

CTD MODULE 1
ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION

Product Name :	IBUREN TABLETS (Ibuprofen 200mg)
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Pack Insert

IBUREN
COMPOSITION
Each tablet contains
Ibuprofen BP 200 mg

PHARMACOLOGY
Ibuprofen is a propionic acid derivative, having analgesic, antipyretic and anti-inflammatory activity. The drug's therapeutic effects as a non-steroidal anti-inflammatory are thought to inhibit prostaglandin synthetase and therefore the synthesis of prostaglandin which are known to be involved in the sensitization of pain receptors and the inflammatory process.

INDICATIONS
As an analgesic and anti-inflammatory in the treatment of rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's Disease), ankylosing spondylitis, osteoarthritis and non-rheumatoid (seronegative) orthopathies. In the treatment of non-articular rheumatic conditions, including frozen shoulder (capsulitis), bursitis, tendonitis, tenosynovitis, low back pain and soft tissue injuries such as sprains and strains. As an analgesic in the relief of mild to moderate pain such as dysmenorrhea, dental and post-operative pain and for the symptomatic relief of headache including migraine.

DOSAGE AND ADMINISTRATION
Adults: The recommended dosage is 1200-1800mg in 3-4 divided doses preferably after food some patients can be maintained on 600-1200 mg daily. In severe or acute conditions the dose can be increased until the acute phase is brought under control; the total daily dosage should not exceed 2400mg in divided doses.
Children: Daily dosage is 20mg/kg of body weight in divided doses. This can be achieved as follows:
1 - 2 years: 50mg three to four times a day.
3 - 7 years: 100mg three to four times a day
8 - 12 years: 200mg three to four times a day


SIDE EFFECTS
The most commonly observed adverse effects are gastrointestinal disturbances such as nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, and gastrointestinal hemorrhage. Less frequently, thrombocytopenia has occurred. Other side effects associated with NSAIDs include fluid retention, headache, dizziness and vertigo.

PRECAUTIONS
Ibuprofen should be given with care to patients with a history of cardiac failure or hypertension since oedema has been reported in association with ibuprofen administration.

CONTRAINDICATIONS
Ibuprofen should not be given to patients with a history of an active, peptic ulceration. It is contraindicated in patients who have previously shown hypersensitivity reactions (asthma, rhinitis and urticaria) in response to ibuprofen, aspirin or other NSAIDs.

PRESENTATION
Jar of 1000 tablets
Blister pack of 10 x 10 tablets

STORAGE
Store in the cool dry place below 30°C
Protect from light.
Keep out of reach of children.

MANUFACTURED BY:
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A Milestone To Golden Health