

Package leaflet: Information for the patient

Ginkgo-Maren[®] 120 mg Film-Coated Tablets

For adults from 18 years of age

Active substance: dry extract of Ginkgo biloba leaf

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

Always take 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.

What is in this leaflet

1. What Ginkgo-Maren[®] 120 mg Film-Coated Tablets are and what they are used for
2. What you need to know before you take Ginkgo-Maren[®] 120 mg Film-Coated Tablets
3. How to take Ginkgo-Maren[®] 120 mg Film-Coated Tablets
4. Possible side effects
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6. Contents of the pack and other information

1. What Ginkgo-Maren[®] 120 mg Film-Coated Tablets are and what they are used for

Ginkgo-Maren[®] 120 mg Film-Coated Tablets contain an extract of ginkgo leaves.

Ginkgo-Maren[®] 120 mg Film-Coated Tablets are used:

For symptomatic treatment of dysfunction due to organic brain changes as part of an overall therapeutic concept in patients with a decline in or loss of acquired cognitive skills (dementia) with primary complaints of impaired memory, difficulty concentrating, depressed mood, dizziness, tinnitus, headaches.

An individual patient's response to the medication cannot be predicted.

Before treatment with this medicine is initiated, it should be clarified whether the symptoms are not due to an underlying disease that requires specific treatment.

In case of frequent dizziness and tinnitus, it is generally required to consult with a doctor.

If hardness or loss of hearing occur suddenly, a doctor must be seen immediately.

2. What you need to know before you take Ginkgo-Maren[®] 120 mg Film-Coated Tablets

Do not take Ginkgo-Maren[®] 120 mg Film-Coated Tablets:

- if you are allergic to Ginkgo biloba or any of the other ingredients of this medicine (listed in section 6),
- during pregnancy

Warnings and precautions

Talk to your doctor or pharmacist before taking Ginkgo-Maren[®] 120 mg Film-Coated Tablets.

Children and adolescents

No adequate studies are available on the use of this medicine in this age group. It should therefore not be used in children and adolescents under 18 years of age.

What else is important?

In case of an unusual susceptibility to bleed (haemorrhagic diathesis) as well as concurrent treatment with anticoagulant medicines, this medicine should only be taken after consulting with a doctor.

Since there is evidence suggesting that products containing Ginkgo may increase the susceptibility to bleed, this medicine must be discontinued before a surgery. Tell your doctor within due time if you have taken Ginkgo-Maren[®] 120 mg Film-Coated Tablets so that they can decide about the further course of action.

If you know that you suffer from epilepsy, please consult with your doctor before taking Ginkgo-Maren[®] 120 mg Film-Coated Tablets.

Please take note of the information provided in 1. "What Ginkgo-Maren[®] 120 mg Film-Coated Tablets are and what they are used for" and 3. "How to take Ginkgo-Maren[®] 120 mg Film-Coated Tablets".

Other medicines and Ginkgo-Maren[®] 120 mg Film-Coated Tablets

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

When taking this medicine at the same time as anticoagulant medicines (such as phenprocoumon, warfarin, clopidogrel, acetylsalicylic acid and other nonsteroidal anti-inflammatory drugs), it cannot be ruled out that the effect of those other medicines might be enhanced.

Like for all medicines, it cannot be ruled out that Ginkgo-Maren[®] 120 mg Film-Coated Tablets might affect the metabolism of various other medicines with view to the effect and/or duration of effect of the latter. Studies are insufficient in that regard. Therefore, please consult with your doctor and pharmacist.

Ginkgo-Maren[®] 120 mg Film-Coated Tablets with food, drink and alcohol

It is not known whether Ginkgo-Maren[®] 120 mg Film-Coated Tablets interact with food, drink and alcohol.

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.

Pregnancy

Since there is anecdotal evidence suggesting that products containing Ginkgo may increase the susceptibility to bleed, this medicine should not be taken during pregnancy (see section 2 "Do not take Ginkgo-Maren[®] 120 mg Film-Coated Tablets").

Breast-feeding

This medicine should not be used during breast-feeding since no sufficient studies are available. It is unknown whether the ingredients of the extract are excreted in human milk.

Driving and using machines

What is important to know when participating in traffic and working with machines or performing other potentially hazardous activities?

It is unknown whether this medicine affects the ability to participate in traffic or operate machines or perform other potentially hazardous activities.

Ginkgo-Maren[®] 120 mg Film-Coated Tablets contain lactose and glucose

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

3. How to take Ginkgo-Maren[®] 120 mg Film-Coated Tablets

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.

Method of administration

Oral use

Unless prescribed otherwise by your doctor, the recommended dose is:

Adults from 18 years of age should take ½-1 film-coated tablet twice daily (equivalent to 120-240 mg Ginkgo extract per day).

When taken twice daily, the medicine is taken in the morning and evening.

Do not take the film-coated tablets while lying down.

Please take the film-coated tablets with plenty of liquid (preferably a glass of water), without chewing. They can be taken with or without meals.

Use in children and adolescents

Ginkgo-Maren[®] 120 mg Film-Coated Tablets should not be used in persons under 18 years of age (see section 2. "Warnings and precautions").

Duration of administration

In patients with dysfunction due to organic brain changes, the duration of treatment should be at least 8 weeks.

After 3 months of treatment, the doctor must review whether it is still justified to continue the treatment.

Talk to your doctor or pharmacist if you think that the effect of this medicine is too strong or too weak.

If you take more Ginkgo-Maren[®] 120 mg Film-Coated Tablets than you should

The side effects listed below may occur in enhanced form if you take more Ginkgo-Maren[®] 120 mg Film-Coated Tablets than you should. Please contact your doctor. The doctor can then decide which measures are to be taken, if any.

If you forget to take Ginkgo-Maren[®] 120 mg Film-Coated Tablets

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

If you stop taking Ginkgo-Maren[®] 120 mg Film-Coated Tablets

When the treatment is discontinued or stopped early, your complaints may worsen or recur.

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.

The following list covers all the known side effects from treatment with dry extract of Ginkgo leaf, including those from higher doses and long-term treatment.

The stated frequencies of the side effects are based on the following categories:

Very common: may affect more than 1 in 10 treated
Common: may affect 1 to 10 in 100 treated
Uncommon: may affect 1 to 10 in 1,000 treated
Rare: may affect 1 to 10 in 10,000 treated

Very rare: may affect less than 1 in 10,000 treated
Not known: cannot be estimated from the available data

Possible side effects

It is not possible to provide robust data regarding the frequency of side effects that have been reported for use of medicine containing Ginkgo biloba as those side effects have been reported individually by patients, doctors or pharmacists. According to those individual reports, the following side effects may occur when taking this medicine:

- Bleeding of individual organs might occur, in particular if anticoagulant medicines such as phenprocoumon, acetylsalicylic acid and other nonsteroidal anti-inflammatory drugs are taken at the same time (see also 2. "Other medicines and Ginkgo-Maren[®] 120 mg Film-Coated Tablets"). Hypersensitive people may experience severe hypersensitivity reactions (allergic shock); furthermore, allergic skin reactions (reddening/swelling of skin, itching) may occur.

If you experience any of the above side effects, stop taking Ginkgo-Maren[®] 120 mg Film-Coated Tablets and promptly contact your doctor so that they can determine the severity and decide about the measures that may be required.

- Furthermore, mild gastrointestinal complaints, headaches, dizziness or a worsening of pre-existing dizziness may occur.

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ginkgo-Maren[®] 120 mg Film-Coated Tablets

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 and blister pack after "EXP:". The expiry date refers to the last day of that month.

Storage conditions:

Do not store above 25°C.

6. Contents of the pack and other information

What Ginkgo-Maren[®] 120 mg Film-Coated Tablets contain

The active substance is: dry extract of Ginkgo biloba leaf

One film-coated tablet contains: 120 mg dry extract of Ginkgo biloba leaf (35 – 67 : 1), extracting agent: acetone 60% (m/m). The extract is quantified to 26.4-32.4 mg flavonoids, calculated as flavonoid glycosides, as well as 6.0-8.4 mg terpene lactones, of which 3.36-4.08 mg ginkgolides A, B and C and 3.12-3.84 mg bilobalide, and contains less than 0.6 µg ginkgolic acids per film-coated tablet.

The other ingredients are:

Spray-dried glucose syrup, colloidal anhydrous silica, lactose, microcrystalline cellulose, citric acid, talc, magnesium stearate (Ph. Eur.) [herbal], basic butylated methacrylate copolymer (Ph. Eur.), sodium dodecyl sulphate, stearic acid (Ph. Eur.) [herbal], saccharin sodium, vanillin, iron(III) oxide-hydroxide (E 172), hydrated castor oil.

What Ginkgo-Maren[®] 120 mg Film-Coated Tablets look like and contents of the pack

Ginkgo-Maren[®] 120 mg Film-Coated Tablets are oval, yellow-brown film-coated tablets with one-sided score line.

Ginkgo-Maren[®] 120 mg Film-Coated Tablets are available in packs of 30 film-coated tablets (N1), 60 film-coated tablets (N2) and 120 film-coated tablets (N3).

Marketing Authorisation Holder and Manufacturer

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