BROCEN-P TABLET

COMPOSITION

Each film coated tablet contains :
Aceclofenac I.P. 100mg.
Paracetamol I.P. 325mg.

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 Metalloproteinases (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. Almost 100% bioavailability; peak plasma levels reached about 1.25-3 hours after oral admin.

Distribution : Widely distributed in the body as 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 in the liver. Main metabolite is 4-hydroxyaceclofenac. Probably metabolised by CYP2C9; average plasma elimination half-life 4-4.3 hours.

Excretion : About two-thirds of the administered dose is removed in the urine, mainly as hydroxy metabolites.

No changes in the pharmacokinetics of aceclofenac have been detected in the elderly.

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. Plasma elimination half-life: 1-4 hours.
Excretion: Most metabolites are removed in the urine within 24 hours.
Onset of Action : 30 - 60 minutes.
Duration of Action : 6 hours.

BROCEN-P TABLET

THERAPEUTIC INDICATIONS :

Brocen – P is indicated for relief from mild to moderate pain and inflammation in Osteoarthritis, Rheumatoid arthritis, Ankylosing spondylitis, Low back pain, Dental pain, Gynaecological pain and painful & Inflammatory conditions of ear, nose & throat.

CONTRAINDICATIONS :

Brocen – P is contraindicated in the following situations -
Patients sensitive to Aceclofenac, Paracetamol or to any of the excipients of the product.

Patients in whom aspirin or other NSAIDs, precipitate attacks of bronchospasm, acute rhinitis or urticaria or patients hypersensitive to these drugs.

Patients with active or suspected peptic ulcer or gastrointestinal bleeding or bleeding disorders.
Patients with severe heart failure, hypertension, hepatic or renal insufficiency.
Third trimester of pregnancy.

PRECAUTIONS :

Brocen – P may cause dizziness. Driving or operating machinery is to be avoided.

Individuals receiving long-term treatment should be regularly monitored for renal function tests, liver function tests and blood counts. It is to be used with caution in hepatic porphyria, coagulation disorders, history of peptic ulcers, ulcerative colitis, Crohn's disease, SLE, cerebrovascular bleeding, pregnancy and lactation.

Caution should be exercised in patients with mild to moderate impairment of cardiac, hepatic or renal function and in elderly patients who are more likely to be suffering from these conditions. Caution is also required in patients on diuretic therapy or otherwise at risk of hypovolemia.

SPECIAL PRECAUTION :

GI disease; renal or hepatic impairment; alcohol-dependent patients; asthma or allergic disorders; haemorrhagic disorders; hypertension; cardiac impairment. Elderly. Caution when driving or operating machinery. Monitor renal and hepatic function and blood counts during long term treatment. Persistently elevated hepatic enzyme levels may require drug withdrawal. Pregnancy and lactation.

DOSAGE :

The recommended dose of Brocen – P is 1 tablet twice daily. Generally, no dose adjustment is necessary in elderly patients and those with mild renal impairment. Safety and efficacy has not been established in children. Maximum doses are 2 tablets a day.

OVERDOSE :

Over dosage may cause nausea, vomiting, pain abdomen, dizziness, somnolence, headache, sweating, pancreatitis, hepatic failure and acute renal failure. Treatment, if required, includes gastric lavage, activated charcoal and other symptomatic measures as per medical advice.

SIDE EFFECTS :

The majority of side effects are related to gastrointestinal system like dyspepsia, abdominal pain, nausea and diarrhea. Most frequent being dyspepsia, abdominal pain and rise in hepatic enzymes. Other rare side-effects include dizziness, constipation, vomiting, ulcerative stomatitis, rash, dermatitis, headache, fatigue, allergic reactions, anemia, granulocytopenia, thrombocytopenia, neutropenia, oedema, palpitation, leg cramps, flushing, purpura, paraesthesia, tremors, gastrointestinal bleeding, gastrointestinal ulceration, pancreatitis, interstitial nephritis, depression, abnormal dreaming, somnolence, insomnia, vasculitis, hypoglycemia, rise in blood urea, serum creatinine and serum potassium.

As with other NSAIDs, severe mucocutaneous skin reactions may occur.

DRUG INTERACTION :

Drug interactions associated with Aceclofenac are similar to those observed with other NSAIDs. Aceclofenac may increase the plasma concentrations of lithium, digoxin and methotrexate. It may increase the activity of anticoagulants, inhibit the activity of diuretics, enhance cyclosporine neurotoxicity and precipitate convulsions when co-administered with quinolone antibiotics.

Co-administration of Aceclofenac with other NSAIDs and corticosteroids are to be avoided due to increased incidence of side-effects.

The risk of Paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce hepatic microsomal enzymes. Co-administration of Paracetamol with rifampicin, isoniazid, chloramphenicol, anti-epileptic drugs and antiviral drugs is to be avoided. Metoclopramide may increase the

absorption of Paracetamol whereas excretion and plasma concentration may be altered when co-administered with probenecid. Cholestyramine also reduces the absorption of Paracetamol.

OTHER INTERACTION :

Interaction with food may be occurred.

STORAGE INSTRUCTIONS :

Store in dry and dark place at temperature below 30° C.

PRESENTATION :

Brocen – P tablet is available 1*10 in an Alu-Alu strip and 10 strips in a carton.