Instruction

for oral usage of medication

PHLEBODIA 600

Trade name: Phlebodia 600.

International off patent name: Diosmine (diosmine).

Pharmaceutical form: Film-coated tablets.

Drug content 1 tablet contains: Active drug substance: clean anhydrous diosmine 600 mg.

Adjuvants: Talc – 10,24 mg, colloidal silicium dioxide – 3,50 mg, staridonic acid – 50, 05 mg, microcrystalline cellulose q. s.p. 910,00 mg.

Film-coat: Sepifilm® 002 (hypromellose (E464) – 9,832 mg, microcrystalline cellulose – 7, 866 mg, Macrogol Stearate Type 1 – 1,967 mg, Sepisperse® AP 5523 pink (propylene glycol – marks, hypromellose (E464) – 0,458 mg, titanium dioxide (E171) – 4,026 mg, dye (Ponso 4R) (E 124) – 0,401 mg, iron oxide black (E172) – 0,130 mg, iron oxide red (E 172) 0,020 mg, Opaglos® 6000 (Carnauba wax (E903) – 0,075 mg, beeswax (E901) – 0,075 mg, shellac (E904) – 0,150 mg, Ethanol 95˚marks.

Description: Round, tablets, convex on both sides, pink lm-coated.

Pharmacotherapeutic group: Angioprotective agent.

TC Code C05CA03.

Pharmacologic property:

Pharmacodynamics: The product has tonic properties, it reduces venous distensibility, increases vein tone, decreases congestion in the veins, increases the tropism of adrenaline and noradrenaline in respect of myocytes. One tablet contains 600 mg diosmine, which represents optimal effective dosage for venous tone effect. Angioprotective action: improves microcirculation, increases capillary resistance and decreases their permeability; improves lymph drainage, strengthens lymph capillary tone and contractibility, decreases lymphatic pressure and assists the increase of capillary functional density.

It is characterized anti-edematous action, decreases inflammatory syndromes (dose-dependent effect), decreases leukocyte adhesion to venous wall and their migration to paravasal tissues. It improves diffusion of oxygen and its perfusion in tissues. It blocks production of free radicals and synthesis of prostaglandins and thromboxane. Clinical studies (Double-blind, placebo-controlled study carried out under Doppler sonography monitoring) has shown decrease of the average venous pressure in the superficial and deep veins system in the lower extremities. Additionally, increase of systolic and diastolic blood pressure was observed in patients with orthostatic hypotension after surgery.

Pharmacokinetics: The product quickly absorbed from the gastrointestinal tract, it can be discovered in blood in 2 hours after administration and the maximum plasma concentration is reached after 15

hours. The product is evenly distributed in all the layers of venous wall, especially in vena cava, veins of the lower limbs, to a lesser extent – in liver, kidneys and lungs. In the other tissues assessed the product concentration is insignificant. Diosmine selective concentration in venous vessels reaches its maximum after 9 hours and is maintained for further 96 hours. The product is mainly excreted in urine (79%), faeces (11%), bile (2,4%).

Indication: Within the frames of complex therapy:

For treatment of symptoms of lymphatic venous insufficiency of lower limbs: feeling of heaviness, fatigue, numbness, pain increasing by the end of the day, swelling; symptom management of hemorrhoid; add-on therapy in case of microcirculation disorders.

Contraindications: Hypersensitivity to other components of the product. Children under the age of 18 (not enough experience of usage); lactation period (not enough experience of usage).

Pregnancy and lactation: The product can be used during pregnancy if the mother's benefit received from the product exceeds the potential risk to the fetus. No teratogenic effect on the fetus was observed during the study. By today, no cases of malformation or fetotoxicity have been observed when used in women who were undergoing treatment during pregnancy.

Prescription of the product during lactation period is not recommended as no data is available whether the product is excreted with mother's milk.

Dosage and rules of use: For oral administration. Lymphatic and venous insufficiency of lower limbs: in case of chronic lymphatic and venous insufficiency 1 tablet q.d. in the morning before breakfast is prescribed.

Acute hemorrhoid and aggravation of chronic hemorrhoid: In case of acute hemorrhoid and aggravation of chronic hemorrhoid: administer 1 tablet t.i.d. with food for 4 days, for the following 3 days – 1 tablet b.d.s. with food. In the event of relapse of symptoms, the treatment regimen can be repeated at doctor's recommendation.

Chronic hemorrhoid: After acute symptoms control, it is recommended to continue the treatment with 1 tablet q.d. for 1-2 months.

In the event of missing one or more doses, the treatment should be continued at the same dosages.

Consult your physician before administration of the product.

Adverse events:

The frequency of adverse events is as follows:

Very frequent (more than 1/10 cases), frequent (more than 1/100 and less than 1/10 cases), not so frequent (more than 1/1000 cases and less than 1/100 cases), rare (more than 1/10 000 cases and less than 1/1000 cases), very rare (more than 1/100 000 cases).

The adverse events the frequency of which cannot be determined from the existing data, are marked as 'frequency unknown.'

The following adverse events were observed during the administration of Phlebodia: Gastrointestinal tract – rare dyspeptic disorders (epigastric burning, vomiting, stomach pain); central nervous system – rare headaches. If the adverse events pointed out in the instructions for medical use get worse or any other adverse events which are not described in the instructions for medical use appear, inform your phycisian.

Overdosage: Not described.

Relation with other medications: Is not described. Inform your physician which treatment medications you are taking.

Warning: Acute hemorrhoid requires combination therapy, if no quick clinical effect is reached during treatment, it is necessary to carry out additional assessments and correct the existing therapy.

Influence on driving and working with machines and equipment: No cases of adverse influence on driving and working with machines and equipment have been described.

Drug form: 15 or 18 tablets in polyvinyl chloride and aluminium blister package. 1,2,4 or 6 blisters with 15 tablets on each and the drug use label in a cardboard box. 1 blister with 18 tablets and the drug use label in a cardboard box.

Expiration date: 3 years. The product may not be used after the expiration date pointed out on the box.

Storage: Should be stored at room temperature not exceeding 30° C. Keep out of reach of children.

Release order:

Pharmacological class III, non-prescription product.

Subject authorized to register (Owner of registration license): LABORATOIRE INNOTECH INTERNATIONAL,22 AVENUE, ARISTIDE BRIANDE, 94110 ARCUEIL, FRANCE

Manufacturer, all stages of production:
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