IBUFEN

	DESCRIPTION	CONTENT
IBUFEN TABLET 200MG MAL19910167AZ	TABLET Colour : White Shape : Oblong Coating : Film-coated Tablet Size : [(14.2x8.0) ± 0.20] mm	Each Tablet Contains: Ibuprofen .....200 mg
IBUFEN TABLET 400MG MAL19910168AZ	TABLET Colour : White Shape : Oblong Coating : Film-coated Tablet Size : [(17.4x8.8) ± 0.20] mm	Each Tablet Contains: Ibuprofen .....400 mg

PHARMACODYNAMICS:
Analgesic action: It may block out pain impulse generation via a peripheral action which may involve inhibition of the synthesis of prostaglandins, and possibly inhibition of the synthesis or action of other substances which sensitise pain receptors to mechanical or chemical stimulation.
Anti-inflammatory action: It may act peripherally in inflamed tissue, probably be inhibiting the synthesis and/or actions of other local mediators of the inflammatory response.

PHARMACOKINETICS:
Ibuprofen is absorbed from the gastrointestinal tract and peak plasma concentrations occurred about 1 to 2 hours after ingestion. Ibuprofen is extensively bound to plasma proteins and has a 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.

INDICATIONS:
- For the relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- For the relief of mild to moderate pain.
- As an antigout agent to treat non-rheumatic inflammatory conditions.
- To relieve dysmenorrhoea.

RECOMMENDED DOSE:
Adults : 400 mg to 600 mg 3 times daily.
Maintenance : 200 mg to 400 mg 3 times daily. This dose may be increased to 2.4 g daily if necessary.
Children : 20 mg per kg body-weight daily in divided doses with a maximum of 500 mg for those weighing less than 30 kg.
Note: Take medicine with food or milk, to avoid gastrointestinal disturbances.
After assessing the risk/benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.

ROUTE OF ADMINISTRATION:
FOR ORAL USE ONLY

CONTRAINDICATIONS:
Patients hypersensitive to Aspirin or Ibuprofen.

WARNINGS AND PRECAUTIONS:
Ibuprofen should be given with care to patients with bleeding disorders, cardiovascular disease, peptic ulceration or a history of such ulceration, and in those who are receiving coumarin anticoagulants, patients with asthma, bronchospasm and renal failure, and should not be given to patients who are sensitive to Aspirin.

Cardiovascular Thrombotic Events
Observational studies have indicated that non-selective NSAIDs may be associated with an increased risk of serious cardiovascular events, principally myocardial infarction, which may increase with dose or duration of use. Patients with cardiovascular disease or cardiovascular risk of an adverse cardiovascular event in patient taking NSAID, especially in those with cardiovascular risk factors, the lowest effective dose should be used for the shortest possible duration.
There is no consistent evidence that the concurrent use of Aspirin mitigates the possible increased risk of serious cardiovascular thrombotic events associated with NSAID use.

Hypertension
NSAIDS may lead to the onset of new hypertension or worsening the pre-existing hypertension and patients taking antihypertensive with NSAIDs may have an impaired antihypertensive response. Caution is advised when prescribing NSAIDs to patients with hypertension. Blood pressure should be monitored closely during initiation of NSAID treatment and at regular intervals thereafter.

Heart Failure
Fluid retention and oedema have been observed in some patients taking NSAIDs, therefore caution is advised in patients with fluid retention or heart failure.

Gastrointestinal Events
All NSAIDs can cause gastrointestinal discomfort and rarely serious, potentially fatal gastrointestinal effects such as ulcers, bleeding and perforation which may increase with dose or duration of use, but can occur at any time without warning. Caution is advised in patients with risk factors for gastrointestinal events e.g. the elderly, those with a history of serious gastrointestinal events, smoking and alcoholism. When gastrointestinal bleeding or ulceration occur in patients receiving NSAIDs, the drug should be withdrawn immediately. Doctors should warn patient about signs and symptoms of serious gastrointestinal toxicity. The concurrent use of Aspirin and NSAIDs also increases the risk of serious gastrointestinal adverse events.

Severe Skin Reactions
NSAIDs may very rarely cause serious cutaneous adverse events such as exfoliative dermatitis, toxic epidermal necrolysis (TEN) and Steven-Johnson Syndrome (SJS), which can be fatal and occur without warning. These serious adverse events are idiosyncratic and are independent of dose or duration of use. Patients should be advised of the signs and symptoms of serious skin reactions and to consult their doctor at the first appearance of a skin rash or any other sign of hypersensitivity.

If acute gastric pain, gastric bleeding, severe diarrhoea or severe skin rashes occur, discontinue the drug and seek medical treatment immediately.

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 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.

DRUG INTERACTIONS:
Ibuprofen should be given with care to patients who are receiving coumarin anticoagulants thiazide diuretics.

PREGNANCY AND LACTATION:
Whilst no teratogenic effects have been demonstrated in animal toxicity studies, the use of Ibuprofen during pregnancy should, if possible, be avoided. Congenital abnormalities have been reported in association with Ibuprofen administration in man; however, these are low in frequency and do not appear to follow any discernible pattern. In view of the known effects of NSAIDs on the foetal cardiovascular system (closure of ductus arteriosus), use in late pregnancy should be avoided.
In the limited studies so far available, Ibuprofen appears in the breast milk in very low concentrations and is unlikely to adversely affect the breast-fed infant.

SIDE EFFECTS:
Gastrointestinal disturbances, peptic ulceration, gastrointestinal bleeding, headache, dizziness, nervousness, skin rash, pruritus, tinnitus, oedema, depression, drowsiness, insomnia, blurred vision, cystitis, haematuria, interstitial nephritis, nephrotic syndrome, anaemias, neutropenia, eosinophilia, toxic amblyopia and other ocular reactions. Hypersensitivity reactions, abnormalities of liver functions tests, impairment of renal function, agranulocytosis and thrombocytopenia have occasionally been observed.

SYMPTOMS AND TREATMENT OF OVERDOSE:
Symptoms include vomiting and gastrointestinal haemorrhage.
Treatment is by aspiration and lavage. Vital functions should be maintained.

PACKING/PACK SIZE(S):
Blister pack of 1x10's and 100x10's.

JAUHI UBAT DARIPADA KANAK-KANAK
KEEP OUT OF REACH OF CHILDREN

MANUFACTURER/PRODUCT REGISTRATION HOLDER:
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