BROCEN- SP TABLET

COMPOSITION

Each film coated tablet contains :

Aceclofenac	I.P.	100mg.
Paracetamol	I.P.	325mg.
Serratiopeptidase	I.P.	15 mg.

DESCRIPTION

ACECLOFENAC :

Aceclofenac is belongs to the category of NSAID, Analgesic, Anti-inflammatory drug. It is a phenylacetic acid derivative that inhibits synthesis of the inflammatory cytokines interleukin-1b and tumor necrosis factor, and inhibits prostaglandin E2 production. It increases Glycosaminoglycans (GAG) synthesis, the Principal macromolecule of the extracellular matrix, which aids in repair and regeneration of articular cartilage. Thus, aceclofenac has positive effects on cartilage anabolism combined with modulating effect of matrix catabolism.

PHARMACOLOGY

Pharmacodynamic :

Aceclofenac has several mechanisms of actions –

1. It inhibits cyclo-oxygenase (COX) activity and to suppress the PGE2 production by inflammatory cells, by inhibiting IL-Beta & TNF in the inflammatory cells (Intracellular Action).

2. It blocks degeneration and stimulates synthesis of extra cellular matrix of cartilages by inhibiting the action of different cytokines.

3. Aceclofenac and its metabolites inhibit IL-6 production by human chondrocytes. This leads to inhibition of increase of inflammatory cells in synovial tissue, inhibition of IL-1 amplification, inhibition of increased Matrix Metalloproteinase (MMP) synthesis and thus ensuring proteoglycan production.

4. A metabolite of aceclofenac 4-hydroxy-aceclofenac inhibits pro MMP1 and pro MMP3 produced by synovial cells (Rheumatoid Synovial Cells) in serum and in synovial fluid and thus inhibits progressive joint destruction by MMPs.

5. Aceclofenac inhibits Neutrophil Adhesion & Accumulation at the inflammatory site in the early phase and thus blocks the pro-inflammatory actions of Neutrophils.

Pharmacokinetics :

Absorption : It is rapidly and completely absorbed after oral administration.

Distribution : Widely distributed in the body as protein-bound form. It is highly protein-bound (>99.7%). Aceclofenac penetrates into the synovial fluid, where the concentrations reach approximately 60% of those in plasma.

Metabolism : Metabolized into metabolites in the liver. Main metabolite is 4-hydroxyaceclofenac.

Excretion : It is excreted through urine mainly as conjugated hydroxy metabolites.

Half Life : The mean plasma elimination half-life is 4 - 4.3 hours.

PARACETAMOL

Paracetamol is acetanilide derivative, non narcotic analgesic and antipyretic action with weak anti-inflammatory activity. It produces analgesia by increasing pain threshold and antipyresis by acting on the hypothalamic heat-regulating centre.

PHARMACOLOGY :

Pharmacodynamic :

Paracetamol has analgesic and antipyretic action.
It is more active on cyclo-oxygenase enzyme in brain. Peripherally it is a poor inhibitor of prostaglandin synthesis.
Analgesic action: Paracetamol raises the pain threshold and produces analgesic effect.
Antipyretic action: Paracetamol lowers fever by direct action on the thermoregulatory centre in the hypothalamus and block the effects of endogenous pyrogen.

Pharmacokinetics :

Absorption: Paracetamol is rapidly and completely absorbed after oral administration.
Distribution: It is distributed mostly in the body in unbound form.
Metabolism: It is extensively metabolised in the liver.
Excretion: Excreted in the urine.
Onset of Action : 30 - 60 minutes .
Duration of Action : 6 hours .
Half Life : 1-4 hours .

SERRATIOPEPTIDASE :

A proteolytic enzyme, powerful anti-inflammatory and anti-endemic. It is produced by enterobacterium Serratia sp. E-15. Serratiopeptidase is present in the silkworm intestine and allows the emerging moth to dissolve its cocoon. Serratiapeptase is produced by purification from culture of Serratia E-15 bacteria.

PHARMACOLOGY :

Pharmacodynamic :

Serratiopeptidase is an anti-inflammatory proteolytic enzyme bind to the alpha-2-macroglobulin in the blood, which helps to mask its antigenicity. Then it is slowly transferred to the site of inflammation. Serratiopeptidase hydrolyze bradykinin, histamine, serotoxin responsible for oedema. It reduces swelling improves microcirculation and expectoration of sputum. Due to this action Serratiopeptidase has anti-inflammatory, antiedemic and fibrinolytic activity and act rapidly on localized inflammation.

Pharmacokinetics :

Orally absorbed. In the case of enteric coated tablet absorption take place in the intestine. After absorption it is directly enter in to the bloodstream. It is excreted via urine and bile.

Duration of Action : 8 to 10 hrs.

BROCEN – SP TAB.

Brocen – SP contains the active ingredients Aceclofenac, Serratiopeptidase and Paracetamol. This combination ensure tremendous efficacy in relieving pain, inflammation and swelling.

INDICATIONS :

Brocen – SP is indicated in the following conditions -
Pain and inflammation, Osteoarthritis, Rheumatoid arthritis, Ankylosing, spondylitis, dysmenorrheal.
Brocen- Post-operative pain, Musculoskeletal pain, Soft tissue trauma including sprains, Tendinitis, Sprain, and back pain.

CONTRAINDICATION :

Brocen-SP Tab. is contraindicated to those patients who are hypersensitivity to Aceclofenac, Paracetamol and Serratiopeptidase.

It is not recommended to those subjects who are bleeding from the stomach or intestines and moderate to severely decreased kidney function, having blood coagulation disorder, Active peptic ulcer and hypersensitivity to other NSAIDs.

Pregnancy : Aceclofenac and Serratiopeptidase are contraindicated in pregnancy, so Brocen - SP cannot be used in pregnancy .

Lactation : Since Aceclofenac and Serratiopeptidase contraindicated in lactation, so Brocen - SP cannot be used in lactation.

PRECAUTIONS :

Hepatic porphyria, Bleeding tendencies, Blood disorders, Crohn`s disease, Decreased heart function, History of peptic ulcers ,Inflammation of the bowel and back passage, Mildly decreased kidney function, Recent major surgery, Stomach disorders, Decreased liver function, Intestinal disorders.

DOSAGE :

The dosage of Brocen-SP will vary patient to patient .
Adults: 1 tablet / day should be taken 1- 2 hour after meals or as directed by the physician.

MISSED DOSE :

If there is missed a dose of Brocen - SP, then the patient should take it as soon as remember. However, if it is almost time for your next dose, then skip the missed dose and go back to the regular dosing schedule. Patient should not double the doses unless otherwise directed.

SIDE EFFECTS :

The side effects of Brocen -SP are most likely to be minor and temporary. However, some may be serious and may require the individual to inform the doctor or visit the nearest hospital immediately.
The possible side effects of Brocen –SP are nausea, headache, dizziness and stomach irritation.

DRUG INTERACTION :

Lithium, digoxin and methotrexate: Aceclofenac may increase plasma concentrations of lithium, digoxin and methotrexate.

Anticoagulants: Activity of anticoagulants may be increased.

Diuretics : Aceclofenac inhibits the activity of diuretics. When concomitantly administrated with potassium sparing diuretics, serum potassium should be monitored.

Cyclosporine: Aceclofenac may enhance cyclosporine nephrotoxicity.

Quinolone : Aceclofenac may precipitate convulsions when co-administered with quinolone antibiotics.

Cholestyramine: Reduces absorption of paracetamol.

Charcoal: Activated, administered immediately reduces absorption of paracetamol.

Domperidone and metoclopramide: Enhance absorption of paracetamol.

Alcohol: Chronic excessive ingestion of alcohol potentiates hepatotoxicity of paracetamol.

STORAGE :

Store cool, dry and dark place in 25 – 30° Celsius.

PRESENTATION :

Brocen – SP tablet is available 1*10 in a blister strip and 10 strips in a carton.