

ULTRAFEN

Suspension & Suppositories

Composition

Suspension

Each 5 ml contains ibuprofen 100 mg

Suppositories

Each suppository contains Ibuprofen 60 or 125 mg

Action

Ibuprofen is a nonsteroidal anti-inflammatory compound used to relieve mild to moderate pain, fever, and inflammation. Ibuprofen is rapidly absorbed after oral administration and peak plasma concentrations occur about one to two hours after ingestion. Ibuprofen 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.

Indications

- In Juvenile Rheumatoid Arthritis
- Indicated for its analgesic effect in the relief of mild to moderate pain such as dental.
- Used in soft-tissue injuries such as sprains and strains
- Used as an antipyretic

Contraindications

Hypersensitivity to Ibuprofen, aspirin or any other non-steroidal anti-inflammatory agent, because of the possibility of cross-sensitivity due to structural relationships that exist among non-steroidal anti-inflammatory medicines, acute allergic reactions may be more likely to occur in patients who have exhibited allergic reactions to these compounds.

Warnings and Precautions

Should be given with care to patients with asthma or bronchospasm, bleeding disorders, cardiovascular disease, a history of peptic ulceration, and in liver or renal failure. Patients with renal insufficiency require local synthesis of vasodilating prostaglandins to maintain renal perfusion, and therefore these patients are at greater risk of developing renal dysfunction due to NSAID-induced inhibition of renal prostaglandin synthesis.

Patients who are sensitive to aspirin or other NSAID's should generally not be given Ibuprofen. Ibuprofen should be discontinued in patients who experience blurred or diminished vision, or changes in colour vision. Patients with collagen disease may be at increased risk of developing aseptic meningitis.

Adverse Reactions

The most frequent side effects occurring with Ibuprofen are gastro-intestinal disturbances; reactions range from abdominal discomfort, nausea and vomiting, and abdominal pain to serious gastro-intestinal bleeding or activation of peptic ulcer.

CNS-related side effects include headache, dizziness, nervousness, tinnitus, depression, drowsiness, and insomnia. Hypersensitivity reactions may occur less frequently and include fever and rashes. Hepatotoxicity and aseptic meningitis which occur less frequently may also be hypersensitivity reactions. Ibuprofen can provoke bronchospasm in patients with asthma. Other side effects include anaemias, thrombocytopenia, neutropenia, eosinophilia, agranulocytosis, abnormalities in liver function tests, blurred vision, changes in visual colour perception, and toxic amblyopia

Pregnancy

Category B (1st and 2nd trimesters)

Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

Category D (If used in 3rd trimester)

There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Nursing Mothers

Safety of use in breastfeeding has not been established. Ibuprofen is not recommended for use in nursing mothers.

Dosage and Administration

Suspension

Children

In Juvenile Rheumatoid Arthritis, the total daily dosage of Ultrafen is 20 mg/kg of body mass given in divided doses.

Safety in children under one year of age has not been proven.

Pain

Initial dose 5 mg/kg of bodyweight.

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. DO NOT EXCEED 20 mg/kg of bodyweight per day. If pain persists for more than 7 days, consult your doctor.

Fever

5 mg/kg of bodyweight every 4 - 6 hours. DO NOT EXCEED 20 mg/kg of bodyweight per day. If fever persists for more than 3 days, consult your doctor.

Age	Bodyweight	Daily dosage in 5 ml spoonfuls
1 - 2 years	7 - 12 kg	2,5 ml up to 3 - 4 times daily
3 - 7 years	14 - 23 kg	2,5 - 5 ml up to 3 - 4 times daily
8 - 12 years	25 - 40 kg	10 ml up to 3 - 4 times daily

Do not give to children less than 7 kg or 1 year of age, except on the advice of your doctor.

Suppositories

Use in babies under 6 months of age requires a doctor's prescription. Doses should be given approximately every 6 to 8 hours, (or with a minimum of 6 hours between each dose if needed).

Infants

6 – 9 months weighing more than 6 kg: one suppository of 60 mg dose may be taken 3 times daily. 9 – 24 months: one suppository of 60 mg dose may be taken 4 times daily.

Children

Over 2 years weighing more than or equal to (12.5 kg): one suppository of 125 mg dose may be taken 3 times daily. 4 – 6 years: one suppository of 125 mg dose may be taken 3 to 4 times daily. 7 – 12 years: one suppository of 125 mg dose may be taken 4 times daily.

Over Dosage

The most likely symptoms of over dosage are epigastric pain and nausea. If recently taken, gastric lavage will remove any unabsorbed Ibuprofen. Electrolytes may be corrected by intravenous infusions, if necessary. There is no specific antidote to Ibuprofen.

Presentation

Suspension

Bottle of 100 ml

Suppositories

Box of 10 suppositories