INFLAFEN TABLETS 200MG

NAME AND STRENGTH OF ACTIVE INGREDIENT(S):
Each tablet contains:
Ibuprofen ……200mg

PRODUCT DESCRIPTION:
A white, scored, convex of diameter 9mm round tablet with 'MPI' logo.

PHARMACODYNAMICS :
Ibuprofen is a non-steroidal anti-inflammatory agent that possess analgesic, antipyretic and anti-inflammatory activities. Its mode of action, like that of other NSAIDs, is not completely understood, but may be related to prostaglandin synthetase inhibition.

PHARMACOKINETICS:
Ibuprofen is absorbed from the gastro-intestinal tract and peak plasma concentration occur about 1 to 2 hours after ingestion. Ibuprofen is extensively bound to plasma proteins and has half-life of about 2 hours. It is rapidly excreted in the urine mainly as metabolites and their conjugates. About 1% is excreted in urine as unchanged ibuprofen and about 14% as conjugated ibuprofen.

INDICATION:
Ibuprofen is used in the management of mild to moderate pain in conditions such as dysmenorrhoea, migraine, postoperative pain, ankylosing spondylitis, osteoarthritis, and rheumatoid arthritis, and in other musculoskeletal and joint disorders such as sprain and strain.

RECOMMENDED DOSAGE:
To be taken orally. It may be given with food or milk to reduce gastro-intestinal disturbances.
Adults : 1.2-1.8g daily in divided doses.
Maintenance dose : 0.6 – 1.2g daily.
Doses should be reduced in patients with impaired renal function.

ROUTE OF ADMINISTRATION:
Oral

CONTRAINDICATIONS:
1. Known hypersensitivity to ibuprofen.
2. Sensitivity to aspirin or other NSAID drugs i.e. in patients who develop bronchospasm, angiodema, nasal polyps or urticaria with those drugs or with a history of bronchial asthma.
3. Ibuprofen should not be used in active gastro-intestinal bleeding or in the presence of peptic ulceration.
4. Use in pregnancy and lactation are not recommended due to inhibition of prostaglandin synthesis.

WARNINGS AND PRECAUTIONS:
1. Ibuprofen should be given with care to patients with bleeding disorders, cardiovascular disease, impaired liver function or a history of liver disease, impaired renal function , peptic ulceration or a history of such ulceration and in those who are receiving coumarin anti coagulants.
2. Ibuprofen should be discontinued in patients who experience blurred or diminished vision, or changes in colour vision.
3. Safety and efficacy of ibuprofen in children younger than 6 months of age have not been fully established. Ibuprofen should not be used as self-medication in children younger than 12 years unless under medical advice.

WARNINGS

RISK OF GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID

Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (e.g. Dyspepsia) are common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms.

Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious GI events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

INTERACTIONS WITH OTHER MEDICAMENTS:

1. ACE inhibitors : Ibuprofen can reduce the antihypertensive effects of ACE inhibitors. This effects probably are result of the inhibition of the synthesis of renal prostaglandins.
2. Cyclosporin : Possible raised serum-cyclosporin trough concentration, together with small increases in serum creatinine and BUN concentration, on a previously-stabilised renal graft recipient taking cyclosporin. Nephrotoxicity, in the absence of significantly raised blood cyclosporin concentration, has been reported.
3. Lithium : Concurrent use with naproxen or piroxicam has been reported to increase steady-rate plasma lithium concentration; possibility must be considered that other NSAIDs may have a similar effect; monitoring of lithium plasma concentration is recommended during and following concurrent use.
4. Methotrexate : Ibuprofen may decrease methotrexate excretion and increase its plasma concentration to potentially toxic levels because severe methotrexate toxicity and fatalities have also been reported following administration of intermediate or high-dose methotrexate infusions to patients receiving indomethacin or ketoprofen; it is recommended that NSAID therapy be discontinued for 12 to 24 hours (for NSAIDs with a short half-life) to up to 10 days (for piroxicam) prior to, and for at least 12 hours following administration of a high-dose methotrexate infusion. Although concurrent use of NSAID with the lower doses of methotrexate used in the treatment of rheumatoid arthritis has not been reported to cause severe methotrexate toxicity, it is recommended that concurrent use be undertaken with caution, with methotrexate dosage being adjusted as determined by monitoring signs of methotrexate toxicity and/or adequacy of the patient's renal function.
5. 4-Quinolone Antibacterial : Concurrent administration of NSAID with quinolone antibiotics may increase the incidence of quinolone CNS adverse effects and the incidence of convulsion have been reported.
6. Sulphonylurea : NSAID may increase the hypoglycemic effect of these medications because prostaglandins are directly involved in regulatory mechanisms of glucose metabolism and possibly because of displacement of the oral antidiabetics from serum proteins; dosage adjustments of the antidiabetic agent may be necessary ; glipizide and glyburide, due to their nonionic binding characteristic, may not be affected as much as the other oral antidiabetic agents; however, caution with concurrent use is recommended.

PREGNANCY AND LACTATION:

Use in pregnancy and lactation are not recommended. Women who are pregnant or breast-feeding should consult a doctor before use.

SIDE EFFECTS:

The most frequent adverse effects occurring with ibuprofen are gastro-intestinal disturbances. Peptic ulceration and gastro-intestinal bleeding have been reported. Other side effects include headache, dizziness, nervousness, skin rash, pruritus, tinnitus, oedema, depression, drowsiness, insomnia, and blurred vision and other ocular reactions. Hypersensitivity reactions, abnormalities of liver function test, impairment of renal function, agranulocytosis, and thrombocytopenia have occasionally been observed.

SYMPTOMS AND TREATMENT OF OVERDOSE:

Symptoms : Drowsiness, nystagmus, apnea, cyanosis and response only to painful stimuli.

Treatment : Symptomatic treatment as there is no specific antidote available.
When acute overdose occurs, the stomach should be emptied by inducing emesis or by lavage, particularly if there is evidence that the drug has been ingested recently (within 1 hour), and standard measure to maintain urine output should be instituted. Since ibuprofen is acidic and is excreted in the urine, force alkaline diuresis might be beneficial.

EFFECT ON ABILITY TO DRIVE AND USE MACHINE:

INFLAFEN may cause dizziness, drowsiness and blurred vision. Affected patients should not drive or operate machinery.

PRECLINICAL SAFETY DATA:
Not applicable

INSTRUCTION FOR USE:
For oral use only.

STORAGE CONDITIONS:
Store below 30°C. Protect from heat and moisture.
Keep out of reach of children / Jauhi dari kanak-kanak.

DOSAGE FORMS AND PACKAGING AVAILABLE:
Pack size: Blister Pack : 100 x 10's

NAME AND ADDRESS OF MANUFACTURER / PRODUCT REGISTRATION HOLDER:
MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)
Plot 14, Lebuhraya Kampung Jawa,11900 Bayan Lepas,
Pulau Pinang, Malaysia.

DATE OF REVISION:
23/10/2017