HOW TO STORE BILOBIL FORTE

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use **BILOBIL FORTE** after the expiry date which is stated on the label.  
Store in the original package to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### ***What BILOBIL FORTE contains***

The active substance is dry extract of the ginkgo leaves.

One hard capsule contains 80 mg of extract (as dry extract, refined and quantitated) of Ginkgo biloba L., folium (ginkgo leaf) (35-67: 1), corresponding to:

17.6 to 21.6 mg of flavonoids expressed as flavone glycosides,

2.24 to 2.72 mg of ginkgolides A, B, C, and

2.08 to 2.56 mg bilobalide.

Extraction solvent: 60 percent (w / w) acetone.

- Other ingredients are: lactose monohydrate; corn starch; talc; colloidal anhydrous silica and magnesium stearate contents in the capsule; and indigo carmine (E132); azorubine (E122); titanium dioxide (E171); red iron oxide (E172); Black iron oxide (E172) and gelatine in the capsule shell.

Excipient in the herbal composition is liquid glucose, prepared by spray drying.

### ***What BILOBIL FORTE looks like and contents of the pack***

Hard capsules are pink in color, containing light to dark brown powder with visible dark particles and possible lumps.

BILOBIL FORTE is available in blisters with 10 hard capsules and each box contains a total of 20 or 60 hard capsules.

### ***Regime of dispensing***

The medicine is issued without doctor's prescription.

### ***Manufacturer***

KRKA, d. d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia