

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF MEDICINAL PREPARATION

GINKOR FORT, capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Standardized Ginkgo biloba extract (EGb 761),

containing 24% ginkgo heterosides and

6% ginkgolides-bilobalides 14 mg

Troxerutin 300 mg

Heptaminol hydrochloride..... 300 mg

For a complete list of excipients, see section 6.1.

3. DOSAGE FORM

Capsules.

Description: capsule body is opaque yellow, cap is opaque green.

The content of the capsule is a pale yellow powder with a characteristic odor.

4. CLINICAL DATA

4.1. Indications for use

- Treatment of symptoms associated with venous lymphatic insufficiency (feeling of heaviness, paresthesia, leg pain).

- Symptomatic treatment of signs of acute hemorrhoids.

4.2. Dosage regimen and method of administration

- For venous lymphatic insufficiency: 2 capsules per day: one in the morning, one in the evening for one to two months, depending on the intensity of the symptoms.

- Hemorrhoidal crises: distribute the daily dose (3-4 capsules) into several doses during the day for 7 days, distributed during meals.

Application in children

The drug is not intended for use in children under 18 years of age due to the lack of data on efficacy and safety.

4.3. Contraindications

- Hypersensitivity to the components of the drug.

- Hyperthyroidism - due to the presence of heptaminol in the composition. Concomitant use with monoamine oxidase (MAO) inhibitors (see section 4.5 "Interaction with other medicinal products").

4.4. Special instructions and precautions for use

- It is recommended in patients with severe arterial hypertension at the initial stage of treatment to carefully monitor the blood pressure level due to the presence of heptaminol in the drug.

- Patients with an increased risk of bleeding (hemorrhagic diathesis), as well as patients

taking anticoagulants and antiplatelet agents, should consult a doctor before taking the drug.

- Medicines containing ginkgo biloba may increase the risk of bleeding. As a precautionary measure, these medicinal products should be discontinued 3-4 days before surgery.
- In patients with epilepsy while taking ginkgo biloba preparations, the risk of provoking a seizure cannot be excluded.
- It is not recommended to take ginkgo biloba and efavirenz at the same time (see the section "Interaction with other medicinal products").
- For hemorrhoidal crisis: the appointment of this drug does not exempt from specific treatment of other diseases of the anal area. Taking this medication should be short-term. If the symptoms do not decrease within a few days, a proctological examination and correction of the therapy are necessary.
- Lymphatic venous insufficiency: This drug is more effective when patients follow a healthy lifestyle:
 - avoid exposure to the sun and heat, prolonged standing, there is no excess body weight.
 - long walks and wearing compression stockings promote venous circulation.
- *For athletes*: this medicinal product contains an active ingredient (heptaminol) that can cause a positive reaction under anti-doping control.

4.5. Interaction with other medicinal products and other forms of interaction

The combination with MAO inhibitors is contraindicated.

Due to the presence of heptaminol in the composition of the drug, there is a risk of a hypertensive crisis.

Ginkgo biloba may interfere with the effects of anticoagulants (eg, phenprocoumon and warfarin), antiplatelet agents (eg, clopidogrel, acetylsalicylic acid, and other nonsteroidal anti-inflammatory drugs).

Studies with warfarin have not shown the presence of interactions between warfarin and ginkgo biloba preparations, but it is recommended that patients receiving warfarin be monitored at the beginning of therapy, when the dose is changed, and at the end of taking ginkgo biloba drugs.

Interaction studies with talinolol have shown that ginkgo biloba can inhibit P-glycoprotein at the intestinal level and thus lead to increased exposure to drugs that are dependent on intestinal P-glycoprotein, such as dabigatran etexilate. Should be observed caution with the simultaneous appointment of ginkgo biloba and dabigatran.

Taking ginkgo biloba medications can increase the maximum concentration of nifedepine in the blood. In some patients, the maximum concentration of nifedepine in the blood increased to 100%, which led to the development of dizziness and hot flashes, the clinical picture of which was more pronounced.

The simultaneous use of ginkgo biloba and efavirenz is not recommended, since the plasma concentration of efavirenz may be reduced due to the induction of CYP3A4.

4.6. Fertility, pregnancy and lactation

Pregnancy.

Animal studies are insufficient to draw a conclusion about reproductive toxicity (see section 5.3. "Non-clinical safety data"). There is no sufficient data on the use of the drug GINKOR FORT in pregnant women.

Considering the vasoactive properties of heptaminol and the antiplatelet properties of ginkgo biloba, the drug GINKOR FORT is contraindicated to take during pregnancy.

Lactation

Due to the lack of data on the excretion of the drug into breast milk, its use during breastfeeding is not recommended.

Fertility

Ginkgo biloba supplementation affects fertility in female mice.

4.7. Influence on the ability to drive vehicles and work with mechanisms

The effect of taking the drug on the ability to drive a vehicle and work with mechanisms has not been studied.

4.8. Adverse reactions

Data on the tolerability of the drug obtained during clinical trials (in which about 15,000 patients took part) and in the post-registration period showed that adverse reactions when taking the drug were mostly detected very rarely and were most often not serious.

Adverse reactions are classified by organs and systems according to the frequency of detection: very often ($\geq 1 / 10$), often ($\geq 1 / 100$ to $< 1/10$), infrequently ($\geq 1 / 1000$ to $< 1/100$), rarely ($\geq 1 / 10,000$ to < 1000), very rare ($< 10,000$), incidence not established (cannot be estimated from available data).

Blood and lymphatic system disorders

Frequency unknown: bleeding (ocular, nasal, cerebral, gastrointestinal).

Immune system disorders

Very rare: anaphylactic reactions, including angioedema.

Frequency unknown: hypersensitivity reactions (allergic shock).

Nervous system disorders

Very rare: headache.

Frequency unknown: dizziness.

Gastrointestinal disorders

Very rare: pain and discomfort in the epigastric region, nausea, diarrhea, vomiting.

Skin and subcutaneous tissue disorders

Very rare: urticaria, pruritus, allergic dermatitis (eczema).

Violations of the heart and blood vessels

Frequency not determined: arterial hypertension

Reporting adverse reactions

If you experience any adverse reactions, consult your doctor. This recommendation applies to any possible adverse reactions, including those not listed in the package insert. Adverse reaction reports can be directed to:

- to the contact person of the company on the territory of the Republic of Belarus by e-mail pv@recordati.by, mob. +375 33 683 00 70, tel / fax +375 17 378-07-71;

- in the Unitary Enterprise "Center for Expertise and Testing in Healthcare" at the address: Tovarishche per. 2f, Minsk, 220037, Republic of Belarus, tel / fax 242-00-29, by e-mail rcpl@rceth.by, by phone 22-00-29 or on the website www.rceth.by.

Complaints about the quality of medicines should be reported to the responsible representative on the territory of the Republic of Belarus by tel / fax + 375-17-378-07-71.

By reporting adverse reactions, you can help provide more information on the safety of this medicine

4.9. Overdose

In case of accidental or intentional overdose, it is recommended to monitor blood pressure and heart rate in a clinical setting.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Drugs that reduce capillary permeability. Troxerutin in combination

ATC code: C05CA54.

5.1. Pharmacodynamic properties

Venotonic and vasoprotective drug GINKOR FORT increases venous tone, capillary resistance, and reduces their permeability. This action is accompanied by a local inhibitory effect on some mediators of pain and inflammation (histamine, bradykinin, serotonin), lysosomal enzymes and free radicals that cause inflammation and degeneration of collagen fibers. GINKOR FORT promotes an increase in venous return to the right heart, due to the presence of heptaminol hydrochloride in the formula.

5.2 Pharmacokinetic properties

Given the presence of a combination of active ingredients, pharmacokinetic studies in humans have not been carried out.

5.3 Preclinical safety data

Preclinical studies of acute toxicity and toxicity with repeated doses of the drug did not reveal any particular risk to humans. No mutagenic or carcinogenic effects of medicinal substances contained in the product were found. Only some information is available regarding reproductive toxicity. There have been conflicting results on the action of Ginkgo biloba extracts in doses exceeding the therapeutic one. Products containing Ginkgo biloba extract may increase the risk of bleeding.

6. PHARMACEUTICAL DATA

6.1. List of excipients

Magnesium stearate, silicon dioxide

Composition of the capsule:

Capsule cap: iron oxide yellow (E 172), indigo carmine, titanium dioxide (E171), gelatin

Capsule body: iron oxide yellow (E 172), titanium dioxide (E171), gelatin

6.2. Incompatibility

Not applicable.

6.3. Expiration date (shelf life)

3 years.

Do not use after the expiration date.

6.4. Special precautions for storage

Store in original packaging at a temperature not exceeding 30°C.

Keep out of the reach of children.

6.5. The nature and content of the package

10 or 12 capsules in a blister made of PVC or PVdC / Aluminum foil. 3 blisters of 10 capsules each or 5 blisters of 12 capsules each together with an insert leaflet are placed in a cardboard box.

6.6. Special precautions when disposing of a used medicinal product or waste resulting from the use of a medicinal product or working with it

Special conditions for processing and disposal are not required.

6.7. Conditions of dispensing from pharmacies

Over the counter

7. REGISTRATION CERTIFICATE HOLDER

TONIPHARM

Immeuble “Le Wilson” 70 Avenue du Général de Gaulle 92800 Puteaux, French Republic

ПРОИЗВОДИТЕЛЬ

BEAUFOUR IPSEN INDUSTRIE

Rue Ethè Virton, 28100 DREUX, France

8. REGISTRATION CERTIFICATE NUMBER

9. DATE OF FIRST REGISTRATION

10. DATE OF TEXT REVISION