Serrata Tablets *(Serratiopeptidase Tablets 10 mg)*

SERRATA

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Description: White, circular, biconvex enteric coated tablets.

Composition:

Each enteric coated tablet contains:

Serratiopeptidase 10 mg

(20,000 Serratiopeptidase units)

Additional substances: Lactose monohydrate, maize starch, light magnesium carbonate, sodium starch glycollate, magnesium stearate, opadry white, opadry enteric white.

Pharmaceutical Form: Enteric coated tablet

Pharmacotherapeutic group: Drugs for disorders of the musculo-skeletal system. Enzymes

ATC Code: M09 AB

Pharmacological properties:

Pharmacodynamics:

Serratiopeptidase acts as a fibrinolytic, anti-inflammatory, anti-oedematous and inactivates bradykinin. It is able to increase the diffusion of antibiotics and cytostatic agents in tissue.

Pharmacokinetics:

There is still no data on the bioavailability in humans. Animal experimental findings shows that Serratiopeptidase is absorbed from the duodenum. After 10 mg/kg Serratiopeptidase administered intraduodenally to dogs, radioimmunoassay identified peak concentrations in the lymph (26 ng / ml), in the portal vein blood (16 ng/ml) and in arterial blood (about 11 ng/ml), by binding to alpha2-macroglobulin Serratiopeptidase loses its antigenicity; while maintaining a sufficient proteolytic activity.

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Indications:

- As an anti-inflammatory therapy in inflammatory swelling and suppuration, in addition to causal - eg antibiotic or surgical – therapy, or when a causal therapy is missing or when it is not applied in individual cases.
- Inflammation after surgery or injury
- ***Inflammation of the following diseases:***

  In otorhinolaryngology: Sinusitis

  In dentistry: Pericoronitis of wisdom teeth or alveolar abscess of other teeth, when a surgical therapy is not possible or advisable.

  In gynecology: Breast swelling and discomfort in the early postpartum lactation due to hormone caused galactostasis.

  In Urology: In case of cystitis in addition to antibiotic therapy.

Contraindications:

- Hypersensitivity to Serratiopeptidase or any of the excipients.
- Gastric ulcers induced in the upper digestive tract.
- This product is not suitable for infants and young children.

Dosage & Direction for Use:

Depending on the severity of the disease swallow 1 - 2 tablets, 3 times a day without chewing 2 hours after meals.

Warning & Precautions:

- If symptoms persist or worsen, discontinue use and consult a health care practitioner.
- If you are pregnant or breastfeeding, consult a health care practitioner prior to use.
- If you have a gastrointestinal lesion/ulcer, are taking anticoagulant/blood thinner or anti-inflammatory medication, or are having surgery, consult a health care practitioner prior to use.
- Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Serrata.

Interaction with other medicaments:

Since the concominant use of Serratiopeptidase with an anticoagulant may intensify the anticoagulant effect, Serratiopeptidase should be administered with care under close observation. In a single case, the co-administration of carbamazepine and Serratiopeptidase led to a decrease in blood serum concentration and thus a decreased effect of carbamazepine.

Pregnancy & Lactation:

Use in pregnancy:

There is no sufficient data to determine the safety of Serratiopeptidase for humans during pregnancy. There are insufficient animal studies regarding the effects of Serratiopeptidase on pregnancy, embryonal/ fetal development, birth and postnatal development. Serratiopeptidase may be prescribed during pregnancy only if clearly indicated.

Use in lactation period:

It is not known that Serrapeptase, the active ingredient of Serrata is excreted in human milk. No adverse effects were observed during lactation in children of mothers undergoing treatment with serrapeptase.

Side effects:

In rare cases: Stomach and intestinal discomfort, nausea, vomiting and diarrhea.

In isolated cases: Hypersensitivity reaction, e.g. skin rash, erythema, urticaria, itching, also dyspnoea and edema.

In individual cases: Elevated liver enzymes (SGOT, SGPT, AP, γ-GT), jaundice and hepatitis, severe skin (Stevens-Johnson-Syndrome, Lyell-syndrome) and respiratory disorders (Löffler-Syndrome, Pneumonitis) and shock.

Influence on ability to drive a car and to operate any other machines:

There have been no studies on the effects on the ability to drive and the ability to drive or operate machinery.

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Overdose & Treatment:

Intoxications have not occurred even after high doses (till 15 tablets a daily for 60 days). If necessary, gastric lavage should be considered.

Storage:

Store below 30°C.

Keep it out of reach of children.

Dosage forms and packaging available:

Serrata tablets are packed in alu-alu strip of 10 or 30 tablets.

1, 3 or 10 strips of 10 tablets are packed in carton alongwith pack insert.

1 or 5 strips of 30 tablets are packed in carton alongwith pack insert.

Name and address of manufacturer:

Kusum Healthcare Pvt. Ltd.

SP 289 (A), RIICO Industrial Area,

Chopanki, Bhiwadi (Raj.),

India

Product Registration Holder:

Pahang Pharmacy Sdn Bhd,

Lot 5979 Jln Teratai,

5 1/2 Miles Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan,

Malaysia

Date of revision of package insert:

3rd Oct. 2017