

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ibuprofen Tablets BP 400mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen Tablets BP 400.00mg

3 PHARMACEUTICAL FORM

Oral Tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Mild to moderate pain.
Rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease).
Ankylosing spondylitis.
Osteoarthritis.
Sero-negative arthropathies.
Pain relief of peri-articular disorders.
Pain relief of soft tissue injuries.

4.2 Posology and method of administration

For oral administration.

Adults: 1200 to 1800mg daily in divided doses. Some patients can be maintained on 600-1200mg daily. Total daily dosage must not exceed 2400mg even in divided doses.

Children: 20mg/kg body weight daily in divided doses. For juvenile rheumatoid arthritis, up to 40mg/kg body weight daily in divided doses. Children under 30kg must not receive more than 500mg daily even in divided doses.

Elderly: No special dose modification required unless renal or hepatic function is impaired, in which case dosage should be assessed individually.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.4).

4.3 Contraindications

Hypersensitivity to Ibuprofen. Patients with a history of peptic ulceration. Should not be given to patients in whom Aspirin and other non-steroidal anti-inflammatory drugs induce the symptoms of asthma, rhinitis or urticaria.

Severe heart failure.

4.4 Special warnings and precautions for use

Caution must be exercised in the use of Ibuprofen in patients receiving oral anti-coagulants and Thiazide diuretics. In patients with renal, cardiac or hepatic impairment caution is required since the use of NSAID's may result in deterioration of renal function. The dose should be kept as low as possible and renal function should be monitored.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.2, and GI and cardiovascular risks below).

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. $\leq 1200\text{mg}$ 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).

4.5 Interaction with other medicinal products and other forms of interaction

Interactions with Aspirin and other NSAID's.

4.6 Pregnancy and lactation

Whilst no teratogenic effects have been demonstrated in animal experiments, the use of Ibuprofen during pregnancy should, if possible be avoided. In the limited studies so far available, Ibuprofen appears in breast milk in very low concentration and is unlikely to effect the breast fed infant adversely.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Dyspepsia, gastrointestinal intolerance and bleeding. Headache, dizziness, nervousness, drowsiness, insomnia and blurred vision have also been reported.

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 of asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritis, urticaria, purpura, angiodema and, less

commonly, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

Less frequently, thrombocytopenia has occurred. NSAID's have been reported to cause nephrotoxicity in various forms and their use can lead to interstitial nephritis, nephrotic syndrome and renal failure.

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 (2400 mg daily), and in long term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).

4.9 Overdose

In children ingestion of more than 400 mg/kg may cause symptoms. In adults the dose response effect is less clear cut. The half-life in overdose is 1.5-3 hours.

Symptoms

Most patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, epigastric pain, or more rarely diarrhoea. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions. In serious poisoning metabolic acidosis may occur and the prothrombin time/ INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics.

Management

Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patient presents within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

IBUPROFEN IS A PHENYLPROPIONIC ACID DERIVATIVE WHICH HAS ANALGESIC, ANTI-INFLAMMATORY AND ANTIPYRETIC ACTIONS.

IT IS USED IN THE TREATMENT OF RHEUMATOID ARTHRITIS AND OTHER MUSCULOSKE

-LATAL DISORDERS. IT HAS ALSO BEEN USED IN THE TREATMENT OF ACUTE GOUT. IBUPROFEN IS USUALLY ADMINISTERED IN DOSES OF 0.6 TO 2.4g DAILY IN DIVIDED DOSES. MAINTENANCE DOSES OF 0.6 TO 1.2g DAILY MAY BE EFFECTIVE IN SOME PATIENTS.

IF GASTRO-INTESTINAL DISTURBANCES OCCUR, IBUPROFEN SHOULD BE GIVEN WITH FOOD OR MILK. A SUGGESTED DOSE FOR CHILDREN IS 20mg PER Kg BODY WEIGHT DAILY IN DIVIDED DOSES WITH A MAXIMUM OF 500mg FOR THOSE WEIGHING LESS THAN 30Kg.

5.2 Pharmacokinetic properties

IBUPROFEN IS ABSORBED FROM THE GASTRO-INTESTINAL TRACT AND PEAK PLASMA CONCENTRATIONS OCCUR ABOUT 1 TO 2 HRS AFTER INGESTION. IBUPROFEN IS EXTENSIVELY BOUND TO PLASMA PROTEINS AND HAS A HALF-LIFE OF ABOUT 2 HRS. IT IS RAPIDLY EXCRETED IN THE URINE AS METABOLITES AND THEIR CONJUGATES. ABOUT 1 PER CENT IS EXCRETED IN URINE AS UNCHANGED IBUPROFEN AND ABOUT 14 PER CENT AS CONJUGATED IBUPROFEN.

5.3 Preclinical safety data

No Data Held

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone K30
Lactose
Starch (Maize)
Microcrystalline Cellulose
Sodium Starch Glycollate
Colloidal Anhydrous Silica
Purified Water

Sugar coating components
Opaglos NA7150 (E904, E472a, E1201)
Mineral Water Sugar
Titanium Dioxide
Starch (Maize)
Talc
Calcium Carbonate
Sodium Benzoate
Acacia
Opalus AS-F-1537 (Sucrose, Purified Water, E171, E127 and E211)
Sugar Syrup 700o (Mineral Water Sugar, E211, Purified Water)
Opaglos 6000P (E901, E903, E904)
Purified Water

Ink Composition
Ferric Oxide Black
Isopropyl Alcohol
Ethyl Alcohol
Shellac (E904)

6.2 Incompatibilities

No approved spc for this product

6.3 Shelf life

No approved spc for this product

6.4 Special precautions for storage

No approved spc for this product

6.5 Nature and contents of container

Securitainer, Tampertainer or Opaque Screw cap plastic containers:
500, 250, 100, 84, 70, 56, 50, 42, 28, 21, 15 and 14 tablets.

Blister packs (blister strips are composed of PVDC coated PVC and aluminium foil): 84, 70, 56, 42, 28, 24, 21, 15, 14 tablets.

Polyethylene lined polypropylene or polyethylene buckets with snap on polypropylene or polyethylene lids: 5,000 and 15,000 tablets (Bulk supply to Ashbourne).

6.6 Special precautions for disposal

No approved spc for this product

7 MARKETING AUTHORISATION HOLDER

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/03/2009

10 DATE OF REVISION OF THE TEXT

05/05/2010

11 DOSIMETRY (IF APPLICABLE)

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)