Applicant/PHCR:	Pharmaceutical Contractors (Pty) Ltd
Product proprietary name:	Ibucine Paediatric Suspension
Dosage form and strength:	5 ml Suspension contains 100 mg Ibuprofen

Final Draft approved by SAHPRA

PROFESSIONAL INFORMATION

SCHEDULING STATUS:

Scheduling 3: When intended for the treatment of inflammatory joint disease.

Scheduling 2: When the recommended daily dose for children up to and including the age of 12 does not exceed 20 mg/kg of body-weight.

1. Name of medicinal product

IBUCINE PAEDIATRIC SUSPENSION

2. Qualitative and quantitative COMPOSITION:

Each 5 ml of suspension contains 100 mg of ibuprofen.

For excipients – see section 6.1

Contains sugar (sucrose, sorbitol solution 70 % and Glycerol) 81 % m/v

3. Pharmaceutical Form

An orange flavoured, orange coloured syrupy suspension.

4. Clinical particulars

4.1 Therapeutic indications:

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Ibucine is indicated for the management of mild to moderate pain and inflammation.

Ibucineis also used to reduce fever.

Ibucineis used in the management of mild to moderate pain and inflammation

in, musculoskeletal and joint disorders such as rheumatoid arthritis, peri-articular disorders such as bursitis, and tensosynovitis, and soft tissue disorder such as pains and sprains.

4.2 Posology and method of administration Children:

Juvenile Rheumatoid Arthritis - 20 mg/kg of body mass daily in divided doses with up to 40 mg/kg being given daily if necessary.

Ibucine is not recommended for children under 1 year of age or in those weighing

less than 7 kg.

Pain: 5 mg/kg of body mass. A second dose of 5 mg/kg may be given after 2 hours if pain is not controlled, thereafter 5 mg/kg every 4-6 hours. If pain persists for more than 7 days, consult your physician.

Fever: 5 mg/kg of body mass every 4-6 hours. If fever persists more than three days consult your doctor

Age	Daily Dosage	Body Mass

1 - 2 years	2,5ml 3 – 4 times daily	7 - 12 kg
3 - 7 years	2,5-5ml 3 – 4 times daily	14 - 23 kg
8 - 12 years	10 ml 3 - 4 times daily	25 - 40 kg

4.3 Contraindications:

Ibucine should not be given to patients with peptic ulceration and should be used with caution in patients with a history of such disorder. Ibucine should not be administered during the third trimester of pregnancy. Hypersensitivity to Ibuprofen. There is considerable cross reactivity between aspirin and other non-steroidal anti-inflammatory medicines and it is generally recommended that patients who have had a hypersensitivity reaction to one particular hon-steroidal anti-inflammatory medicine should avoid all non-steroidal anti-inflammatory medicines.

4.4 Special warnings and Precautions for use

Ibucine should be used with caution in patients with a history of peptic ulceration. Other precautions to be observed include patients with haemorrhagic disorders, asthma, a history of hypersensitivity reactions to aspirin or other NSAIDs, hypertension, and impaired renal, hepatic or cardiac function. Patients should be monitored for the development of blood, kidney, liver or eye disorders. Ibucine should be used with caution in the elderly.

Care is required in those receiving oral anti-coagulants, lithium, methotrexate and cardiac glycosides.

Patients with collagen disease may be at increased risk of developing aseptic meningitis.

Ibucine should be discontinued in patients who experience blurred or diminished vision,

or changes in colour vision.

Ibucine contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucosegalactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Ibucine contains sucrose and sorbitol. This should also be taken into account in patients with diabetes mellitus. May be harmful to the teeth.

4.5 Interaction with other medicines and other forms of interaction

There is considerable cross reactivity between aspirin and other non-steroidal anti-inflammatory medicines (see 4.3)

4.6 Fertility,pregnancy amd lactation

Ibucine should not be administered during the third trimester of pregnancy (see 4.3)

4.5 Undesirable effects

The most common side effects with Ibucine are gastro-intestinal disturbances; these are usually

mild and reversible but in some patients peptic ulcer and gastro-intestinal bleeding have been

reported.

CNS -related side effects include headache, dizziness, nervousness, tinnitus, depression, drowsiness and insomnia. Hypersensitivity reactions may occur and include fever, asthma and rashes. Hepatotoxicity and aseptic meningitis which occur less frequently may also be hypersensitivity reactions.

Some patients may experience visual disturbances, such as blurred vision, changes in visual colour perception and toxic amblyopia.

Haematological adverse effects include anaemias, thrombocytopenia, neutropenia, eosinophilia, and agranulocytosis. They may cause nephrotoxicity such as interstitial nephritis, nephrotic syndrome and renal failure. Ibucine can provoke bronchospasm in patients with asthma.

Ibuprofen may cause cystitis and haematuria.

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

4.6 Overdose

Epigastric pain and nausea, electrolites may be corrected by intravenous infusions, if necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

A/3.1 Antirheumatics (anti-inflammatory agents) Ibuprofen ((RS)-2-(4-isobutylphenyl) propionic acid) is a non-steroidal anti-inflammatory compound used to relieve mild to moderate pain, fever and inflammation.

5.2 Pharmacodynamic Properties

Ibucine is rapidly absorbed after oral administration and peak plasma concentrations occur about one to two hours after ingestion. Ibucine is 90 to 99 % bound to plasma proteins and has a plasma half life of about 2 hours.

It is rapidly excreted in the urine mainly as metabolites and their conjugates. About 1 % is excreted in urine as unchanged ibuprofen and about 14 % as conjugated ibuprofen. There appears to be little if any excretion in breast milk. Ibuprofen is stereoselective and there is some metabolic conversion of the inactive R(-)-enantiomer to the active S(+)-enantiomer (dexibuprofen).

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the PI.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Preservatives: Methyl Hydroxybenzoate 0,1 % m/v, Propyl Hydroxybenzoate 0,05 % m/v, Sodium Benzoate 0,25 % m/v.

Contains sugar (sucrose, sorbitol solution 70 % and Glycerol) 81 % m/v

6.2 Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines.

6.3 Special precautions for storage

Store in a well closed container Store at or below 25 0C.

KEEP OUT OF THE REACH OF CHILDREN.

6.4 Nature and contents of container

100 ml amber glass bottle.

7. THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Pharmaceutical Contractors (Pty) Ltd

44 Monteer Road Isando

1601

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8. REGISTRATION NUMBER:

36/3.1/0436

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/03/2006

10. DATE OF REVISION OF TEXT