

INSTRUCTION LEAFLET
FOR MEDICAL USE OF THE MEDICINAL PRODUCT
AESCUZAN®

Product licence number: II N 013385/01

Brand name: AESCUZAN®

International nonproprietary name or generic name: Aesculus hippocastanum Seed Extract
+ Thiamine Hydrochloride

Pharmaceutical form: oral drops

Product formulation:

100 g of the drug contain:

Active ingredients:

Dry Aesculus hippocastanum Seed Extract (5-7:1)	4.7725 g
extractant ethanol 60% (v / v)	
Thiamine Hydrochloride	0.50 g

Excipients:

Ethanol 96 %	26.400 g
Purified water	67.675 g
Lactose monohydrate	0.432 g
Colloidal silicon dioxide	0.243 g

Description

Clear or slightly cloudy liquid from yellow to reddish brown with a characteristic odor.
Sediment may form during storage.

Therapeutic category

Herbal venotonic agent.

ATC code: C05CX

Pharmacological properties

It has an antiexudative and venotonic effect. It was found that Aesculus hippocastanum seed extract reduces the concentration of lysosomal enzymes, as a result of which the disintegration of mucopolysaccharides in the region of the capillary walls decreases.

Aescusan® reduces vascular permeability, preventing the filtration of low molecular weight proteins, electrolytes and water into the extracellular space.

Indications

Chronic venous insufficiency of I-III classes according to the CEAP classification: varicose veins, edema, cramps in the calf muscles, a feeling of heaviness in the legs.

Contra-indications

Hypersensitivity to the components of the drug, liver disease, lactose intolerance, lactase deficiency, glucose-galactose malabsorption, children's age (up to 12 years).

Carefully

Alcoholism, traumatic brain injury, brain diseases, childhood (over 12 years old).

Administration during pregnancy and breast-feeding period

Due to the lack of sufficient research, the drug is not recommended to be taken during pregnancy and during breast-feeding.

Posology and method of administration

The drug is administered orally before meals, 12-15 drops 3 times a day, before use, dilute in a small amount of water. The duration of therapy is determined by the attending physician. Shake well before use.

Adverse drug reaction

Allergic reactions, irritation of the mucous membrane of the gastrointestinal tract, headaches, dizziness are possible.

Overdosage

In case of an overdose, a feeling of heaviness in the epigastric region may appear. The drug should be withdrawn. Treatment: symptomatic.

Interaction with other medicinal products

The effect of thiamine is reduced when used simultaneously with sulfite-containing infusion solutions. Fluorouracil, vinblastine, bleomycin, cisplatin interfere with the absorption of vitamin B1. Penicillamine, isoniazid reduce the effectiveness of vitamin B1, increasing its excretion.

Precaution

The product contains 31% ethanol. If the recommended dosages are observed, up to 0.128 g of ethanol enters the body with each intake of the drug, the maximum daily dose of the drug contains up to 0.384 g of ethanol.

During the period of use of the drug, care should be taken when performing potentially hazardous activities that require increased attention and speed of psychomotor reactions (driving and other vehicles, working with moving mechanisms, the work of the dispatcher and operator).

With long-term storage of drugs (liquid dosage forms) based on medicinal plant materials, turbidity and precipitation may occur, which does not affect the quality of the drug.

Pharmaceutical form and presentation

Oral drops.

20 ml of the drug in a dark glass bottle equipped with a plastic dropper stopper and a plastic screw cap. One bottle in a cardboard box along with a package insert.

Storage conditions

Store at temperatures between 8°C and 25°C.

Keep out of reach of young children!

Expiry date

3 years. Do not use after the expiry date.

Dispensing requirements

No prescription.

Manufacturer

Pharma Wernigerode GmbH

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38855 Wernigerode, Germany

Marketing authorization holder:

Esparma GmbH,

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Organization accepting complaints from consumers:

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