

Patient Package insert according to Pharmacists' Regulations (Preparations) - 1986

Use under 6 months of age is according to a doctor's prescription only

Over 6 months of age – the medicine is dispensed without a doctor's prescription

iBOO 2% for Children Suspension

Composition

Each 5 ml contain: Ibuprofen 100 mg

For information about inactive ingredients and allergens, see section 2 "Important information about some of the ingredients of this medicine" and section 6 "Additional information".

Read this leaflet carefully in its entirety before you start using this medicine. The leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Use this medicine in accordance with the instructions in the dosage section in this leaflet. Consult a pharmacist if you need additional information. You must contact a doctor if the symptoms of the illness worsen or do not improve after 24 hours in infants between 3-6 months of age, or after 3 days in 6-months-old or older children.

This medicine is suitable for most infants over the age of 3 months, children and adults. Use in infants between 3-6 months of age is according to a doctor's prescription.

Contact a doctor if your child is taking more than 75 mg of aspirin a day, or if your child is developing a rash, breathing difficulties, diarrhea, or increased fatigue.

1. What is this medicine intended for?

For relief of mild to moderate pain and for reduction of fever.

Therapeutic group: Non-steroidal anti-inflammatory drugs (NSAIDs).

2. Before using this medicine

This medicine is suitable for most people, but some people should avoid using it. If you are not sure, consult a doctor or pharmacist.

Do not use this medicine if:

- You or your child are sensitive (allergic) to ibuprofen or to any of the additional ingredients contained in this medicine (see section 6).
- You or your child have had allergic reactions (such as asthma, runny nose (rhinitis), subcutaneous swelling (angioedema) or hives (urticaria)) as a result of taking ibuprofen, acetylsalicylic acid (aspirin) or any other non-steroidal anti-inflammatory drugs (NSAIDs).
- You or your child have (or you or your child have had) peptic ulcer/gastric bleeding (two or more significant confirmed incidents of perforation or bleeding).
- You or your child have suffered in the past from gastrointestinal bleeding or perforation as a result of treatment with non-steroidal anti-inflammatory drugs (NSAIDs).
- You or your child have severe liver, kidney, or heart failure.
- You are in the last three months of pregnancy.

Special warnings regarding the use of this medicine

Before treatment with iBOO 2% for Children, tell the doctor if:

- You or your child suffer or have suffered from high blood pressure, heart problems or stroke, since there is a slight increase in the risk of heart problems when using ibuprofen.
- You or your child suffer from a risk factor for heart problems, such as diabetes or high cholesterol.
- You or your child suffer from asthma or any allergic disease of the lungs.
- You or your child suffer or have suffered from liver, kidney, or bowel problems.
- You or your child suffer from dehydration, since there is a risk of kidney problems.
- You or your child suffer from systemic lupus erythematosus (SLE, an autoimmune disease) or from another similar disease.
- You or your child suffer from an inflammatory bowel disease such as Crohn's disease or ulcerative inflammation of the colon (ulcerative colitis).
- You or your child suffer from chickenpox (Varicella). It is recommended to avoid using iBOO 2% for Children while the patient has chickenpox.

Additional warnings

The following warnings refer mainly to adults. In any case, they should be carefully taken into consideration before administering or taking this medicine:

- There might be a connection between medicines like iBOO 2% for Children and a slight increase in the risk of heart attack (myocardial infarction) or stroke. The probability of any risk will increase in case of taking high dosages and prolonged treatment. Do not exceed the recommended dose or duration of treatment.
- If you have heart problems, have undergone a stroke or you think you are at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol, or if you smoke), talk to a doctor or pharmacist about the treatment.

If you are elderly, consult a doctor before using this medicine.

Tell the doctor immediately if:

- **Your child's symptoms do not subside quickly or worsen.**
- **You are not sure what is your child's illness or the illness is accompanied by a rash, breathing difficulties, diarrhea, or increased fatigue.**

Drug interactions:

If you or your child are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Especially if you or your child are taking:

- **Other medicines containing ibuprofen or other non-steroidal anti-inflammatory drugs**, including those sold without a prescription
- **Low doses of aspirin** (up to 75 mg daily)
- **Diuretics** (helping with urination)
- **Anticoagulants** (blood-thinners such as warfarin)
- **Antihypertensives** (such as captopril, atenolol, losartan)
- **Lithium** (for mood disorders)
- **Methotrexate** (for psoriasis, arthritis and different types of cancer)
- **Zidovudine** (for HIV, the Human Immunodeficiency Virus)
- **Corticosteroids** (anti-inflammatory medicine)
- **Cardiac glycosides** (for heart problems)
- **Cyclosporine or tacrolimus** (to prevent organ rejection after transplantation)
- **Mifepristone** (for pregnancy termination)
- **Quinolone type antibiotic** (for infections)
- **Antidepressants of the SSRI group**
- **Antiplatelet medicines** such as dipyridamole, clopidogrel

If you are unsure about the types of medicines your child is taking, show the medicine to a doctor or a pharmacist.

Using this medicine and food:

Patients with a sensitive stomach may take this medicine with or after a meal.

Pregnancy, breastfeeding and fertility:

Pregnancy

Consult a doctor before using this medicine during the first 6 months of pregnancy.

Do not use iBOO 2% for Children if you are in the last 3 months of pregnancy.

Breastfeeding

Several studies found very low concentrations of ibuprofen in breast milk, although it is unlikely that such amounts would have an effect on the nursing baby.

Fertility

Ibuprofen belongs to a group of medicines which may impair fertility in women. This condition is reversible after discontinuing the use of the medicine. If taken occasionally, it is unlikely that this medicine will affect your chances of getting pregnant. However, if you are having difficulties getting pregnant, consult a doctor before using this medicine.

Driving and using machines:

This medicine is not expected to affect the ability to drive or operate machines when taken at the recommended dose and duration of treatment.

Important information about some of the ingredients of this medicine:

This medicine contains maltitol. If you have been told by a doctor that you have intolerance to certain sugars, consult the doctor before taking this medicine.

Maltitol may cause mild diarrhea.

The caloric value of maltitol is 2.3 kilocalories/gram.

This medicine contains 17.92 mg sodium in 5 ml.

This medicine contains 2.5 mg sodium benzoate in 5 ml.

3. How to use this medicine?

Check with the doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dosage is usually:

Dosage chart by weight

Weight (kg)	Dosage	Number of times per 24 hours
	in ml for use with a measuring syringe	
Below 5 kg	According to doctor's prescription	
5-5.4	2 ml	3-4
5.5-8.1	2.5 ml	3-4
8.2-10.9	3.75 ml	3-4
11-15	5 ml	3-4
16-21	7.5 ml	3-4
22-26	10 ml	3-4
27-32	12.5 ml	3-4
33-43	15 ml	3-4

Dosage chart by age

Age (years)	Dosage	Number of times per 24 hours
	in ml for use with a measuring syringe	
3-6 months	According to doctor's prescription	
6-11 months	2.5 ml	3-4
12-23 months	3.75 ml	3-4
2-3	5 ml	3-4
4-5	7.5 ml	3-4
6-8	10 ml	3-4
9-10	12.5 ml	3-4
11-12	15 ml	3-4

The weight of children of the same age can differ significantly.

Therefore, effort must be made to verify the weight of the child and determine the dosage according to the dosage chart by weight. Only if you cannot verify the weight of the child, the dosage can be determined according to this chart.

Do not administer this medicine to infants below the age of 3 months (unless instructed by the doctor) or to infants who weigh less than 5 kg without a doctor's instruction.

The doses should be administered every 6-8 hours at intervals of at least 4 hours between doses. Do not use more than the recommended dose in 24 hours.

Use in infants between 3-6 months of age is according to a doctor's prescription. Over the age of 6 months, the use is without a doctor's prescription.

If you know the weight of the child - administer the dosage as indicated in the dosage chart by weight.

Only if the child's weight is unknown - the dosage will be determined according to the age as indicated in the dosage chart by age of the child.

Warning: do not exceed the recommended dose.

Treatment duration

For short-term use only.

Do not administer this medicine to infants between 3-6 months of age for more than 24 hours.

If the symptoms persist longer than 24 hours or worsen, consult a doctor.

Do not administer this medicine to infants over the age of 6 months for more than 3 days. If the symptoms persist longer than 3 days or worsen, consult a doctor.

Manner of use

Always shake the bottle well before use.

Opening instructions

Child-resistant safety caps have significantly reduced the number of yearly drug-induced poisoning cases. However, if you have difficulties opening the package, you can ask the pharmacist to remove the cap's safety mechanism and turn it into a standard, easy to open cap.

Directions for use:

The package contains a syringe for measuring a dose of up to 5 ml.

Use the measuring syringe enclosed for measuring the correct amount of the medicine.

Do not use a household teaspoon to measure the amount of the medicine. Household teaspoons vary in size and you may not get the correct amount of the medicine.

1. Insert the syringe into the special opening in the neck of the bottle.
2. To fill the syringe, turn the bottle upside down. While holding the syringe in place, gently pull the plunger down while drawing the medicine to the correct mark on the syringe. See dosages charts.
3. At the end of filling, turn the bottle right side up and release the syringe gently.
4. Insert the tip of the syringe into the mouth (towards the cheek) and empty its content slowly and gently.
5. After use, close the bottle tightly. Separate the syringe parts, wash them in lukewarm water and soap and let them dry.

If you use or administer to your child a higher dosage

If you have taken or your child has taken a higher dose than necessary or if a child has accidentally swallowed some medicine, proceed immediately to a doctor or to the nearest hospital and seek medical advice on the risk involved and consult about the action to be taken.

Symptoms may include nausea, abdominal pain, vomiting (there may be a small amount of blood), headache, ringing in the ears, confusion and jerky eye movement.

At high doses, drowsiness, chest pain, intense palpitations, loss of consciousness, convulsions (especially in children), weakness and dizziness, blood in the urine, cold sensation in the body, and breathing problems have been reported.

If you forgot to use this medicine

If you forgot to administer or take a dose, administer or take the next dose as required, provided that at least 4 hours have passed since the previous dose was taken. Do not administer or take a double dose.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult a doctor or pharmacist.

4. Side effects

As with any medicine, the use of iBOO 2% for Children may cause side effects in some users.

Do not be alarmed while reading the list of side effects. You might not suffer from any of them.

The most common side effect is gastric irritation, which can cause problems such as indigestion and heartburn.

Stop administering this medicine to your child and contact a doctor immediately in case of:

- Blood in the stools.
- Black tarry stools.
- Vomiting blood or dark particles that look like coffee grounds.
- Unexplained wheezing, asthma, shortness of breath, skin rash (which might be severe and accompanied by blisters or skin peeling), itching or appearance of bruises, severe skin reactions including Stevens – Johnson syndrome, rapid heart rate, fluid retention (swollen ankles or decrease in the amount of urine).
- Stiff neck, headache, nausea, vomiting, fever and disorientation.
- Swelling of the face, tongue or throat (these can be signs of severe allergic reactions).
- Severe skin reaction known as DRESS syndrome (Drug Reaction with Eosinophilia and Systemic Symptoms). DRESS symptoms include skin rash, fever, swelling of the lymph nodes and an increase in the number of eosinophils (a type of white blood cell).

Stop administering this medicine to your child and talk to a doctor in case of:

- Unexplained abdominal pain, indigestion, heartburn, nausea or vomiting.
- Yellowing of the eyes, pale stool and dark urine (these can be signs of kidney or liver problems).
- Severe sore throat accompanied by high fever.
- Unexplained bruising or bleeding, fatigue, contracting more infections than usual such as mouth ulcers, colds, sore throat, fever (these can be signs of anemia or other blood disorders).

Additional side effects

Uncommon side effects:

- Headache.

Rare side effects:

- Diarrhea, flatulence or constipation. Tell the doctor if these side effects last several days or are bothersome.

Very rare side effects:

- Kidney or liver problems may occur when using ibuprofen.
- Stroke or heart problems may occur when using ibuprofen. The likelihood of this is low at the dosage level administered to children.
- Worsening of inflammation of the colon (colitis) and Crohn's disease.
- High blood pressure.
- Peptic ulcer, gastric bleeding, inflammation of the gastric mucosa.

Side effects of unknown frequency:

In rare cases, severe skin and soft tissue infections have occurred during chickenpox (Varicella).

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health via the link "Report Side Effects of Drug Treatment" found on the home page of the Ministry of Health's website (www.health.gov.il), which directs to the online form for reporting side effects, or by using the link:

<https://sideeffects.health.gov.il>

5. How to store this medicine?

- Avoid poisoning! This medicine and any other medicine should be stored in a close place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use this medicine after the expiry date (exp. date) stated on the package and bottle. The expiry date refers to the last day of that month.
- **Storage conditions: Store below 25°C.**

After first opening of the bottle, the medicine can be used for up to 6 months, but no later than the expiry date.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Liquid maltitol, glycerol (E-422), sodium citrate, citric acid anhydrous, sodium chloride, hypromellose, xanthan gum, sodium benzoate, strawberry flavor, saccharin sodium, purified water.

What the medicine looks like and contents of the pack:

Viscous suspension, white/off-white in color.

Each pack contains a suspension bottle and a syringe for dosage precision.

Quantity per pack: 100 ml, 150 ml, 200 ml.

Not all pack sizes may be marketed.

Registration holder's name and address: Abic Marketing Ltd., POB 8077, Netanya

Manufacturer's name and address: Farmalider S.A., Alcobendas 28108, Madrid, Spain

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 153.81.34080

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