DISCAN-S

Each tablet contains Diclofenac 50 mg and Serratiopeptidase 10 mg

Dosage Form and Strength

Dosage Form: Tablets.

Dosage Strength: Diclofenac potassium 50 mg and Serratiopeptidase 10 mg per tablet.

Clinical Particulars

Therapeutic Indication

DISCAN-S Tablets are indicated for reducing swelling and inflammation associated with surgery, trauma, infection, and other painful inflammatory conditions.

Posology and Method of Administration

For oral administration in adults. Usual recommended dose: 1 tablet of DISCAN-S to be administered three times daily. DISCAN-S Tablets should be administered preferably 2 hours after a meal. The tablet should be swallowed whole with water and strictly not to be cut, crushed or chewed.

The recommended maximum daily dose of diclofenac in adults is 150 mg in 2 or 3 divided doses. The maximum recommended dose of paracetamol in adults is 4 grams per day in divided doses. The maximum dose of serratiopeptidase is 60 mg/day in divided doses.

Or, as prescribed by the physician.

Contraindications

DISCAN-S Tablets are contraindicated in following conditions:

- Known hypersensitivity to diclofenac or to paracetamol or to serratiopeptidase or to any component of the formulation.
- Active or history of recurrent peptic ulcer/hemorrhage.
- Severe heart failure, hepatic failure, and renal failure.
- History of GI bleeding or perforation, relating to previous NSAID therapy.
- During the last trimester of pregnancy.
- Patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by aspirin or other NSAIDs.
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Pharmacological Properties

Mechanism of Action

Diclofenac

Like all other NSAIDs, the mechanism of action of diclofenac is related to inhibition of prostaglandin biosynthesis by inhibition of the cyclooxygenase (COX) enzyme. Diclofenac potassium is a non-

selective, reversible, and competitive inhibitor of COX, subsequently blocking the conversion of arachidonic acid into prostaglandin (PG) precursors. This leads to an inhibition of the formation of prostaglandins that are involved in pain, inflammation and fever.

Serratiopeptidase

Anti-inflammatory Effect: Anti-inflammatory activity of serratiopeptidase has been attributed to hydrolysis of inflammatory mediators such as bradykinin, histamine, and serotonin. It may also act by modifying cell-surface adhesion molecules that guide inflammatory cells to their target site of inflammation.

Analgesic Effect: Serratiopeptidase may help alleviate pain by inhibiting the release of pain- inducing amines like bradykinin from inflamed tissues.

Anti-edemic Effect: Serratiopeptidase reduces swelling by the process of decreasing the amount of fluid in the tissues, thinning the fluid, and by facilitating the drainage of fluid. In addition, enzyme activity of serratiopeptidase dissolves dead tissue surrounding the injured area to accelerate the healing process.

Pharmacodynamic Properties

Diclofenac

Diclofenac is a non-steroidal anti-inflammatory drug which exhibits anti-inflammatory, analgesic, and antipyretic effects.

Serratiopeptidase

Serratiopeptidase also known as serrapeptase is a proteolytic enzyme derived from bacterium *Serratia E-15 spp. L*. Serratiopeptidase has been used for reducing swelling and inflammation associated with surgery, trauma, infection, and other inflammatory conditions. Serratiopeptidase possesses anti- inflammatory, analgesic, and anti-edemic properties.

Pharmacokinetic Properties

Diclofenac

Diclofenac is rapidly absorbed from the gut and is subject to first-pass metabolism. Tablets give peak plasma concentrations after 1 to 4 hours. The active substance is 99.7% protein bound and plasma half-life for the terminal elimination phase is 1 to 2 hours.

Approximately 60% of the administered dose is excreted via the kidneys in the form of metabolites and less than 1% in unchanged form. The remainder of the dose is excreted via the bile in metabolized form. In patients with impaired renal function no accumulation of diclofenac has been reported.

Serratiopeptidase

Serratiopeptidase when administered in unprotected form is destroyed by acid in the stomach. Enteric coated granule formulation, enable the serratiopeptidase to pass through the stomach unchanged and reach in the intestine. Orally administered serratiopeptidase (in the form of enteric coated granules) has been shown to be absorbed unchanged from the small intestine and reaches into the systemic circulation in enzymatically active form. From circulation, serratiopeptidase penetrates into all the tissues. It reaches higher concentrations in the inflamed tissues. Peak plasma concentration occurs in one hour. Metabolism of serratiopeptidase takes place in the liver. The metabolites of serratiopeptidase

are excreted through the urine and faeces.