

IBUFENE



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Instruction for Medicinal Use

(for patients)

IBUFENE

oral suspension, 100 ml

TRADE NAME

IBUFENE

REGISTRATION NUMBER

7803

INN

Ibuprofen

COMPOSITION

Each 5ml contains active ingredients: 100 mg Ibuprofen, inactive ingredients: propylene glycol, methylparaben (E218), propylparaben (E216), sunset yellow (E110), orange flavour, sorbitol liquid, saccharose.

DOSAGE FORM

Oral pediatric suspension with orange flavor.

PARACOLOGICAL GROUP

Nonsteroidal anti-inflammatory drugs

ATC CODE

M01AE01

PHARMACOLOGY

IBUFENE is a non-steroidal anti-inflammatory agent, with analgesic and antipyretic properties.

IBUFENE is immediately absorbed after 1-2 hours by its oral taking from the gastrointestinal tract and it is excreted rapidly from the urine. The medicine is effective until 8 hours.

INDICATIONS

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

As antipyretic: acute respiratory diseases, flu, pediatric 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 post operative pains, neuralgia and migraine.

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

CONTRAINDICATIONS

- infants above 3 month
- hypersensitivity to ibuprofen or other non-steroidal anti-inflammatory agents
- bronchial asthma, urticaria
- gastro-intestinal ulcer in children
- gastro-intestinal bleeding
- colon inflammation
- blood disease leucopenia, hemophilia
- liver or kidney insufficiency

SIDE EFFECTS

Following side effects may occur during use of IBUFEN suspension

- Gastro-intestinal disorders: nausea, vomiting, loss of appetite, diarrhea, dyspeptic disorders, ulcer, rarely: gastro-intestinal bleeding
- Allergic reactions: skin rashes, itching, urticaria, exacerbation of bronchial asthma, bronchial spasm, anaphylaxis reactions, rarely: peripheral edema
- Cardio-vascular disorders. increasing of blood pressure, tachycardia
- Nervous system. dizziness, headache, irritability
- Blood system. neutropenia, thrombocytopenia, agranulocytosis, aplastic anemia

DRUG INTERACTION

IBUFENE should not be taken in combination with Sulfamides, Lithium products and Methotrexate.

IBUFENE increases the plasma concentration of digoxin. IBUFENE reduces the effect of diuretics. Diuretics and ciclosporins increase nephrotoxic effect of non-steroidal anti-inflammatory drugs. IBUFENE increases side effects of mineralocorticosteroids and glucocorticosteroids.

IBUFENE increases the effect of coagulant taking by mouth and increases the effect of Heparin.

PRECAUTIONS

It is recommended to consult a physician before using IBUFENE in case that a child has:

- urticaria in anamnesis
- bronchial asthma
- gastro-intestinal diseases
- blood content disorders
- arterial hypertension
- heart disease
- blood coagulation disorders
- H. pylori

It is not recommended to use IBUFEN suspension with other non-steroidal anti-inflammatory agents.

DOSAGE AND ADMINISTRATION

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

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

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

OVERDOSAGE

If symptoms of overdosage occur immediately consult a physician. Symptoms of overdosage are: abdominal pain, nausea, vomiting, headache, tinnitus, low blood pressure, bradycardia, and tachycardia.

Treatment: gastric lavage only through 1 hour after ingestion, activated coal, lot of liquids, and treatment of symptoms.

PACKAGING

Bottle of 100 ml with measuring cup

STORAGE

Store below 25°C.

SHELF LIFE

3 years

LEGAL STATUS

OTC drug

MANUFACTURED BY MEDICAL HORIZON

RA, Ararat province, Masis city,
Masis Station, Gorisaranain 22

