SEROTEK Instructions on medical use of the drug

Tradename: Serotec.

International nonproprietary name: Serratiopeptidase.

Dosage form: Tablets for oral administration, enteric - coated.

Compound: Each enteric - coated tablet contains:

Serratiopeptidase 10 mg (equiv. 20,000 enzymatic activity).

Pharmacotherapeutic group: Drugs used for pathology of the musculoskeletal system. Enzymes. Proteolytic enzymes.

ATX code: M09AB.

Pharmacological properties:

Pharmacodynamics:

The drug contains the active component serratiopeptidase. Serratiopeptidase is an enzyme with proteolytic activity, which is isolated from the bacterium Serratia E15, which is part of the non-pathogenic intestinal microflora. The drug has fibrinolytic and anti-inflammatory activity. When using the drug, a pronounced decongestant effect is also noted. The pharmacological effects of serratiopeptidase are carried out by reducing the concentrations of bradykinin, histamine and serotonin at the site of inflammation. A decrease in the concentrations of mediators in synaptic clefts occurs due to their hydrolysis under the influence of serratiopeptidase, while the intensity of release and reuptake of mediators does not change. The drug reduces vascular dilatation and reduces their permeability. Painkillers the effect of the drug is carried out by reducing the release of amines from inflamed tissues.

Serratiopeptidase and blood a2-macroglobulin bind in the body, which leads to a decrease in antigenicity serratiopeptidase, but does not reduce its proteolytic activity. The drug reduces the activity of plasmin inhibitors, thereby increasing the fibrinolytic activity of plasmin.

The drug also helps improve sputum discharge, since serratiopeptidase can reduce swelling and improve blood microcirculation.

Pharmacokinetics:

The drug after oral administration is well absorbed in the intestinal tract, without changing under action of gastric juice. Some time after application, the concentrations at the site of inflammation significantly exceed the concentrations of serratiopeptidase in the blood. Excreted from the body in urine .

Indications for use:

- use in surgery: sprains and ruptures of ligaments, fractures and dislocations, swelling, including those caused by plastic surgery;
- diseases of the upper respiratory tract: reduces the viscosity of sputum and facilitates its removal from the respiratory tract;
- diseases of the ENT organs: facilitates the discharge of secretions from the paranasal sinuses;
- dermatology: acute inflammatory dermatoses;
- obstetrics and gynecology: hematomas, congestion in the mammary glands.

Contraindications:

- increased sensitivity to the components of the drug;
- blood clotting disorder;
- age under 18 years;
- pregnancy and lactation.

Directions for use and dosage:

The drug is prescribed to adults, 1 tablet 2-3 times a day after meals. The tablets should be swallowed without chewing and washed down with 1 glass of water. The maximum daily dose is 30 mg. The duration of treatment depends on the nature and dynamics of the pathological process and is determined in each case individually.

Side effects:

In some cases, when using the drug, the following may be observed:

Gastrointestinal disorders: diarrhea, nausea, vomiting, anorexia, epigastric discomfort.

Disorders of the respiratory system: very rarely, nosebleeds and sputum mixed with blood are possible; cases of acute eosinophilic pneumonia have been described.

In persons with hypersensitivity, allergic reactions and skin rashes are possible.

Overdose:

Symptoms: nausea, vomiting, anorexia, epigastric discomfort, in some cases - bleeding and blood in the sputum. *Treatment:* Symptomatic therapy.

Drug interactions:

When used simultaneously, the drug enhances the effect of anticoagulants. This combination of drugs should be used under close medical supervision.

Special instructions:

Since the drug affects blood clotting, it should be used with caution in patients with risk of bleeding and impaired clotting time, as well as in patients taking anticoagulants. In case of severe liver and kidney diseases, the drug is used with caution. **With caution:** prescribed to patients who suffer from liver and/or kidney diseases.

Use during pregnancy or breastfeeding:

The use of the drug during pregnancy and lactation is not recommended due to the lack of clinical data.

Application in pediatrics:

Due to the lack of experience in using the drug in children, its prescription is possible only for health reasons and under the strict supervision of the attending physician.

The ability to influence the reaction rate when driving vehicles or other mechanisms:

Does not affect.

Release form:

10 enteric-coated tablets in each blister . 3 blisters along with instructions for use in cardboard packaging.

Storage conditions:

Store in a dry place, protected from light, no higher than 25 °C and out of the reach of children.

Expiration date:

Indicated on the packaging.

Do not use after expiration date.

Vacation conditions:

Over the counter.

Made for: MAXX PHARM LTD. London, Great Britain

