BREN
Ibuprofen Tablets BP

COMPOSITION

BREN-200
Each film coated tablet contains Ibuprofen BP 200mg

BREN-400
Each film coated tablet contains Ibuprofen BP 400mg

BREN-600
Each film coated tablet contains Ibuprofen BP 600mg

THERAPEUTIC CLASSIFICATION:

Pharmacotherapeutic group:

Nonsteroidal anti- inflammatory drug (NSAID) derivative of propionic acid with anti-inflammatory, analgesic, and antipyretic properties.

ATC code: MO1AE01

PHARMACODYNAMICS:

Mechanism of Action:
Ibuprofen is a phenylpropionic acid derivative NSAID that has demonstrated its efficacy by non-selective, reversible inhibition of the cyclooxygenase enzymes COX-1 and COX-2 Furthermore, ibuprofen reversibly inhibits platelet aggregation. Ibuprofen exerts its anti-inflammatory and analgesic effects through inhibition of both COX isoforms. In addition, ibuprofen scavenges HO. radical, NO and ON00 - and can potentiate or inhibit nitric oxide formation through its effects on nitric oxide synthase (NOS) isoforms. Ibuprofen may activate anti-nociceptive axis through binding to the cannabinoid receptors and through inhibition of fatty acid amide hydrolase (FAAH) that metabolizes endocannabinoid anandamide.

PHARMACOKINETICS:

Ibuprofen is rapidly absorbed following administration and is rapidly distributed throughout the whole body. The excretion is rapid and complete via the kidneys.

Maximum plasma concentrations are reached 45 minutes after ingestion if taken on an empty stomach. When taken with food, peak levels are observed after **1** to 2 hours. These times may vary with different dosage forms.

The half-life of ibuprofen is about 2 hours.

Ibuprofen appears in thebreast milk in very low concentrations.

INDICATIONS:

IBUPROFEN tablets are indicated for the treatment of:

- Pain and inflammation in rheumatic disease (including juvenile idiopathic arthritis) and other musculoskeletal disorders;
- Mild to moderate pain including dysmenorrhoea;
- Postoperative analgesia;
- Migraine;
- Dental pain;
- Fever with discomfort and pain in children;
- Post-immunisation pyrexia.

CONTRAINDICATIONS:

- NSAIDs should be used with caution in the elderly, in allergic disorders and in coagulation defects.
- In patients with cardiac impairment, caution is required since NSAIDs may impair renal function. All NSAIDs are contraindicated in severe heart failure. Ibuprofen should be used with caution in uncontrolled hypertension, heart failure, ischaemic heart disease, peripheral artery disease, cerebrovascular disease, and when used long-term in patients with risk factors for cardiovascular events. All NSAIDs including ibuprofen is contra-indicated.
- In patients with active gastro-intestinal ulceration or bleeding.
- Patients at risk of gastro-intestinal ulceration (including the elderly), who need NSAID treatment should receive gastroprotective treatment.
- Hepatic impairment: NSAIDs should be used with caution in patients with hepatic impairment.
- Renal impairment: NSAIDs should be avoided if possible or used with caution in patients with renal impairment; the lowest effective dose should be used for the shortest possible duration, and renal function should be monitored. Sodium and water retention may occur and renal function may deteriorate, possibly leading to renal failure.

DOSAGE AND ADMINISTRATION:

- ADULT and CHILD over 12 years, initially 300-400mg 3-4 times daily; increased if necessary to max.2.4g daily; maintenance dose of 0.6-1.2 g daily may be adequate.
- Pain and fever in children, CHILD 1-4 years, 100 mg 3 times daily (max 30mg/kg daily in 3-4 divided doses);

CHILD 4-7 years, 150mg 3 times daily (max 30mg/kg daily in 3-4 divided doses);
Child 7-10 years, 200mg 3 times daily (up to 30 mg/kg daily (max 2.4 g) in 3-4 divided doses);
Child 10-12 years, 300mg 3 times daily (up to 30 mg/kg) daily (max 2.4 g) in 3-4 divided doses;

- Rheumatic disease in children (including juvenile idiopathic arthritis)

Child 3 months-18 years (30-40 mg/kg (max 2.4g) daily in 3-4 divided doses)

- Systemic juvenile idiopathic arthritis, up to 60mg/kg (max.2.4g) daily in 4-6 divided doses.

SIDE EFFECTS:

Gastro-intestinal disturbances including discomfort, nausea, diarrhoea, and occasionally bleeding and ulceration. Hypersensitivity reactions particularly rashes, angioedema and bronchospasm; Headache, dizziness, nervousness, depression, drowsiness, Insomnia, vertigo, hearing disturbances such as tinnitus, photosensitivity and haematuria, Blood disorders , Fluid retention. Renal failure may be provoked especially in patients with pre-existing renal impairment (rarely, Papillary necrosis or interstitial fibrosis) can lead to renal failure.

DRUG-DRUG INTERACTIONS:

Analgesics: Ibuprofen reduces antiplatelet effect of aspirin;

Antifungals: Plasmaconcentration of ibuprofen increased by fluconazole and voriconazole;

Cytotoxics: Ibuprofen reduces excretion of methotrexate (increased risk of toxicity);

Muscle relaxants: Ibuprofen reduces excretion of baclofen (increased risk of toxicity);

Tacrolimus: Increased risk of nephrotoxicity;

WARNINGS:

GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with hemorrhage or perforation and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents.

PRECAUTIONS:

Elderly, increased risk of gastrointestinal bleeding and perforation , Ulceration who need NSAID treatment should receive gastroprotection treatment.

Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotoninreuptake inhibitors or anti-platelet agents.

Respiratory disorders-

Cautionis required if Ibuprofen is administered to patients suffering from, or with a previous history of bronchial asthma since NSAIDs have been reported to precipitate bronchospasm in such patients. Associated with an increased risk of thrombotic events.

PREGNANCYAND LACTATION:

Pregnancy:

Ibuprofen should be avoided in pregnancy.

Lactation:

Ibuprofen should be avoided during breast-feeding.

OVERDOSE:

The most frequently reported symptoms of overdose include nausea, vomiting, abdominal pain, lethargy and drowsiness. Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose. Good urine output should be ensured. Renal and liver function should be closely monitored. Patients should be observed for at least four hours after ingestion of potentially toxic amounts. Frequent or prolonged convulsions should be treated with intravenous diazepam. Other measures may be indicated by the patient's clinical condition.

TREATMENT OF OVER DOSAGE:

In the event of overdose, symptomatic treatment should be implemented. No specific antidote exists.

PRESENTATION :

Blister of 10x10 Tabs

Jar of 500's Tabs, 1000's Tabs, 5000's Tabs

STORAGE:
Store below 30°C. Protect from light.

PRESCRIPTION ONLY MEDICINE.
KEEP OUT OF SIGHT AND REACH OF CHILDREN.

Manufactured in India by:

KOPRAN LIMITED
Village Savroli, Tal. Khalapur,
Dist. Raigad-410202