

PACKAGE LEAFLET: INFORMATION FOR THE USER

Bilobil

40 mg hard capsules

GINKGO BILOBAE FOLII EXTRACTUM SICCUM

• 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.

• 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 •

What is in this leaflet?

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1. WHAT BILOBIL IS AND WHAT IT IS USED FOR

Bilobil contains the active substance which is a dry extract of the ginkgo leaves.

Bilobil is used to improve cognitive disorders (age-related), and improve the quality of life of adult patients with mild forms of dementia.

If you do not feel better after 3 months or if you feel worse when taking this medicine, you should contact your doctor.

2. BEFORE YOU TAKE BILOBIL

Do not take BILOBIL

- 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 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 only after consulting with your doctor.

If you are planning surgery, tell your doctor that you are taking Bilobil. As a precaution, stop taking Bilobil 3-4 days before surgery.

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

Taking Bilobil together with medicines containing efavirenz is not recommended (see section Other medicines and Bilobil).

Children and adolescents

There are no reasons for the application of Bilobil in children and adolescents. Bilobil should not be used in this age group.

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 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.

If you are taking warfarin, a medicine used to prevent blood clotting, your doctor may monitor you during treatment, especially if you change the dose or medicine you use, but also when you start or stop taking Bilobil.

If you are taking Bilobil with dabigatran, medicine used to prevent blood clotting, the effect of dabigatran may be increased. Consult your doctor before starting treatment.

If Bilobil is taken together with nifedipine, a medicine used in treatment of certain cardiac disorders and hypertension (high blood pressure), its effect can be increased, which may result in dizziness or strong hot flushes. Talk to your doctor if this happens.

Bilobil is not recommended when taking efavirenz (a medicine used to treat HIV infection) because it can reduce effect of efavirenz.

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 should not affect your ability to drive and use machines.

Bilobil contains dye 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

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.

The recommended individual dose for adults and elderly people is 3 capsules of 40 mg (equivalent to 120 mg) 2 times per day, or 6 capsules of 40 mg (equivalent to 240 mg) once daily.

The maximum daily dose is 6 capsules of 40 mg (equivalent to 240 mg daily).

Swallow the capsule with water.

Bilobil can be taken with or without food.

Duration of treatment

Bilobil should be taken at least 8 weeks.

If there is no improvement after 3 months of treatment, or if your symptoms get worse while taking the medicine, the doctor needs to decide whether to continue treatment.

Use in children and adolescents

This medicine is not intended for use in children and adolescents.

If you take more BILOBIL 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

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.

If you stop taking Bilobil

If you stop taking this medicine, contact your doctor or pharmacist.

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

4. POSSIBLE SIDE EFFECTS

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

In case of a hypersensitivity reaction, stop taking these capsules and ask for advice.

Very common side effects (may occur in more than 1 in 10 people):

- Headache.

Common side effects (may occur in fewer than 1 in 10 people):

- Dizziness,
- Diarrhea, abdominal pain, nausea, vomiting.

Not known (cannot be estimated from available data):

- Allergic skin reactions (swelling, redness, itching and rash)
- Hypersensitivity reaction (allergic shock)
- Bleeding in certain organs (eye, nose, brain, digestive system).

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

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use BILOBIL 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 contains

The active substance is dry extract of the ginkgo leaves.

One hard capsule contains 40 mg of extract (as dry extract, refined and quantitated) of Ginkgo biloba L., folium (ginkgo leaf) (35-67: 1), corresponding to:

- From 8.8 to 10.8 mg of flavonoids, expressed as flavone glycosides,
- From 1.12 to 1.36 mg of ginkgolide A, B, and C
- From 1.04 to 1.28 mg of 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 looks like and contents of the pack

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

Bilobil is available in blisters with 10 hard capsules and each box contains a total of 60 hard capsules.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

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