

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ibuprofen BP 200mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen BP 200.00mg

3 PHARMACEUTICAL FORM

Oral Tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Indications recommended for 'POM' packs:

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

Indications recommended for 'P' and 'GSL' packs:

Rheumatic and muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of cold and influenza.

4.2 Posology and method of administration

For oral administration.

Dosage for 'POM' Packs

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 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 is 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).

Dosage for 'P' and 'GSL' Packs

Adults: One or two tablets (200 - 400mg) three times daily. Not more than 6 tablets (1200mg) in 24 hours.

Children: Not for use in children under 12 years of age without medical advice.

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. Not for use by children under 12 years of age without medical advice.

Severe heart failure.

4.4 Special warnings and precautions for use

Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease. Undesirable effects may be minimised by using the minimum effective dose for the shortest possible duration. The elderly are at risk of the serious consequences of adverse reactions. Caution is required in patients with renal, cardiac or hepatic

impairment since renal function may deteriorate. The dose should be as low as possible and renal function should be monitored.

The label will state: Do not use if you have ever had a stomach ulcer or are allergic to ibuprofen or aspirin. If you are allergic to or are taking any other painkiller, pregnant or suffer from asthma, speak to your doctor before taking ibuprofen. Do not exceed the maximum dose. Keep out of reach of children. If symptoms persist, consult your doctor.

POM

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. ≤ 1200 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).

GSL & P

Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.

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

Cardiovascular and cerebrovascular effects

Clinical trial and epidemiological data suggest that use of ibuprofen, particularly at high doses (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.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent aspirin or other NSAID's may result in an increased incidence of adverse reactions. May enhance the effects of anti-coagulants. NSAID's may diminish the effect of anti-hypertensives or diuretics.

4.6 Pregnancy and lactation

Whilst no teratogenic effects have been demonstrated in animal studies, ibuprofen should be avoided during pregnancy. The onset of labour may be delayed and the duration of labour increased. Ibuprofen appears in breast milk in very low concentrations and is unlikely to affect the breast fed infant adversely.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Gastrointestinal: abdominal pain, nausea and dyspepsia. Occasionally peptic ulcer and gastro-intestinal haemorrhage.

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).

Haematological: thrombocytopenia.

Renal: papillary necrosis which can lead to renal failure. Others: rarely hepatic dysfunction, headache, dizziness, hearing disturbances.

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 doses 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) (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 ANALGESIC, ANTI-FLAMMATORY AND ANTIPYRETIC ACTIONS.

IT IS USED IN THE TREATMENT OF RHEUMATOID ARTHRITIS AND OTHER MUSCULOSKETAL DISORDERS.IT HAS ALSO BEEN USED IN THE TREATMENT OF ACUTE GOUT.

IBUPROFEN IS USUALLY ADMINSTERED 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 GIVEN WITH FOOD OR MILK.A SUGGESTED DOSE FOR CHILDREN IS 20MG KG BODY WEIGHING LESS THAN 30KG.

5.2 Pharmacokinetic properties

IBUPROFEN IS ABSORBED FROM THE GASTYRO-INTESTINAL TRACT AND PEAK PLASMA

CONCENTRATES OCCUR ABOUT 1 TO 2 HRS AFTER INGESTION.IBUPROFEN IS EXTENSIVELY BOUND TO PLASMA PROTEINS AND HAS A HALF-LIFE OF ABOUT 2HRS.IT IS RAPIDLY EXCRETED IN THE URINE AS METABOLITIES AND THEIR CONJUTAES.ABOUT 1 PER CENT IS EXCRETED IN URINE AS UNCHANGED IBUPROFEN AND ABOUT 14 PER CENT AS CONJUATED 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

No approved spc for this product

6.6 Special precautions for disposal

No approved spc for this product

7 MARKETING AUTHORISATION HOLDER

Goldshield Pharmaceuticals Limited.

NLA Tower,

12-16 Addiscombe Road,

Croydon, Surrey,

CR0 0XT

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 12762/0432

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/03/2009

10 DATE OF REVISION OF THE TEXT

06/03/2009

11 DOSIMETRY (IF APPLICABLE)

**12 INSTRUCTIONS FOR PREPARATION OF
RADIOPHARMACEUTICALS (IF APPLICABLE)**