

Ibufene 100 mg/5ml

Pharmaceutical form: Oral paediatric suspension with orange flavour.

Composition: Each 5 ml contains active ingredients: 100 mg Ibuprofen.

inactive ingredients: Propylene glycol, Glycerine, Methylparaben, Propylparaben, Sunset yellow, Sorbitol liquid, Polysorbate 80, Orange flavour, Saccharose, Aerosol 200, Xanthan, Purified water.

Pharmacological group: Nonsteroidal anti-inflammatory drugs.

Pharmacodynamic:

Ibuprofen inhibits prostaglandin synthesis by decreasing the activity of the enzyme, cyclooxygenase, which results in decreased formation of prostaglandin precursors. Ibuprofen 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. In the treatment of non-articular rheumatic conditions, Ibuprofen is indicated in particular 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. Ibuprofen is indicated for its analgesic effect in the relief of mild to moderate pain such as dysmenorrhea, dental and post-operative pain and for the symptomatic relief of headache including migraine headache. Ibuprofen is also indicated for its antipyretic properties especially for children.

Pharmacokinetic:

Ibuprofen is absorbed from the gastrointestinal tract and peak plasma concentrations occur about 1 to 2 hours after ingestion. Ibuprofen is also absorbed following rectal administration. 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. There appears to be little if any distribution into breast milk.

Indications:

IBUFENE suspension is indicated for children from 6 months to 12 years, but for infants 3-6 month only after medical prescription, taking into account baby's weight over 5 kg.

As antipyretic: acute respiratory diseases, flu, paediatric infections, post-vaccination period, and diseases which proceed with high temperature.

As analgesic: mild to moderate pain such as: dentation, headache, toothache, earache, throat ache, traumatic and postoperative pains, neuralgia and migraine.

As anti-inflammatory: juvenile rheumatoid arthritis, osteoarthritis, bursitis, tendovaginitis.

Contraindications:

- Infants above 3 month
- Hypersensitivity to ibuprofen or other non-steroidal anti-inflammatory agents
- Bronchial asthma, urticarial
- Gastro-intestinal ulcer in children
- Gastro-intestinal bleeding
- Colon inflammation

- Blood disease leucopenia, haemophilia
- Liver or kidney insufficiency
- **Last trimester of pregnancy**

Undesirable effects:

Following side effects may occur during use of IBUFENE suspension

- Gastro-intestinal disorders. Nausea, vomiting, loss of appetite, diarrhea, dyspeptic disorders, ulcer, rarely: gastro-intestinal bleeding
- Allergic reactions: skin rashes, itching, urticarial, exacerbation of bronchial asthma, bronchial spasm, anaphylaxis reactions, rarely: peripheral edema
- Cardiovascular disorder: Increasing of blood pressure, tachycardia
- Nervous system: Dizziness, headache, irritability - Blood system: Neutropenia, thrombocytopenia, agranulocytosis, aplastic anemia.

Pregnancy and Lactation:

Pregnancy: Teratogenic Effects: Pregnancy Category C:

Reproductive studies conducted in rats and rabbits have not demonstrated evidence of developmental abnormalities. However, animal reproduction studies are not always predictive of human response. There are no adequate and well-controlled studies in pregnant women. Ibuprofen should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Non-teratogenic Effects:

Because of the known effects of NSAIDs on the fetal cardiovascular system (closure of ductus arteriosus), use during late pregnancy should be avoided.

Lactation: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Ibuprofen, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Precautions and Warnings:

Ask a doctor before use if the child has

- Ulcers
- Bleeding problems
- Stomach problems that last or come back, such as heartburn, upset stomach or pain
- High blood pressure, heart or kidney disease or is taking a diuretic
- Not been drinking fluids
- Lost a lot of fluid due to continued vomiting or diarrhea
- Problems or serious side effects from taking fever reducers or pain relievers

Ask a doctor or pharmacist before use if the child is

- Under a doctor's care for any serious condition
- Taking a prescription product for anticoagulation (blood thinning)
- Taking any other drug

- Taking any other product that contains ibuprofen, or any other pain reliever/fever reducer

When using this product give with food or milk if stomach upset occurs Stop use and ask a doctor if

- An allergic reaction occurs. Seek medical help right away
- Fever or pain gets worse or lasts more than 3 days
- The child does not get any relief within first day (24 hours) of treatment
- Stomach pain or upset gets worse or lasts
- Redness or swelling is present in the painful area
- Any new symptoms appear

Keep out of reach of children. In case of overdose, get medical help.

Warnings:

Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:

- Hives asthma (wheezing)
- Facial swelling shock

Stomach bleeding warning: Taking more than recommended may cause stomach bleeding.

Sore throat warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not take for pain for more than 10 days or for fever more than 3 days and Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor. Do not use if the child has ever had an allergic reaction to any other fever reducer/pain reliever.

It especially important not to use Ibuprofen during the last months of pregnancy unless specially directed to do so by a doctor because it may be cause problems in the unborn child or complications during delivery. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine. Each 5 ml contains 1750 mg saccharose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. The saccharose content should be taken into account in patients with diabetes mellitus. It may also be harmful to teeth. Ibufene oral suspension contains sorbitol. Sorbitol may cause gastrointestinal discomfort and mild laxative effect. Ibufene oral suspension contains methylparaben and propylparaben. These may cause allergic reactions (possibly delayed). Ibufene oral suspension contains sunset yellow (E110). Which may cause allergic reactions.

Posology and method of administration:

Dosage depends on children age and weight. Single dose of IBUFENE suspension varies between 5-10mg/kg per body weight, maximum daily dose is 30mg/kg per body weight. IBUFENE suspension can be given 3-4 times during 24 hours. The medicine is effective until 8 hours.

Age	Average weight	Single dose	Maximum daily dose
3-6 month		By medical advise	
6 month-1year	7-10 kg	2.5 ml (mg)	200 mg
1-3 year	10-16 kg	2.5-5 ml (50-100 mg)	300 mg
4-6 year	18-22 kg	7.5 ml (150 mg))	450 mg
7-9 year	24-28 kg	10 ml (200 mg)	600 mg
10-12 year	30-36 kg	15 ml (300 mg)	900 mg

- It is not recommended to use IBUFENE suspension for more than 5 days as analgesic
- And for more than 3 days as antipyretic

Packaging:

Bottle of 100 ml with measuring cup.

Storage:

Keep out of reach of children. Store below 25°C.

Shelf life:

3 years. Use within 6 months after first opening.

Legal status:

OTC drug.