Applicant/PHCR: Pharmaceutical Contractors (Pty) Ltd

Product proprietary name: Ibucine Tablets

Dosage form and strength: Each tablet contains 200 mg 400 mg Ibuprofen respectively

Final Draft approved by SAHPRA

Professional information

SCHEDULING STATUS:

S3: When specifically intended for the treatment of inflammatory joint diseases.

S2: a. Where the recommended daily dose for adults does not exceed 1,2 g and that for children up to and including the age of 12 years does not exceed 20 mg/kg of body weight.

b. When intended for emergency treatment of acute gout attacks.

c. When intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days.

1. NAME OF THE MEDICINE

IBUCINE 200 (Tablets)

IBUCINE 400 (Tablets)

2. QUALITIVE AND QUANTITIVE COMPOSITION:

IBUCINE 200 tablet:

Each sugar coated tablet

contains: 200 mg ibuprofen.

206,7 mg sugar (lactose monohydrate & sucrose)

IBUCINE 400 tablet:

Each sugar coated tablet

contains: 400 mg ibuprofen.

320,4 mg sugar (lactose monohydrate & sucrose)

3. PHARMACEUTICAL FORM

IBUCINE 200 mg tablet:

A round pink sugar coated tablet with a diameter of 11,30 mm.

IBUCINE 400 mg tablet:

A round pink sugar coated tablet with a diameter of 13,15 mm.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

IBUCINE is indicated as an anti-inflammatory and analgesic in the treatment of rheumatoid arthritis (including Still's disease or juvenile rheumatoid arthritis), osteoarthritis, acute gouty arthritis and ankylosing spondylitis; the treatment of non-articular rheumatism, including fibrositis; the treatment of periarticular conditions such as bursitis, capsulitis, synovitis, tendonitis and lower back pain and the treatment of soft-tissue injuries (strains and sprains). IBUCINE is also indicated as an analgesic in the relief of mild to moderate pain such as, dental-, post episiotomy- and post-partum pain, dysmenorrhoea, headache and pain associated with migraine. IBUCINE may be used as an antipyretic.

4.2 Posology and method of administration

Use the lowest effective dose for the shortest possible duration of treatment.

Adults:

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Recommended dose:

1200 mg per day in divided doses.

This equals 6 x 200 mg tablets or 3 x 400 mg tablets.

Acute dose:

In severe cases until the acute phase is under control - 2 400 mg per day in divided doses. This equals 12 x 200 mg tablets or 6 x 400 mg tablets.

Early morning stiffness can be relieved by taking the first dose of the day immediately after waking up. The following doses are recommended for mild and moderate pain: Dysmenorrhoea - 1200 mg per day in 3 divided doses. For dental pain or post-episiotomy pain, an initial dose of 800 mg may be given. The total daily dose of IBUCINE should not be more than 2400 mg. A maintenance dose should be followed once the acute phase is under control.

Maintenance dose:

600 mg to 1200 mg per day in divided doses.

Acute gout:

2400 mg daily (800mg 8 hourly or 600mg 6 hourly) until the acute phase has relieved. Consult a doctor if acute symptoms do not resolve within 3 days.

Children:

Juvenile rheumatoid arthritis - 20 mg/kg of body mas in divided doses daily. Safety in children under one year of age has not been established.

Pain:

Initial dose of 5 mg/kg of body weight. After 2 hours a second dose of 5 mg/kg may be given and thereafter. If pain is not controles 5 mg/kg every 4-6 hours.
Do not exceed 20 mg/kg of bodyweight per day. Consult a doctor if pain persists more than 7days.
Fever:
5 mg/kg of body weight every 4-6 hours. Do not exceed 20 mg/kg of bodyweight per day. Consult doctor if fever persists more than 3 days.
IBUCINE tablets may be taken with food to minimize gastro-intestinal side-effects. If gastrointestinal disturbances occur, IBUCINE should be given with food or milk.

4.3 Contraindications

IBUCINE should not be administered during pregnancy and is not recommended for use by breastfeeding women (see "PREGNANCY AND LACTATION"). It should not be given to patients with a history of gastrointestinal bleeding (PUBs) or perforation related to previous nonsteroidal anti-inflammatory (NSAID) use (see "WARNINGS"). IBUCINE is contra-indicated in patients with active or a history of recurrent ulcer/haemorrhage/perforations. IBUCINE is contraindicated in heart failure (see "WARNINGS").

Caution is advised in those patients who are receiving coumarin anticoagulants such as warfarin (see "INTERACTIONS").
IBUCINE should not be given to patients who are sensitive to aspirin.

IBUCINE should be prescribed with caution for those with asthma and especially for patients who have developed bronchospasm with other non-steroidal agents.
When IBUCINE is taken together with antiplatelet agents and selective serotonin reuptake inhibitors (SSRIs), there may be an increased risk of gastrointestinal bleeding.

4.4 Special warnings and precautions for use

Caution is required in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with IBUCINE therapy (see "CONTRAINDICATIONS").
IBUCINE should be given with caution to patients with a history of gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as the condition may be exacerbated (see "CONTRA INDICATIONS").
The risk of gastrointestinal bleeding (PUBs) or perforation is higher with increasing doses of IBUCINE, in patients with a history of ulcers, and the elderly (see "CONTRA-INDICATIONS").
When gastrointestinal bleeding or ulceration occurs in patients receiving IBUCINE, treatment with IBUCINE should be stopped.
The elderly has an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding (PUBS) and perforation which may be fatal.
Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported. IBUCINE should be discontinued at the first appearance of skin rash, mucosal lesions, or any other Sign of hypersensitivity.

4.5 Interaction with other medicines and other forms of interaction

The action of furosemide and the anti-hypertensive effects of thiazide diuretics, beta-adrenergic antagonists, prazosin and captopril may be reduced when taken concomitantly with ibuprofen. IBUCINE is a non-steroidal anti-inflammatory agent (NSAID). The use of two or more NSAIDs concomitantly could result in an increase in side-effects. IBUCINE taken concomitantly with corticosteroids, increases risk of gastrointestinal ulceration or bleeding (PUBs). IBUCINE may enhance the effects of anticoagulants such as warfarin (see "CONTRA-INDICATIONS").

Urinary system disorders:

- Impairment of renal function has been observed. Acute reversible renal failure has been reported.

IBUCINE should be used with care in patients with impaired renal failure.

Fertility,PREGNANCY AND LACTATION:

IBUCINE should not be used in pregnancy or by breastfeeding mothers (see "WARNINGS").

4.6 Undesirable effects

General disorders:

- Vomiting, diarrhoea, oedema.

Skin and appendages disorders:

- Bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis. Because of the possibility of cross-sensitivity due to structural relationships which exist among non steroidal anti-inflammatory medicines, acute

allergic reactions may be more likely to occur patients who have exhibited allergic reactions to these compounds.

Blood and lymphatic system disorders:

- Thrombocytopenia and agranulocytosis have been reported.

Central and peripheral nervous system disorders

- Headache, dizziness, nervousness and other central effects.

Special senses disorders:

- Toxic amblyopia has occurred, Tinnitus.

Cardiovascular system disorders:

- Oedema, hypertension

Respiratory system disorders:

- Bronchospasm.

Gastrointestinal system disorders:

- The most observed adverse events are gastrointestinal nature. Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal. Nausea vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematernesis ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis.

Hepatobiliary disorders:

- Abnormalities of liver function tests have been observed.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: http://www.sahpra.org.za/publications/index/8

4.7 Overdose

The most likely symptoms of overdosage are nausea and epigastric pain. Further treatment is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 3.1 Antirheumatics (anti-inflammatory agents).

IBUCINE contains ibuprofen, a propionic acid derivative, which is a non-steroidal compound. Ibuprofen is an anti-inflammatory agent and also has analgesic and antipyretic properties.

5.2 Pharmacokinetic properties

Ibuprofen is absorbed following oral administration, and peak serum concentrations are observed after to 2 hours, Ibuprofen is extensively bound to plasma proteins (99 %). It passes slowly into the synovial spaces and remains there in higher concentrations as the concentrations in plasma decline.

The excretion of ibuprofen is rapid and complete. Greater than 90 % of an ingested dose is excreted in the urine as metabolites or their conjugates, and no ibuprofen by itself is found in the urine. The major metabolites are hydroxylated and carboxylated compounds.

6. Special precautions for storage

Store below 25 °C, in a dry place.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

7. Nature of contents of container

IBUCINE 200 mg tablet:

Plastic container with 24 tablets.

Plastic container with 1000 tablets.

IBUCINE 400 mg tablet:

Plastic container with 24 tablets.

Plastic container with 1000 tablets.

8. REGISTRATION NUMBERS

IBUCINE 200: V/3.1/350

IBUCINE 400: V/3.1/351

9. THE HOLDER OF THE OF REGISTRATION:

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Pharmaceutical Contractors (Pty) Ltd

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Isando

1601

10. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

September 2007

11. DATE OF REVISION OF TEXT

November 2020