

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully because it contains important information for you.

This medicinal product is sold without a prescription. However, you still need to use GINGUS carefully to get the best results from it.

- Keep these leaflet. You can need to read again.
- If you need more information or advice, ask your doctor or pharmacist.
- If your symptoms worsen or do not improve during use, you should see a doctor.

In these leaflet :

1. What is GINGUS INTENS® and what is it used for?

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GINGUS INTENS® 120 mg Film Tablet

It is taken orally.

- **Active ingredient:** Each film-coated tablet contains 120 mg of dry extract of Ginkgo biloba L. leaves (35-67:1), standardized to be equivalent to 28.8 mg of Ginkgo flavone glycosides as an active ingredient..
- **Excipients:** pregelatinized corn starch, lactose monohydrate, microcrystal cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate. In the coating content, polyvinyl alcohol-partially hydrolyzed, talc, macrogol/PEG, red iron oxide, carmoicin (azorubin) aluminum lacquer, lecithin (soy) and black iron oxide.
- **Marketing Authorization Holder:** Drogan İlaçları San. Ve Tic. A.Ş. Balgat/ANKARA
- **Manufacturing Site:** Drogan İlaçları San. Ve Tic. A.Ş. Balgat/ANKARA

1. What is GINGUS INTENS® and what is it used for?

GINGUS INTENS® is presented as red colored tablets, in blister packs and boxes containing 30 and 60 film tablets.

The special Ginkgo biloba extract in GINGUS INTENS®, with its effects on red blood cells and blood coagulation cells, increases blood fluidity, increases blood circulation in organs, reduces some age-related cellular changes in the brain, increases memory performance and learning capacity, and improves balance in balance disorders. It neutralizes free oxygen radicals that are harmful to the cell and has a protective effect on nerve cells.

GINGUS INTENS®,

- Alzheimer type dementia (dementia), dementia due to vascular diseases and mixed forms of dementia,
- In the treatment of leg pain due to occlusive vascular diseases (peripheral arterial occlusive diseases)
- Dizziness and
- It is used in the treatment of tinnitus.

2. Precautions before using GINGUS INTENS®

Information that GINGUS INTENS® is intended for babies, children or adults

GINGUS INTENS® is not used in children under the age of 18.

DO NOT USE GINGUS INTENS® in the following situations

If you are allergic to any of the ingredients in this medicine, if you have a coagulation disorder, if you have had a cerebral hemorrhage or if you are pregnant.

USE GINGUS INTENS® CAREFULLY in the following situations

- Before starting treatment with GINGUS INTENS® in the areas of use related to the brain, your physician should determine whether your disease is due to any other cause that requires special treatment.
- Individual response to treatment is unpredictable
- Frequent dizziness and tinnitus should always be determined by a doctor. In case of sudden hearing loss or impairment, consult your doctor.

- If you have an increased tendency to bleed and you are using concomitant medications that reduce clotting, consult your doctor before using this medication. Some reports indicate that medications containing Ginkgo may increase the tendency to bleed.
- If you have epilepsy, consult your doctor before using this medicine.
- Use of GINGUS INTENS® should be interrupted before any surgical procedure, as there are some case examples of increased bleeding after surgery.
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If these warnings apply to you, even at any time in the past, please consult your doctor.

Use of GINGUS INTENS® with foods and beverages that may affect its effect:

GINGUS INTENS® can be used with or without meals.

Pregnancy:

Consult your doctor or pharmacist before using this medicinal product.

GINGUS INTENS® should not be used in pregnant women.

If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding:

Consult your doctor or pharmacist before using this medicinal product.

It is not known whether GINGUS INTENS® passes into breast milk. It should not be used in breastfeeding women.

Driving and using machines:

There is no information that GINGUS INTENS® affects your ability to drive or use machines.

Important information about some components of GINGUS INTENS®:

GINGUS INTENS® contains lactose. If you have intolerance to some sugars (hereditary galactose intolerance, lactase deficiency or glucose-galactose malabsorption) please consult your doctor before using this medicine.

This medicinal product contains less than 1 mmol (23 mg) sodium per dose; ie essentially "sodium free".

Carmoisine (azorubin) aluminum lacquer contained in the tablet structure of this medicinal product may cause allergic reactions.

Using GINGUS INTENS® with other medicinal products:

The use of Ginkgo together with drugs used to thin the blood or reduce blood clotting (phenprocoumon, warfarin, clopidogrel, some drugs containing acetylsalicylic acid), non-steroidal anti-inflammatory drugs (naproxen, ibuprofen, etc.), drugs used in epilepsy and may increase the risk of bleeding. Therefore, concomitant use should be avoided.

GINGUS INTENS® can change the potency and/or duration of action of some drugs that are inactivated by the liver.

Avoid concomitant use as it may lead to an increased risk of bleeding when used with drugs that reduce blood clotting.

When used with drugs used in the treatment of epilepsy, avoid using them together because of the risk of stimulating seizures.

Avoid concomitant use with buspirone (anxiety reliever).

Ginkgo can lower insulin levels in people with diabetes. For this reason, if insulin and Ginkgo are to be used together, be careful and closely monitor your blood sugar level and the signs observed due to an increase or decrease in blood sugar.

Avoid concomitant use with MAO inhibitors (a treatment group used in the treatment of depression).

Caution should be exercised in the concomitant use of selective serotonin reuptake inhibitors (a treatment group used in the treatment of depression).

In combination with thiazide diuretics (a treatment group used in high blood pressure), your blood pressure may increase, so use it carefully.

When used together with aminoglycosides (an antibiotic group used in various diseases), your hearing loss and balance may be impaired, so be careful when using them together.

If you are currently using or have recently used any prescription or non-prescription drugs, please inform your doctor or pharmacist about them.

3.How to use GINGUS INTENS®

Always strictly follow your doctor's instructions when using GINGUS INTENS®. If you are unsure, ask your doctor or pharmacist.

- **Instructions for proper use and dose/frequency of administration:**

Unless your doctor has suggested otherwise; recommended doses:

- Treatment of dementia: 1 tablet 2 times a day (morning and evening)
- The duration of treatment should be at least 8 weeks. If the symptoms do not improve or worsen after 3 months of treatment, the physician should check whether the treatment will continue.
- In the treatment of leg pain due to occlusive vascular diseases: 1 tablet 2 times a day (morning and evening)
Requires at least 6 weeks of treatment.
- Treatment of dizziness and tinnitus: 1 tablet 2 times a day (morning and evening)
Treatment of dizziness should not exceed 8 weeks.
Treatment of tinnitus should be continued for at least 12 weeks.
If no treatment success is observed after 6 months, no improvement is expected during longer treatment.

- **Method of Administration**

- GINGUS INTENS® is for oral use only.
- GINGUS INTENS® should be swallowed without chewing with a sufficient amount of liquid (preferably a glass of water) in the above-mentioned doses. It can be taken with or without meals.

If you have an impression that the effect of GINGUS INTENS® is too strong or weak, talk to your doctor or pharmacist.

If you use more GINGUS INTENS® than you should:

If you have used more than you should use from GINGUS INTENS®, talk to a doctor or pharmacist.

No overdose has been reported with GINGUS INTENS®. If you use GINGUS INTENS® in more doses than you should, the possible side effects may increase. Please inform your doctor. Your doctor can take necessary precautions.

If you forget to use GINGUS INTENS®:

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

Continue to use GINGUS INTENS® according to your doctor's instructions.

Effects when treatment with GINGUS INTENS® is discontinued:

No effects are expected.

4. What are the possible side effects?

Like all medicines, there may be side effects in people who are sensitive to the ingredients of GINGUS INTENS®. GINGUS INTENS® has been shown to be generally well accepted by the body. As with all medications, side effects can occur, but not everyone.

Rarely:

- Itching
- Rash
- Redness
- Vision problems

Very Rare:

- Cerebral hemorrhage
- Bleeding in the eye
- Formation of blisters on the skin, mouth, eyes and genital area (Stevens Johnson syndrome)

Unknown:

- Bleeding (brain hemorrhage)
- Some organ bleeding
- Post-surgical vascular inflammation
- A picture that starts with difficulty in breathing and extends to shock and death in sensitive individuals.
- Headache
- Dizziness
- Nausea
- Vomiting
- Diarrhea
- Mild digestive system disorders

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. Storage of GINGUS INTENS®

Keep GINGUS INTENS® out of the sight and reach of children and in its package.

Store at room temperature below 25°C.

Do not use GINGUS INTENS® if you notice any defects in the product and/or its packaging.

Use in accordance with expiration dates.

Do not use GINGUS INTENS® after the expiry date on the package.

6. Other Informations

For any information about this medicinal product, please contact the Registration Holder.

Marketing Authorization Holder:

Drogsan İlaçları San. ve Tic. A.Ş.

Oğuzlar Mah. 1370. Sok. 7/3

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Manufacturing Site:

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7. Last Approval Date

These leaflet was approved on 30/10/2017.

8. Warning that GINGUS INTENS® will only be sold in pharmacies

SOLD IN PHARMACIES ONLY.