

## **Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

Use between 3-6 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 1 ml contains: ibuprofen 20 mg

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

**Read the entire leaflet carefully 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 according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Consult your doctor if the symptoms of illness get worse or do not improve within 24 hours in infants between 3-6 months of age, or within 3 days in children who are 6-months-old or older.

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 your doctor if your child is taking aspirin at a dose above 75 mg a day or if your child develops a rash, breathing difficulties, diarrhea, or increased fatigue.

### **1. What is this medicine intended for?**

**For the reduction of fever and relief of mild to moderate pain, for babies and children from the age of 3 months to 12 years (who weigh approximately 40 kg).**

**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 your pharmacist or doctor.

#### **Do not use this medicine if:**

- You or your child are sensitive (allergic) to ibuprofen or to any of the other ingredients 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 episodes 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 about using this medicine**

**Before using iBOO 2% for Children, tell your doctor if:**

- You or your child have or have had **high blood pressure, heart problems** or a **stroke**, because there is a slight increased 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 have or have had **liver, kidney, heart or bowel problems**.
- You or your child are dehydrated, 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 a **chronic inflammatory bowel disease** such as Crohn's disease or ulcerative inflammation of the colon (ulcerative colitis).
- You or your child suffer from an inherited problem coping with fructose/fruit sugar (hereditary fructose intolerance), because the body can make some fructose from the ingredient maltitol.
- It is recommended to avoid using the medicine when the patient has **chickenpox** (varicella).
- The patient has an infection** – because this medicine may hide signs of an infection such as fever and pain. Therefore, this medicine may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chicken pox. If you or your child take this medicine while having an infection and the symptoms of the infection persist or worsen, consult a doctor without delay.

**Skin reactions** - serious skin reactions have been reported in association with this medicine. You should stop taking/giving this medicine and seek medical care immediately, if you or your child develop a skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first sign of a very serious skin reaction. See section 4.

#### **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:

- Medicines such as iBOO 2% for Children may be associated with a slight increase in the risk of heart attack (myocardial infarction) or stroke. The probability of any risk will increase when taking high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.
- If you have heart problems, have had a stroke or 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 your doctor or pharmacist about the treatment.

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

#### **Tell your doctor immediately if:**

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

#### **Drug interactions:**

**If you or your child are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.**

Particularly if you or your child are taking:

- Other medicines containing ibuprofen or other non-steroidal anti-inflammatory drugs**, including those you can buy over the counter
- Low dose aspirin** (up to 75 mg daily)
- Diuretics** (help with urination)
- Anticoagulants** (blood thinners such as warfarin)
- Medicines for high blood pressure** (such as captopril, atenolol, losartan)
- Lithium** (for mood disorders)
- Methotrexate** (for psoriasis, arthritis and different types of cancer)
- Zidovudine** (for HIV, human immunodeficiency virus)
- Corticosteroids** (anti-inflammatory medicine)
- Cardiac glycosides** (for heart problems)
- Cyclosporine or tacrolimus** (to prevent organ rejection after transplant)
- Mifepristone** (for pregnancy termination)
- Quinolone antibiotics** (for infections)
- SSRI antidepressants**
- Antiplatelet medicines** such as dipyridamole, clopidogrel

**If you are unsure about the types of medicines your child is taking, show the medicine to your 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**

- This medicine has a potential side effect of kidney damage to your unborn baby and lower levels of amniotic fluid as of the 20<sup>th</sup> week of pregnancy. It is recommended that you refrain from using NSAIDs from the 20<sup>th</sup> week of pregnancy and that you consult a medical professional if necessary.
- 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 a 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 becoming pregnant. However, if you are having difficulties becoming pregnant, tell your doctor before using this medicine.

#### **Driving and using machines:**

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

#### **Important information about some of this medicine's ingredients:**

- Maltitol** - 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.
- Sodium** - This medicine contains 17.92 mg sodium (the main component in table salt) in 5 ml, equivalent to 0.9% of the maximum recommended daily sodium intake for adults.
- Sodium benzoate** - This medicine contains 5 mg sodium benzoate in 5 ml. May cause yellowing of the skin and eyes in newborns (up to 4 weeks old).
- Propylene glycol** - This medicine contains 0.0035 mg propylene glycol in 5 ml.
- Benzyl alcohol** - This medicine contains 0.0008 mg benzyl alcohol in 5 ml. Benzyl alcohol may cause:
  - Allergic reactions
  - Risk of serious side effects, including breathing difficulties in young children (gaspng syndrome)
  - Do not use in newborns (up to the age of 4 weeks), unless recommended by the doctor
  - Do not use for more than one week in young children (under the age of 3), unless recommended by the doctor due to increased risk of accumulation of the substance in their body
  - Consult the doctor or pharmacist if you are pregnant or breastfeeding or if you have liver or kidney disease, because large amounts of benzyl alcohol may accumulate in your body and cause a side effect (called "metabolic acidosis")

### **3. How to use this medicine?**

Check with your 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)	Dose in ml for use with a measuring syringe	Number of times per 24 hours
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)	Dose in ml for use with a measuring syringe	Number of times per 24 hours
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, make every effort to establish the weight of the child and determine the dosage according to the dosage chart by weight. Only if you cannot establish 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. Use in infants between 3-6 months of age or who weigh less than 5 kg is according to a doctor's prescription.** Over the age of 6 months, use does not require a prescription. 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.

**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 your 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 your doctor.

Take the lowest dose for the shortest possible time to relieve symptoms.

If your child is taking this medicine while they have an infection and symptoms of the infection persist or worsen, consult your doctor without delay.

#### **Manner of use**

**Always shake the bottle well before use.**

#### **Directions for use:**

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

Use the measuring syringe enclosed to measure the correct amount of medicine.

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 the medicine.

- Insert the syringe into the special opening in the neck of the bottle.
- To fill the syringe, turn the bottle upside down. While holding the syringe in place, gently pull the plunger down to draw the medicine to the correct mark on the syringe. See dosages charts.
- At the end of filling to the right dose, turn the bottle right side up and gently release the syringe.
- Insert the end of the syringe into the mouth (towards the cheek) and empty its content slowly and gently.
- 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 a higher dosage to your child** If you have taken or your child has taken a higher dose than necessary or if a child has accidentally swallowed some medicine, immediately see a doctor or go 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 forget to take this medicine**

If you forget to administer or take a dose, administer or take the next dose as necessary, 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 every time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

### **4. Side effects**

Like with all medicines, using iBOO 2% for Children may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The most common side effect is stomach 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 blistering or peeling of the skin), 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).

- A red, scaly widespread rash with bumps under the skin and blisters mainly localised on the skin folds, trunk, and upper extremities, accompanied by fever at the initiation of treatment (acute generalized exanthematous pustulosis) (AGEP) (frequency not known). See section 2.

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

- Unexplained stomach pain, indigestion, heartburn, nausea or vomiting.
- Yellowing of the eyes, pale stools 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 your 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 other problems may occur when using ibuprofen. The likelihood of this is low at the dose 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).
- Skin becomes sensitive to light.

**If you experience a side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

#### **Reporting side effects**

You can report side effects to the Ministry of Health by following the link 'Report Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

### **5. How to store the medicine?**

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is 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.

Strawberry flavoring containing substances identical to natural flavorings, natural flavoring preparations, maize maltodextrin, triethyl citrate (E-1505) 8.4%, propylene glycol (E-1520) 0.1% and benzyl alcohol 0.0236%.

**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:**

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020

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

**The leaflet was revised in July 2022 according to MOH guidelines.**

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