

Package leaflet: Information for the patient

Bilobil intense, 120 mg hard capsules:

Ginkgo biloba leaf refined and standardised dry extract

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist 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 or pharmacist. 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 30 days.

What is in this leaflet

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1. What Bilobil intense is and what it is used for

Bilobil intense capsules contain *Ginkgo biloba* leaf refined and standardised dry extract that improves oxygen and glucose supply to the brain. Active substance in the extract is flavone glucoside, ginkgolides and bilobalide. The named substances dilate blood vessels, improve blood flow, decrease platelet aggregation and regulate metabolism and protect the cells and tissues from damage caused by lack of oxygen. *Ginkgo biloba* extract is effective in brain and limb circulation problems. Bilobil capsules improve brain circulation and metabolism and thereby inhibit cognitive decline. By improving limb circulation the product decreases cold feeling in limbs.

Bilobil intense capsules is a plant medical product that is recommended for the symptomatic treatment of:

- functional brain problems in elderly,
- arterial circulation problems in limbs.

2. What you need to know before you use Bilobil intense

Do not take Bilobil intense

- if you are allergic to the active substances or any other ingredients of this medicine (listed in section 6),

Warnings and precautions

Talk to your doctor or pharmacist before taking any Bilobil intense.

Before starting treatment with Bilobil intense capsules it must be made sure that the listed symptoms are not caused by any earlier disease that would require specific treatment.

If hypersensitivity occurs, the use of the capsules should be stopped.

Before any surgery the patients should tell their doctor that they are using Bilobil intense capsules.

If you have a tendency for abnormal spontaneous bleeding (haemorrhagic diathesis) or if you are using medicines that inhibit blood coagulation (coumarin anticoagulants, acetylsalicylic acid or other non-steroid anti-inflammatory drugs), you may take Bilobil intense only after consulting with your doctor.

There is no appropriate indication for using Bilobil intense in children under 18 years. Therefore, Bilobil intense capsules are not recommended in this age group.

Do not use higher doses than recommended.

Other medicines and Bilobil intense

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Bilobil intense capsules are not recommended if you are using medicines that inhibit blood coagulation (coumarin anticoagulants, acetylsalicylic acid or other non-steroid anti-inflammatory drugs). Concomitant use of these medicines may increase the risk of haemorrhage.

If you use anti-epileptic medicines (like valproic acid, phenytoin), please talk to your doctor before starting treatment with Bilobil intense capsules.

Bilobil intense capsules may affect the metabolism of medicines that are metabolised by cytochrome P450 enzyme system. If you use any other medicines consult your doctor before taking Bilobil intense capsules.

Bilobil intense capsules are not recommended to be taken with these medicines.

Bilobil intense with food, drink or alcohol

It is not important that the capsules are taken with food. There is no data that food or drink could affect the effect of ginkgo biloba. It is not recommended to take the capsules with alcoholic drinks.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The medicine may not be used during pregnancy or breast-feeding because the data for its use during pregnancy or breast-feeding is limited.

Driving and using machines

Bilobil intense has no effect on the ability to drive and use machines.

Bilobil intense contains lactose and glucose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to use Bilobil intense

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

In elderly persons with cognitive dysfunction:

The regular dose is 1 capsule twice daily, in the morning and evening.

Arterial circulation disorders in limbs:

The regular dose is 1 capsule once or twice daily, in the morning and/or evening.

Swallow the capsules with water. The capsules may be taken with or without food.

First signs of improvement usually appear after a month-long treatment. For a sustained result it is recommended to use Bilobil intense for at least 3 months, especially in the elderly. After 3 months you should consult a doctor or pharmacist on the need to continue treatment.

If you take more Bilobil intense than you should

There are no data on intoxication with Ginkgo biloba leaf dry extract.

If you forget to use Bilobil intense

Do not take a double dose to make up for a forgotten dose. If you forgot to take the medicine please take the regular dose as soon as possible. However, if it is almost time to take the next dose (in a couple of hours), skip the forgotten dose and continue taking the medicine on the usual time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Very common:	Occurs in more than 1 user out of 10
Common:	Occurs in one to 10 users out of 100
Uncommon:	Occurs in 1 to 10 users out of 1000
Rare:	Occurs in 1 to 10,000 users out of 10,000
Very rare:	Occurs in less than 1 user out of 10,000
Unknown:	Cannot be evaluated based on the available data

Very rare:

- Headache
- Gastrointestinal disorders
- Hypersensitivity reaction resulting in itching, redness and skin oedema.
- Gastrointestinal bleeding, cerebral haemorrhaging, eye haemorrhaging, especially if you use medicines that inhibit blood coagulation (see section Taking with other medicines)

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 www.ravimiamet.ee. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Bilobil intense

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25 °C

Keep in original packaging and protected from moisture.

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 Bilobil intense contains

- The active substance is dry extract of Ginkgo biloba leaf. One hard capsule contains 120 mg of Ginkgo biloba leaf refined and standardised dry extract (35-67:1) that equals to:
 - 26.4 to 32.4 mg of flavonoids as flavonglycosides
 - 3.36 to 4.08 mg of ginkgolides A, B, C
 - 3.12 to 3.84 mg of bilobalidesExtracting environment: Acetone 60% m/m.
- Other excipients in the capsule are lactose monohydrate, corn starch, talc, colloid water-free silicon oxide, magnesium stearate (E572), hydrogenated and spray dried glucose and black ferric oxide (E172), red ferric oxide (E172), yellow ferric oxide (E172), titanium dioxide (E171), in gelatine capsule shell.

What Bilobil intense looks like and contents of the pack

The capsules are brown and contain light to dark brown powder in visible darker particles and possibly smaller pieces. Dimensions of the capsule: size 0, average length 21.7 mm.

20 or 60 hard capsules in a blister package. Blisters are packed into outer packaging.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last revised in January 2017.