SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

IBUFEN (Ibuprofen) Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

IBUFEN (Ibuprofen) 400mg Tablet

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film coated Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

1. Rheumatoid arthritis, osteoarthritis and acute gout; adults: 200～600mg, 3～4times daily.

The daily dosage does not exceed 3,200mg

2. Juvenile rheumatoid arthritis; 30～40mg per kg of body weight, daily 3～4 times divided dose.

3. Mild to moderate pain; adults: 200～400mg, 3～4times daily.

Dosage can be adjusted by age and severity of symptoms.

4.3 Contraindications

IBUFEN Tab. is contraindicated in patients with following conditions; peptic ulcer, severe hepatic-, renal-, cardiac disfunction, hypertension. IBUFEN Tab. is contraindicated in patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis or urticaria) in response to Ibuprofen, aspirin or other non-steroidal anti-inflammatory drugs.

4.4 Special warnings and precautions for use

Caution is required if Ibuprofen is administered to patients suffering from, or with a previous history of, bronchial asthma since Ibuprofen has been reported to cause bronchospasm in such patients.

Ibuprofen 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. Ibuprofen should be given with care to patients with a history of heart failure or hypertension since edema has been reported in association with Ibuprofen administration.

4.5 Interaction with other medicinal products and other forms of interaction

1. Antihypertensives: Reduced antihypertensive effect.
2. Diuretics: Reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs.
3. Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels.
4. Lithium: Decreased elimination of lithium.
5. Methotrexate: Decreased elimination of methotrexate.
6. Cyclosporin: Increased risk of nephrotoxicity with NSAIDs.
7. Mifepristone: NSAIDs should not be used for 8～12 days after mifepristone administration as NSAIDs can reduce the effects of mifepristone.
8. Other analgesics: Avoid concomitant use of two or more NSAIDs.
9. Corticosteroids: Increased risk of gastrointestinal bleeding.
10. Anticoagulant: Enhanced anticoagulant effects.
11. 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.

4.6 Fertility, pregnancy and lactation

Use in pregnancy and lactation:

While no teratogenic effects have been demonstrated in animal toxicology studies, the use of Ibuprofen during pregnancy should, if possible, be avoided. Ibuprofen appears in the breast milk in very low concentrations and is unlikely to adversely affect the breast-fed infant.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable effects

Gastrointestinal :

Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, melaena, hematemesis, ulcerative stomatitis and gastrointestinal hemorrhage have been reported following Ibuprofen administration. Less frequently, gastritis, duodenal ulcer, gastric ulcer and gastrointestinal perforation have been observed.

Hypersensitivity :

These may consist of non-specific allergy reaction and anaphylaxis, respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, less commonly, bullous dermatoses including epidermal necrolysis and erythema multiforme.

Cardiovascular:

Edema has been reported in association with Ibuprofen treatment.

Renal:

Nephrotoxicity in various forms, including interstitial nephritis, nephrotic syndromes and renal failure.

Hepatic:

Abnormal liver function, hepatitis and jaundice.

Neurological and special senses:

Visual disturbances, optic neuritis, headaches, paraesthesia, depression, confusion, hallucinations, tinnitus, vertigo, dizziness, malaise, fatigue and drowsiness.

Hematological:

Thrombocytopenia, neutropenia, agranulocytosis, aplastic anemia and hemolytic anemia.

4.9 Overdose

Toxicity

Signs and symptoms of toxicity have generally not been observed at doses below 100 mg/kg in children or adults. However, supportive care may be needed in some cases. Children have been observed to manifest signs and symptoms of toxicity after ingestion of 400 mg/kg or greater. 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 significant amounts of ibuprofen will manifest symptoms within 4 to 6 hours.

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, dizziness, occasionally excitation, nystagmus and disorientation or coma. Occasionally patients develop convulsions, fainting, hypothermia, apnoea and respiratory or CNS depression, cardiovascular toxicity resulting in hypotension, bradycardia or tachycardia. 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

Group – Anti-inflammatory and anti-rheumatic products, non-steroids

Ibuprofen is a propionic acid derivative NSAID that has demonstrated its efficacy by inhibition of prostaglandin synthesis. In human ibuprofen reduces inflammatory pain, swellings and fever. Furthermore, ibuprofen reversibly inhibits platelet aggregation.

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen 400mg was taken within 8 hours before or within 30 minutes after immediate release aspirin dosing (81mg), a decreased effect of aspirin on the formation of thromboxane or platelet aggregation occurred. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use.

5.2 Pharmacokinetic properties

Ibuprofen is rapidly absorbed following administration and is rapidly distributed throughout the whole body. The excretion is rapid and complete via the kidneys. Maximum plasma concentrations are reached 45 minutes after ingestion if taken on an empty stomach. When taken with food, peak levels are observed after 1 to 2 hours. These times may vary with different dosage forms.

The half-life of Ibuprofen is about 2 hours. In limited studies, Ibuprofen appears in breast milk in very low concentrations.

5.3 Preclinical safety data

No relevant information additional to that already contained elsewhere in the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Opadry03F63233 Orange
lactose hydrate
Microcrystalline Cellulose
Sodium Starch Glycolate
Magnesium Stearate
Light anhydrous silicic acid
Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a dry place below 30°C.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

10 Tabs./Blister, 50 Blisters/Box

6.6 Special precautions for disposal <and other handling>

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

08320/09364/NMR/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of latest renewal: Jan 3, 2023

10. DATE OF REVISION OF THE TEXT

July, 2023