AGOG Pharma Ltd.
(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)
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LEAFLET

AGOFEN-200 TABLETS

(Ibuprofen Tablets BP 200 mg)

DESCRIPTION: White, circular, biconvex, film coated tablets having both side plain

COMPOSITION:
Each film coated tablet contains:
Ibuprofen BP..... 200 mg
Excipients..... q.s
Approved colour used

INDICATIONS:
Pain and inflammation in rheumatic disease (including juvenile idiopathic arthritis) and musculoskeletal disorders; mild to moderate pain including dysmenorrhea; postoperative analgesic ; migraine; dental pain; fever with discomfort and pain in children; post immunization pyrexia.

CLINICAL PARMACOLOGY:
Ibuprofen is supplied as tablets with a potency of 200 to 800 mg. The usual dose is 400 to 800 mg three times a day. It is almost insoluble in water having pKa of 5.3. It is well absorbed orally; peak serum concentrations are attained in 1 to 2 hours after oral administration. It is rapidly bio-transformed with a serum half-life of 1.8 to 2 hours. The drug is completely eliminated in 24 hours after the last dose and eliminated through metabolism.The drug is more than 99% protein bound, extensively metabolized in the liver and little is excreted unchanged.
Although highly bound to plasma proteins (90-99%), displacement interactions are not clinically significant, hence the dose of oral anti-cogulants and oral hypoglycemic needs not be altered. More than 90% of an ingested dose is excreted in the urine as metabolites or their conjugates, the major metabolites are hydroxylated and carboxylated compounds.
Old age has no significant effects on the elimination of ibuprofen. Renal impairment also has no effect on the kinetics of the drugs, rapid elimination still occur as a consequence of metabolism. The administration of ibuprofen tablets either under fasting conditions or immediately before meals yield quiet similar serum concentrations-time profile. When it is administered immediately after a meal, there is a reduction in the rate of absorption but no appreciable decrease in the extent of absorption.

DOSAGE & ADMINISTRATION
• ADULT and CHILD over 12 years, initially 300-400 mg 3-4 times a daily: increased if necessary to maximum 2.4g daily; maintenance dose of 0.6-1.2 g daily may be adequate.
• Pain and fever in children, CHILD 1-3 months, CHILD 3-6 months (body weight under 5 Kg), 50 mg 3 times da..., max. 30 mg/kg daily in 3-4 divided dose); CHILD 6 months- 1 year, 50 mg 3-4 times daily (max. 30 mg/kg daily in 3-4 divided dose); CHILD 1-4 years,100 mg 3 times daily (max. 30mg/Kg daily in 3-4 divided doses); CHILD 4-7 years 150 mg 3 times daily (max. 30mg/kg daily in 3-4 divided doses) CHILD 7-10 years, 200 mg 3 times daily (upto 30 mg /kg daily (max 2.4 g) in 3-4 divided doses) CHILD 10-12 years, 300 mg 3 times daily (upto 30mg/kg daily (max. 2.4g) in 3-4 divided doses)
• Rheumatic disease in children (including juvenile idiopathic arthritis), CHILD 3 months -18 years (body-weight over 5 kg), 30-40 mg/kg (max 2.4g) daily in 3-4 divided doses, in systemic juvenile idiopathic arthritis upto 60mg/kg (max 2.4g) daily (unlicensed in 4-6 divided doses.

SIDE EFFECTS & ADVERSE REACTIONS
SIDE EFFECTS: Possible side effects: If you get any of these serious side effects, stop taking the tablets. See a doctor at once:
• You are sick and it contains blood or dark particles that look like coffee grounds
• Pass blood in your stools or pass black tarry stools
• Tiredness or severe exhaustion, change in the blood which may cause unusual bruising or unexplained bleeding and an increase in the number of infections that you get (e.g. sore throats, mouth ulcers, flu-likesymptoms including fever) Stomach problems including pain, indigestion or heartburn
• Unexplained wheezing (asthma), worsening of existing asthma, difficulty in breathing, swelling of the face, tongue, neck or throat, fast heart rate, feeling faint or dizzy or collapse (severe allergic reactions)
• Allergic skin reactions such as itchy, red, raised rash (which can sometimes be severe and include peeling, blistering and lesions of the skin)
• Worsening of existing severe skin infections (you may notice a rash, blistering and discolouration of the skin, fever, drowsiness, diarrhoea and sickness), or worsening of other infections including chicken pox or shingles
• A severe skin reaction knows as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells)
• Meningitis (e.g. stiff neck, fever, disorientation) High blood pressure, heart failure (you may be tired, have difficulty breathing or swollen legs)
• A small increased risk of heart attack or stroke if you take large amounts for a long time
• Yellowing of the skin or eyes, pale stools or upper abdominal pain (these may be signs of liver problems)
• Swellings or ulcers of the stomach Kidney problems, which may lead to kidney failure (you may pass more or less urine, have blood in the urine or cloudy urine, or feel breathless, very tired or weak, have no appetite, or have swollen ankles)

ADVERSE REACTIONS
NSAIDs are widely used, frequently taken inappropriately and potentially dangerously. Nevertheless, ibuprofen exhibits few adverse effects. The major adverse reactions include the effects on the gastrointestinal tract (GIT), the kidney and the coagulation system.Based on clinical trial data, serious GIT reactions prompting withdrawal of treatment because of hematemesis, peptic ulcer,and severe gastric pain or vomiting showed an incidence of 1.5% with ibuprofen compared to 1% with placebo and 12.5% with aspirin. Ibuprofen was a potential cause of GI bleeding, increasing the risk of gastric ulcers and damage, renal failure, epistaxis, apoptosis, heart failure, hyperkalaemia, confusion and bronchospasm.7It has been estimated that 1 in 5 chronic users (lasting over a long period of time) of NSAIDs will develop gastric damage which can be silent.
Other adverse effects of ibuprofen have been reported less frequently. They include thrombocytopenia, rashes, headache, dizziness, blurred vision and in few cases toxic amblyopia, fluid retention and edema. Patients who develop ocular disturbances should discontinue the use of ibuprofen.Effects on kidney (as with all NSAIDs) include acute renal failure, interstitial nephritis, and nephritic syndrome, but these very rarely occur.

WARNING
• The use of OTC products containing aspirin, acetaminophens, ibuprofen, naproxen or ketoprofen may increase the risk of hepato-toxicity and gastrointestinal hemorrhage in individuals who consume three or more alcoholic drinks daily.
• Tamburini et al. have reported an atypical presentation of meningitis due to Neisseria meningitidis in a patient who received large doses of ibuprofen. Anti-inflammatory therapy such as NSAIDs could reduce CSF inflammation and modify the clinical outcome in patients with bacterial meningitis. However, the use of NSAIDs is not recommended in bacterial meningitis due to a lack of studies.
Ibuprofen may exacerbate severe asthma. With this perception, ibuprofen was administered for postoperative pain management to a 17-year-old boy with allergic rhinitis and previous severe asthma (at a time when well controlled), who then had a severe asthma exacerbation. Also, it has been reported that gastrointestinal tract anatomical abnormalities or dysmotility may be contraindications for therapy with high-dose ibuprofen in patients with cystic fibrosis.
• A closer look at the nonprescription analgesics revealed their potential harm when used by solid-organ transplant recipients. Excretion into breast milk is thought to be minimal; however it should be used with caution by women who are breast feeding.

STORAGE:
Store under normal storage conditions (15°C to 30°C)
Protect from light.

Keep all Medicines out of reach of children's.

Presentation:
Jar Pack of 1000 Tablets
Blister Pack of 10 X 10 Tablets

Manufactured in India by:
AGOG PHARMA LTD.
Plot No. 33, Sector – II, The Vasai Taluka Indl. Co-op. Estate Ltd., Vasai (East), Dist. Thane. INDIA.