

PACKAGE LEAFLET: INFORMATION FOR THE USER

Bilobil intense

120 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?

1. What BILOBIL INTENSE is and what it is used for
2. Before you take BILOBIL INTENSE
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1. WHAT BILOBIL INTENSE IS AND WHAT IT IS USED FOR

Bilobil intense capsules contain dry extract of ginkgo leaves (refined and quantified).

Ginkgo leaf extract belongs to a group of herbal medicines used to relieve the symptoms of dementia. Dementia is a chronic progressive disease of the brain, of which the most obvious symptom is memory loss.

Bilobil intense 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:

- In mild to moderate dementia of all types (from primary degenerative dementia, vascular dementia or mixed form), for the relief of fading memory and intellectual abilities, indisposition, vertigo, tinnitus, headaches and sleep disorders,
- The initial disturbance of blood supply to the extremities, together with appropriate physical therapy, especially with training walk.

You should talk to your doctor if you do not feel better or if you feel worse after 30 days of use.

2. BEFORE YOU TAKE BILOBIL INTENSE

Do not take BILOBIL INTENSE

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

Take special care with BILOBIL INTENSE 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 intense only after consulting with your doctor.

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

If you are taking medicines to lower blood sugar or medicines to lower blood pressure, you have before starting treatment with Bilobil consult a doctor.

Do not take higher doses than recommended.

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 intense 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.

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

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

Bilobil intense 120 mg capsules, hard can affect the metabolism of medicines metabolized via the cytochrome P450 enzyme system. If you are taking any other medicines, consult your doctor before taking Bilobil intense 120 mg capsule.

You should not take Bilobil intense 120 mg capsule together with these medicines.

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 INTENSE should not affect your ability to drive and use machines.

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 INTENSE

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.

Mild to moderate dementia:

The usual dose is one capsule twice daily, preferably in the morning and evening.

The initial disorders of blood circulation in the extremities:

The usual dosage is one capsule once daily, preferably in the morning.

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.

Use in children and adolescents

This medicine is not intended for use in children and adolescents under 18 years.

If you take more BILOBIL INTENSE 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 INTENSE

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 INTENSE can cause side effects, although not everybody gets them.

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 INTENSE

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use BILOBIL INTENSE after the expiry date which is stated on the label.

Store in the original package to protect from moisture.

Shelf life: 3 years.

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 INTENSE 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:

26,4 to 32,4 mg of flavonoids expressed as flavone glycosides,

3,36 to 4,08 mg of ginkgolides A, B, C, and

3,12- do 3,84 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 INTENSE looks like and contents of the pack

The medicine is available in boxes of 20 and 60 capsules, hard, in the blister. Each blister contains 10 capsules, hard. The capsules are brown. They contain light to dark brown powder with visible dark particles and possible small lumps.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

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