For the use of Registered Medical Practitioner or a Hospital or Laboratory only.

IBUPROFEN TABLETS BP 400 mg.

Balfen™-400

COMPOSITION
Each film coated tablet contains:
Ibuprofen BP 400 mg

PHARMACOLOGICAL CLASSIFICATION
(2.1) Analgesics and Antipyretics

PHARMACOLOGICAL ACTION
Chemically, ibuprofen is described as 2-(4-isobutylphenyl)propionic acid and is a non-steroidal compound, which exhibits anti-inflammatory, analgesic and antipyretic activities.
Ibuprofen is well absorbed on oral administration. An oral dose taken on an empty stomach by human volunteers produced peak serum levels after three quarters of an hour.
Absorption was slower and peak serum levels lower after food.
Excretion is rapid with no evidence of accumulation. Two major metabolites of ibuprofen have been isolated from human urine. They are (+)2,4'(2-hydroxy-2-methylpropyl) phenylpropionic acid (metabolite A) and (+)2,4'(2-carboxylpropyl) phenylpropionic acid (metabolite B).
The levels in human serum of both metabolites have been measured after single and repeated doses. About 60% of a dose is excreted in the urine, and the excretory products are in the form of either free or conjugated metabolites A and B. No ibuprofen is found.

INDICATIONS

Ibuprofen is indicated for its analgesic and anti-inflammatory effect in the treatment of rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), ankylosing spondylitis and osteo-arthritis, and acute gouty arthritis. Ibuprofen is indicated in the treatment of non-articular rheumatism including fibrositis. Ibuprofen is indicated in peri-articular conditions such as frozen shoulder (capsulitis), bursitis, tendinitis, tenosynovitis and low-back pain. Ibuprofen can also be used in soft-tissue injuries such as sprains and strains. Ibuprofen is also indicated for its analgesic effect in the relief of mild to moderate pain such as dysmenorrhoea, dental, post-episiotomy pain and post-partum pain. Ibuprofen may also be used as an antipyretic.

CONTRAINDICATIONS

Ibuprofen should not be given to patients with peptic ulceration. The safety of Ibuprofen in pregnancy has not been established.
Hypersensitivity to Ibuprofen, aspirin or any other non-steroidal anti-inflammatory agent. Because of the possibility of cross-sensitivity due to structural relationships which exist among non-steroidal anti-inflammatory medicines, acute allergic reactions may be more likely to occur in patients who have exhibited allergic reactions to these compounds.

DOSAGE AND DIRECTIONS FOR USE

Adults: The recommended dosage of Ibuprofen is 1200 mg daily in divided doses. Some patients can be maintained on 600 to 1200 mg daily. In severe conditions it can be advantageous to increase the dosage until the acute phase has been brought under control.
To relieve early morning stiffness, the first dose of the day can be given immediately after the patient awakes.

For the relief of mild to moderate pain the following doses are recommended:
Dysmenorrhoea - 1200 mg per day in three divided doses. In cases of dental or post-episiotomy pain an initial dose of 800 mg may be given.

The total daily dose of Ibuprofen should not exceed 2400 mg. Once the acute phase has been brought under control, it is normal practice to revert to a maintenance dosage.
Acute gout: 2400 mg daily either as 800 mg 8 hourly or 600 mg 6 hourly until the acute symptoms have been relieved. If the acute symptoms do not resolve within three days, consult a doctor.
Children: In Juvenile Rheumatoid Arthritis, the total daily dosage of Ibuprofen is 20 mg/kg of body mass given in divided doses.
Safety in children under one year of age has not been proven.
Pain: Initial dose 5 mg/kg of bodyweight.

A second dose of 5 mg/kg may be given after 2 hours if pain is not controlled, thereafter 5 mg/kg every 4 - 6 hours. **DO NOT EXCEED** 20 mg/kg of bodyweight per day. If pain persists for more than 7 days, consult your doctor.

Fever: 5 mg/kg of bodyweight every 4 - 6 hours. **DO NOT EXCEED** 20 mg/kg of bodyweight per day. If fever persists for more than 3 days, consult your doctor.

Age

Do not give to children less than 7 kg or 1 year of age, except on the advice of your doctor.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

The most frequent side effects occurring with Ibuprofen are gastro-intestinal disturbances; reactions range from abdominal discomfort, nausea and vomiting and abdominal pain to serious gastro-intestinal bleeding or activation of peptic ulcer.
CNS-related side effects include headache, dizziness, nervousness, tinnitus, depression, drowsiness and insomnia. Hypersensitivity reactions may occur less frequently and include fever and rashes. Hepatotoxicity and aseptic meningitis which occur less frequently may also be hypersensitivity reactions. Ibuprofen can provoke bronchospasm in patients with asthma. Ibuprofen may cause cystitis and haematuria. They may also cause acute renal failure, interstitial nephritis, and nephrotic syndrome.
Other side effects include anaemias, thrombocytopenia, neutropenia, eosinophilia, agranulocytosis, abnormalities in liver function tests, blurred vision, changes in visual colour perception, and toxic amblyopia.

Precautions: Ibuprofen should be given with care to the elderly, to patients with asthma or bronchospasm, bleeding disorders, cardiovascular disease, a history of peptic ulceration, and in liver or renal failure. Patients with congestive heart failure, cirrhosis, diuretic-induced volume depletion, or renal insufficiency require local synthesis of vasodilating prostaglandins to maintain renal perfusion, and therefore these patients are at greater risk of developing renal dysfunction due to NSAID-induced inhibition of renal prostaglandin synthesis.
Care is required in those who are also receiving coumarin anticoagulants. Patients who are sensitive to aspirin or other NSAIDs should generally not be given Ibuprofen.
Ibuprofen should be discontinued in patients who experience blurred or diminished vision, or changes in colour vision. Patients with collagen disease may be at increased risk of developing aseptic meningitis.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

The most likely symptoms of overdosage are epigastric pain and nausea. If recently taken, gastric lavage will remove any unabsorbed ibuprofen. Electrolytes may be corrected by intravenous infusions, if necessary. There is no specific antidote to Ibuprofen.

STORAGE INSTRUCTIONS
Store in a cool place.

Keep out of reach of children.
TM-Trade Mark

Lit-1523

Manufactured by:
BAL PHARMA LIMITED
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