

NAME OF THE MEDICINAL PRODUCT

Brufen Tablets 400 mg
 Brufen Tablets 600 mg
 Brufen Retard Tablets
 Brufen Syrup

COMPOSITION

Brufen 400mg: Each tablet contains 400mg ibuprofen BP
 Brufen 600mg: Each tablet contains 600mg ibuprofen BP
 Brufen Retard: Each tablet contains 600mg ibuprofen BP
 Brufen Syrup: Each teaspoonful contains 100mg/5ml ibuprofen BP

PHARMACEUTICAL FORM

Brufen 400mg & 600mg : Film coated tablets
 Brufen Retard : Sustained release tablets
 Brufen Syrup : Orange colored, Orange flavoured Syrupy Suspension

CLINICAL PARTICULARS**Therapeutic Indications**

Brufen is indicated for its analgesic and anti-inflammatory effects in the treatment of rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), ankylosing spondylitis, osteoarthritis and other non-rheumatoid (seronegative) arthropathies.

In the treatment of non-articular rheumatic conditions, Brufen is indicated in postarticular conditions such as frozen shoulder (capsulitis), bursitis, tendinitis, tenosynovitis and low back pain; Brufen can also be used in soft tissue injuries as sprains and strains. Brufen is also indicated for its analgesic effect in the relief of mild to moderate pain such as dysmenorrhoea, dental and post-operative pain and for symptomatic relief of headache, including migraine headache.

Brufen Syrup: Brufen Syrup is indicated in short term use for the treatment of pyrexia in children over one year of age.

Dosage and Method of Administration**Adults:**

Brufen 400mg & 600mg: The recommended dosage of Brufen is 1200-1600 mg daily in divided doses. Some patients can be maintained on 800-1200 mg daily. In severe or chronic conditions, it can be advantageous to increase the dosage until the acute phase is brought under control, provided that the total daily dose does not exceed 2400mg in divided doses.

Brufen Retard: Two tablets taken as a single daily dose, preferably in the early evening well before retiring to bed. In severe or acute conditions, total daily dosage may be increased to three tablets in two divided doses.

Note: Brufen Retard is not recommended for children under 12 years.

Elderly:

No special dosage modifications are required unless renal or hepatic function is impaired, in which case dosage should be assessed individually.

Children:

Brufen Syrup: The daily dosage is 20mg/kg of body weight in divided doses. This can be achieved as follows:

1-2 years : One 2.5ml spoonful (50mg), 3-4 times daily
 3-7 years : One 5ml spoonful (100mg), 3-4 times daily
 8-12 years : Two 5ml spoonful (200mg), 3-4 times daily

Brufen is not recommended for children weighing less than 7 kg

In juvenile rheumatoid arthritis, up to 40 mg/kg of body weight daily in divided doses may be taken.

Contraindications

Patients with a history of, or active, peptic ulceration. Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis or urticaria) in response to ibuprofen, aspirin or other NSAIDs. Severe heart failure.

Special Warnings and Precautions for Use

Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms. Caution is required if Brufen is administered to patients suffering from, or with a previous history of bronchial asthma since ibuprofen has been reported to cause bronchoospasm in such patients. Brufen should only be given with care to patients with a history of gastrointestinal disease. Caution is required in patients with renal, hepatic or cardiac impairment since the use of NSAIDs may result in deterioration of renal function. The dose should be kept as low as possible and renal function should be monitored in these patients. Brufen should be given with care to patients with a history of heart failure or hypertension since oedema has been reported in association with ibuprofen administration.

Cardiovascular and cerebrovascular effects: Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy. Clinical trial data suggest that use of ibuprofen, particularly at a high dose (2400mg daily) and in long term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤1200mg daily) is associated with an increased risk of myocardial infarction. Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with ibuprofen after careful consideration. Similar consideration should be made before initiating longer-term treatment of patients with risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking).

Interactions with Other Medicinal Products and Other Forms of Interactions

Care should be taken in patients treated with any of the following drugs as interactions have been reported in some patients.

Antihypertensives: Reduced antihypertensive effect.

Diuretics: Reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels.

Lithium: Decreased elimination of lithium.

Methotrexate: Decreased elimination of methotrexate.

Cyclosporin: Increased risk of nephrotoxicity with NSAIDs.

Milprostone: NSAIDs should not be used for 8-12 days after milprostone administration as NSAIDs can reduce the effects of milprostone.

Other analgesics: Avoid concomitant use of two or more NSAIDs.

Corticosteroids: Increased risk of gastrointestinal bleeding.

Anticoagulants: Enhanced anticoagulant effect.

Quinolone antibiotics: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.

Pregnancy and Lactation

Whilst no teratogenic effects have been demonstrated in animal toxicology 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.

Effects on Ability to Drive and Use Machines

No adverse effects known.

Undesirable Effects

Gastrointestinal: The most commonly observed adverse events are gastrointestinal in nature. Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, malaise, haematemesis, ulcerative stomatitis and gastrointestinal haemorrhage have been reported following ibuprofen administration. Less frequently, gastritis, duodenal ulcer, gastric ulcer and gastrointestinal perforation have been observed. Epidemiological data indicate that of the seven most widely used oral, non-aspirin NSAIDs, ibuprofen presents the lowest risk of upper gastrointestinal toxicity.

Hypersensitivity: Hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchoospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, less commonly, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

Cardiovascular: Oedema has been reported in association with ibuprofen treatment. Oedema, hypertension, and cardiac failure, have been reported in association with NSAID treatment. Clinical trial and epidemiological data suggest that use of ibuprofen, particularly at high dose (2400mg daily), and in long term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke).

Other adverse events reported less commonly and for which causality has not necessarily been established include:

Renal: Nephrotoxicity in various forms, including interstitial nephritis, nephrotic syndrome and renal failure.

Hepatic: Abnormal liver function, hepatitis and jaundice.

Neurological & special senses: Visual disturbances, optic neuritis, headache, paraesthesiae, depression, confusion, hallucinations, tinnitus, vertigo, dizziness, malaise, fatigue and drowsiness.

Haematological: Thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia and haemolytic anaemia.

Dermatological: Photosensitivity.

Overdose

Symptoms include nausea, vomiting, dizziness and rarely, loss of consciousness. Large overdoses are generally well tolerated when no other drugs are involved. Treatment consists of gastric lavage and, if necessary, correction of serum electrolytes and appropriate supportive measures. There is no specific antidote to ibuprofen.

PHARMACOLOGICAL PROPERTIES**Pharmacodynamic Properties**

Ibuprofen is a propionic acid derivative with analgesic, anti-inflammatory and antipyretic activity. The drug's therapeutic effects as an NSAID are thought to result from its activity on prostaglandin synthesis.

Pharmacokinetic Properties

Ibuprofen is rapidly absorbed from the gastrointestinal tract, peak serum concentrations occurring 1-2 hours after administration. The elimination half-life is approximately 2 hours.

Ibuprofen is metabolized in the liver to two inactive metabolites and these, together with unchanged ibuprofen, are excreted by the kidney either as such or as conjugates. Excretion by the kidney is both rapid and complete. Ibuprofen is extensively bound to plasma proteins.

Brufen Retard: The pharmacokinetic profile of Brufen Retard compared with that of conventional release 400mg tablets showed that the sustained release formulation reduced peaks and troughs characteristic of the conventional release tablets and gave higher levels at 5, 10, 15 and 24 hours. Compared with conventional release tablets the area under the plasma concentration time curve for sustained release tablets was also identical. Both mean plasma profiles and the pre-dose plasma levels showed no major difference between the young and elderly age groups. In several studies, Brufen Retard produced a double peak plasma profile when taken under fasting conditions.

PHARMACEUTICAL INFORMATION**Incompatibilities**

None.

Special precautions for storage

Brufen Tabs: Store in a dry place below 25°C.
 Brufen Syrup: Store below 25°C. Protect from light.

How Supplied

Brufen 400 mg tablets : 20 / 25 / 30 / 50 / 100 / 250 : Blister packs of 30 tablets
 Brufen 600 mg tablets : 12 / 20 / 30 / 50 / 100 / 250 : Blister packs of 30 tablets
 Brufen Retard tablets : Blister packs of 20 tablets
 Brufen Syrup : Bottles of 100ml with dispensing spoon

Not all packs are available

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March 2007

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THIS IS A MEDICATION

- Medication is a product, which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine, their benefits.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

KEEP ALL MEDICATIONS OUT OF REACH OF CHILDREN

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