MINISTRY OF HEALTHCARE AND SOCIAL DEVELOPMENT
OF THE RUSSIAN FEDERATION

INSTRUCTION
on pharmaceutical composition administration for medical purpose
Trombovazim*

Therapeutic drug name

International nonproprietary name or chemical name: ----------

Commercial name: Trombovazim®

Pharmaceutical form

Capsules

Description: Hard gelatin capsules # 0 with a white body-part and a dark-rose cap with white overprint "Trombovazim®". Capsules content – white with a yellowish-brown hue to pale brown powder.

Composition: A capsule contains:

Active substance – Trombovazim ® 400 U, 600 U, 800 U;

Potato starch,	0,261 g
Microcrystalline cellulose,	0,120 g
Sodium chloride	0,009 g

Gelatin capsules contain:

Dyes: Azorubine E 122, Patent-Blue V E 131, Titania E 171, Gelatin

Pharmacotherapeutic group

Fibrinolytic agent

Code ATXB01AD

PHARMACOLOGICAL PROPERTIES

The drug has thrombolytic, anti-inflammatory and cardioprotective activity.

Pharmacodynamic

Thrombolitic mechanism is connected with direct destruction of fibrin strings, which form the main frame of thrombus. Anti-inflammatory mechanism is connected with influence on blood neutrophils and tissue macrophages oxidizing function. Cardioprotective mechanism is connected with myocarditis blood supply improvement. Trombovazim is a low-toxic preparation. Trombovazim® neither decreases platelet levels, nor influences coagulation time and bleeding duration.

Pharmacokinetics

Bioavailability of the drug when taken inside is 16-18 %. Maximum effect is observed 6 h. after intake. Systemic clearance is 1.2 ml/min, elimination rate constant with single intake is 0,057 min-1. It does not bind to blood plasma proteins and blood corpuscles. The preparation half-life at blood specific activities measurement is 12 minutes. It does not bind to plasma proteins and blood corpuscles. The drug has no cumulative effect if recommended doses and dosage frequency are observed. The preparation major pathway is renal (80 %). Partially metabolized and excreted by liver (20 %).

THERAPEUTIC INDICATIONS

As an adjuvant in complex therapy in venous insufficiency.

CONTRAINDICATIONS

- Preparation hypersensitivity;
- Pregnancy;
- Lactation;
- Age under 18 (efficacy and safety are not determined);
- gastric and duodenal ulcer (acute);
- Simultaneous intake of drugs containing bivalent metal salts (calcium, magnesium, zinc, iron) and antibiotics of tetracycline group (tetracycline, Chlorotetracyclin HCl, and oxytetracycline HCl).

DOSAGE REGIMEN, ROUTE OF ADMINISTRATION

The drug should be taken orally 30-40 minutes before meals in the doses of 800-1600 U/day divided into two doses. Maximum daily dose is 2000 U. Course of treatment is 20 days. If no efficacy observed during the course of treatment, one should consult the doctor. Courses of retreatment can be given if necessary upon the doctor's recommendation.

INTAKE PRECAUTIONS

With caution:

- polyvalent allergy;
- chronic obstructive pulmonary disease;
- esophageal varicose veins bleeding risk;
- Urolithiasis;
- gastric and duodenal ulcer (remission);

OVERDOSE SYMPTOMS, OVERDOSE FIRST AID MEASURES

No cases of overdose was observed.

POTENTIAL SIDE EFFECTS

Allergic reactions and occasional dyspeptic effects (nausea, vomiting, sense of heaviness in stomach) are possible. Temporary sense of arching in lower limbs.

INTERACTION WITH OTHER PHARMACEUTICAL DRUGS

Heparin, dipiridamol, acetylsalicylic acid increase antithrombotic effect not increasing the risk of bleeding. Administration of the drug with antibiotics of tetracycline group (tetracycline, chlortetracycline, hydrochloride, oxytetracycline hydrochloride) increases effect of fibrinolytics. When necessary to use drugs containing bivalent metal salts (calcium, magnesium, zinc, iron) one should observe time interval of 40 minutes minimum between intake of Trombovazim and the drugs mentioned because of the possible enzyme activity reduction.

ADMINISTRATION DETAILS IN CASE OF PREGNANCY AND LACTATION

The drug is contraindicated in pregnancy and lactation period.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Studies on possible effects on ability to operate machinery was not carried out hence the drug and its components are not related to those able to influence psychomotor human condition.

PHARMACEUTICAL FORM

Capsules of 400 U, 600 U, 800 U. Each cardboard pack contains 3, 5, 7 blisters with package insert, each blister maid of PVC and aluminium foil coated with heat seal lacquer contains 10 capsules.

SHELF-LIFE

2 years.

Do not use after shelf-life. **STORAGE CONDITIONS**

Store in dry, protected from light place at temperature not exceeding 25 °C.

Keep away from children.

PRESCRIPTION STATUS

Available without a prescription.

MANUFACTURER

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