

CTD MODULE 1
ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION

Product Name :	IBUREN SUSPENSION (IBUPROFEN SUSPENSION 100MG/5ML)
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Pack Insert

IBUREN ORAL SUSPENSION BP

Description

Iburen oral suspension is a pink coloured; strawberry flavoured liquid containing 100 mg of Ibuprofen BP in 5 ml.

Indications

Ibuprofen is a non-steroidal anti-inflammatory drug with analgesic, anti-inflammatory and anti-pyretic actions. Ibuprofen suspension is used for the relief of pain associated with low backache, tendinitis and frozen shoulder. It can also be used in soft tissue injuries like sprains and strains. The analgesic effect of ibuprofen makes it of use to relieve pain associated with mild to moderate toothache and headache. Ibuprofen suspension is indicated for reduction of fever and for the relief of mild to moderate pain in children older than one year.

Dosage and Administration

Ibuprofen should be taken three times a day, preferably after food, as indicated below.

Children under 12 years

Iburen Oral suspension is recommended

Under 1 yr	Not recommended
1-3 yrs	one 5ml teaspoonful
4-6 yrs	7.5ml (one and half teaspoonful)
7-9 yrs	Two 5ml teaspoonfuls
10-12 yrs	Three 5ml teaspoonful

Or as directed by a doctor

DO NOT EXCEED THE STATED DOSE

If symptoms persist seek medical advice

Contra-indications, Warnings etc

Ibuprofen should NOT be taken by patients with severe or active peptic ulceration, or with a history of it.

Precautions

- Medical advice should be sought if suffering from asthma or aspirin sensitivity, before taking Ibuprofen.
- Pregnant or lactating women should take the advice of a doctor or pharmacist before taking Ibuprofen.

Side effects

- The side effects of Ibuprofen include dyspepsia, gastro-intestinal intolerance, bleeding, skin rashes and Oedema.

Storage

Store in a cool dry place below 30°C.

Keep out of reach of children.

Package Quantities

Iburen oral suspension: 60ml

MANUFACTURED BY
RENE INDUSTRIES LTD.
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P. O. BOX 6034



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