

**PATIENT PACKAGE INSERT  
IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS  
(PREPARATIONS) – 1986**

Use under 6 months of age is according to a doctor's prescription only  
Above 6 months of age – the medicine is dispensed without a doctor's prescription

# iBOO 4% for Children Sugar-free Suspension Strawberry Flavor

## Composition

Each 5 ml contains:  
Ibuprofen 200 mg

For the list of inactive ingredients in the preparation, see section 6 – “Further Information”.

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

**This medicine is not intended for infants below 3 months of age or who weigh less than 5 kg. Use in children between 3-6 months of age is according to a doctor's prescription.**

You must use the medicine properly. Consult the doctor or pharmacist if you need further information.

Refer to the doctor as soon as possible if the signs of the illness (symptoms) worsen or are not improving after 3 days.

Refer to the doctor immediately if you are uncertain which illness your child has or if the illness is accompanied by a rash, difficulty breathing, diarrhea or increased fatigue.

**This medicine contains a double concentration of ibuprofen as compared to most other ibuprofen-containing suspensions. Pay attention to adjust the dosage in accordance with the child's age and weight.**

**The medicine is intended for children but can also be taken by adults.**

## 1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for relief of mild to moderate pains and for reduction of fever from the age of 3 months.

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

## 2. BEFORE USING THE MEDICINE

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**❗ Before treatment with this medicine, tell the doctor if:**

- You or your child are suffering, or have suffered, from high blood pressure, heart problems or stroke, since there is a slightly increased risk of heart problems when using the medicine.
- You or your child are suffering, or have suffered, from liver, kidney, heart or intestinal problems.
- You or your child are suffering from a risk factor of heart problems (e.g., diabetes or high cholesterol), from asthma or a pulmonary allergy disease, dehydration or risk of kidney failure, systemic lupus erythematosus (SLE, an autoimmune disease) or another similar disease (e.g., connective tissue diseases).
- You or your child are suffering from intestinal diseases (e.g., Crohn's disease and ulcerative colitis).
- You are elderly.

**❗ Special warnings regarding use of the medicine:**

The following warnings primarily refer to use of the medicine in adults. In any case, take them into consideration before administering or taking the medicine:

- Use of ibuprofen in women may impair fertility. This effect is reversible. It is unlikely that occasional use of ibuprofen will affect the chances of becoming pregnant. However, if you are having difficulties becoming pregnant, consult the doctor before using the medicine.
- Consult the doctor before taking this medicine during the first 6 months of pregnancy.
- There may be a connection between use of medicines such as ibuprofen and a slightly increased risk of heart attack (myocardial infarction) or stroke. The likelihood of this risk increases in cases of prolonged treatment and when taking high dosages. Therefore, do not exceed the recommended dose or required treatment period.
- If you suffer from heart problems, experienced a stroke or think you are at risk of these conditions (e.g., if you have high blood pressure, diabetes, high cholesterol, or if you smoke), refer to a doctor or pharmacist.

**Refer to a doctor immediately** if you are uncertain which illness your child has or if the illness is accompanied by a rash, breathing difficulties, diarrhea or increased fatigue.

**❗ If you or your child are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements and vitamins, tell the doctor or pharmacist.** In particular, inform the doctor or pharmacist if you are taking a medicine from the following groups or if you have just finished treatment with:

- Other ibuprofen-containing medicines or another non-steroidal anti-inflammatory drugs, including those sold without a prescription
- Aspirin – do not take a dosage that exceeds 75 mg
- Diuretics
- Blood thinners (such as warfarin)
- Antihypertensives (e.g., atenolol, captopril, losartan)
- Lithium (for mood disturbances)
- Methotrexate (for cancer, arthritis or psoriasis)
- Zidovudine (for HIV, human immunodeficiency virus)
- Corticosteroids (an anti-inflammatory medicine) – do not take in combination with ibuprofen due to increased risk of gastrointestinal perforation or bleeding
- Cardiac glycosides – to treat heart problems, e.g., digoxin
- Ciclosporin or tacrolimus (to prevent organ rejection after transplantation)
- Mifepristone (to terminate pregnancy)
- Quinolone antibiotics (for infections)
- Medicines from the SSRI group to treat depression
- Platelet aggregation inhibitor (clopidogrel, dipyridamole)

**❗ Pregnancy and breastfeeding:**

Ibuprofen belongs to a group of medicines that may impair fertility in women. This condition is reversible upon discontinuation of use of the medicine. It is unlikely that occasional use of ibuprofen will affect your chances of becoming pregnant; however, it is recommended to consult the doctor before taking this medicine if you are having difficulties becoming pregnant.

In the first 6 months of pregnancy, use the medicine with a doctor's recommendation only.

Do not take the medicine in the last three months of pregnancy.

Before treatment with this medicine, tell the doctor if you are breastfeeding. A few studies have found very low concentrations of ibuprofen in breast milk; however, it is unlikely that such levels will have an effect on the baby.

If you are breastfeeding, pregnant, think you are pregnant or are planning to become pregnant, consult the doctor or pharmacist before using the medicine.

**❗ Important information about some of the ingredients of the medicine**

- The medicine contains maltitol. If you have been told by a doctor that you have an intolerance to fructose, consult a doctor before using the medicine. Maltitol may cause mild diarrhea. The caloric value of maltitol: 2.3 kcal/gram.

## 3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about how to use the medicine.

Take the lowest dose that achieves the desired result. Do not use this medicine frequently or for a prolonged period without consulting the doctor. **Do not exceed the recommended dose.**

**This medicine is not intended for infants below 3 months of age, or who weigh less than 5 kg. Use in children between 3-6 months of age is according to a doctor's prescription. From 6 months of age, use is without a doctor's prescription.**

**The usual dosage, unless instructed otherwise by the doctor:**

See the appropriate dosage in the tables below.

**If you know the child's weight** – administer the dosage as it appears in the weight table that indicates the dosage according to weight.

**Only if the child's weight is not known** – the dosage will be determined according to age, as shown in the age table that indicates dosage according to the child's age.

Take the medicine every 6-8 hours, at intervals of at least 4 hours between doses, but do not take the medicine more than 4 times in 24 hours.

## Dosage table according to weight

Weight (kg)	Dose in ml for use with a syringe	Number of doses per day (24 hours)
5-5.4	1 ml	3-4 times a day
5.5-8.1	1.25 ml	3-4 times a day
8.2-10.9	1.75 ml	3-4 times a day
11-15	2.5 ml	3-4 times a day
16-21	3.75 ml	3-4 times a day
22-26	5 ml	3-4 times a day
27-32	6.25 ml	3-4 times a day
33-43	7.5 ml	3-4 times a day

## Dosage table according to age

**Children of identical ages can have significantly different weights. Therefore, effort must be made to find out the child's weight and to determine the dosage according to the weight table. Only if it is not possible to find out the child's weight should the dosage be determined according to the table below.**

Age (years)	Dose to be measured with a syringe	Number of doses per day (24 hours)
3-6 months	According to doctor's prescription	
6-11 months	1.25 ml	3-4 times a day
12-23 months	1.75 ml	3-4 times a day
2-3 years	2.5 ml	3-4 times a day
4-5 years	3.75 ml	3-4 times a day
6-8 years	5 ml	3-4 times a day
9-10 years	6.25 ml	3-4 times a day
11-12 years	7.5 ml	3-4 times a day

**Do not exceed the recommended dose.**

## Directions for use:

Use the provided measuring syringe to measure the correct amount of the medicine. If a measuring device was not provided with the package, consult a pharmacist. Do not use a household teaspoon to measure the amount of medicine. Household teaspoons vary in size and you may not get the correct amount of medicine.

1. Shake the bottle well before use.
2. Insert the syringe into the special opening in the neck of the bottle.
3. To fill the syringe, turn the bottle upside down, with the syringe held in place; gently pull the plunger downward, thereby allowing the medicine to reach the appropriate marking on the syringe.
4. After filling, turn the bottle right side up and gently release the syringe.
5. Insert the tip of the syringe into the child's mouth (toward the cheek) and slowly empty its contents.
6. After use, close the bottle tightly; separate the parts of the syringe, wash them in lukewarm water and soap and dry them.

Duration of treatment – **for short-term use only.** For infants ages 3-6 months, do not use for more than 24 hours. For infants ages 6 months and above, do not use for more than 3 days without consulting the attending doctor.

**If the signs of the disease (symptoms) worsen or are not improving, refer to the doctor as soon as possible.**

**Refer to a doctor immediately if you are uncertain about which illness your child has or if the illness is accompanied by rash, breathing difficulties, diarrhea or increased fatigue.**

**If you accidentally took a higher dosage, or if a child has accidentally swallowed the medicine,** immediately refer to the doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

**If you forgot to take the medicine at the scheduled time,** do not take a double dose. Take the next dose as needed, according to the instructions for use in the table above, on the condition that at least 4 hours have passed since taking the last dose.

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

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

## 4. SIDE EFFECTS

As with any medicine, use of iBOO 4% for Children may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Discontinue use and refer to the doctor immediately if the following effects occur:**

- Bloody or black stools, bloody vomit or vomit with black particles that look like coffee grinds.
- Unexplained abdominal pain, indigestion or heartburn.
- Unexplained wheezing, shortness of breath, skin rash (which may be severe and accompanied by blistering and peeling of the skin), itching or bruising, rapid heart rate, fluid retention (swelling of the ankles or reduced amount of urine).
- Stiff neck, headache, nausea, vomiting, fever or confusion.

**Discontinue use and refer to a doctor in the event of:**

- Unexplained abdominal pain, indigestion, heartburn, vomiting or nausea.
- Yellowing of the eyes, pale stools and dark urine.
- Severe sore throat accompanied by high fever.
- Unexplained bruises or tiredness, or more infections (such as: more frequent colds).

**Additional side effects:**

**Uncommon side effects (occur in 1-10 in 1,000 users):**

- Headache.

**Rare side effects (occur in 1-10 in 10,000 users):**

- Diarrhea, swelling or constipation. Tell the doctor if these effects persist for a few days or if they bother you or your child.

**Very rare side effects (occur in less than one in 10,000 users):**

- Kidney problems may occur when using ibuprofen.
- Stroke or heart problems may occur when using ibuprofen. The likelihood of this is low at the dosages given to children.
- Exacerbation of colitis and Crohn's disease.
- High blood pressure.

**If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

## 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (Exp. Date) that appears on the bottle and the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- After first opening the bottle, the medicine can be used for up to six months, but no later than the expiry date.
- Do not store different medicines in the same package.

## 6. FURTHER INFORMATION

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

Maltitol liquid, glycerol (E-422), sodium chloride, sodium citrate, citric acid anhydrous, hypromellose 15cP, xanthan gum, sodium benzoate, strawberry flavor, saccharin sodium, thaumatin, purified water.

Each ml of suspension contains 5.79 mg sodium.

**What the medicine looks like and the contents of the package:**

The suspension is thick and white/off-white in color.

Each package contains a bottle and a syringe for dosage accuracy.

Amount in package: 30 ml

**Manufacturer:** Farmalider, Madrid, Spain

**License Holder:** Abic Marketing Ltd., P.O.B. 8077, Netanya

This leaflet was checked and approved by the Ministry of Health in: July 2018

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

160.27.34833