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 4% for Children Suspension

Composition
Each 1 ml contains: ibuprofen 40 mg

For information on inactive ingredients and allergens see section 2 under - '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. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

You must use this medicine according to the instructions in the dosage section in this leaflet. **The concentration of this medicine is double the concentration of the standard suspension of iBOO 2% for Children and you should be cautious about using the right dosage.** Consult your pharmacist if you need further information. Consult your doctor if the symptoms of the illness worsen or do not improve within 3 days.

This medicine is suitable for infants and children from the ages of 3 months to 12 years (who weigh approximately 40 kg). Use in infants between 3-6 months of age is according to a doctor's prescription.

1. What is this medicine intended for?

For the reduction of fever and relief of mild to moderate pain, for infants 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

Do not use this medicine if you or your child:

- are sensitive (allergic) to the active ingredient ibuprofen or to any of the other ingredients in this medicine (see section 6).
- have had allergic reactions (such as bronchospasm, asthma, nose inflammation (rhinitis), subcutaneous swelling (angioedema) or hives (urticaria)) as a result of taking ibuprofen, acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs (NSAIDs).
- have suffered in the past from gastrointestinal bleeding or perforation related to previous treatment with NSAIDs.
- have or have had peptic ulcer/gastric bleeding (two or more significant confirmed episodes of perforation or bleeding).
- have severe liver or severe kidney failure.
- have severe heart failure.
- have cerebrovascular bleeding or other active bleeding.
- have unclarified blood-formation disturbances.
- have severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake).
- you are in the last three months of pregnancy.

Special warnings regarding use of this medicine
Before using iBOO 4% for Children, tell your doctor if:
- you or your child have certain hereditary blood formation disorders (e.g. acute intermittent porphyria).
- you or your child suffer from coagulation disturbances.
- you or your child have certain diseases of the skin (systemic lupus erythematosus (SLE) or mixed connective tissue disease).
- you or your child have or have ever had bowel disease (ulcerative colitis or Crohn's disease) as these conditions may be exacerbated (see section 4 'Side effects').
- you or your child have or have ever had high blood pressure and/or heart failure.
- you or your child have reduced kidney function.
- you or your child have liver disorders. In prolonged administration of this medicine regular checking of liver function, kidney function and blood count is required.
- you or your child are taking medicines which could increase the risk of ulceration or bleeding, such as oral corticosteroids (such as prednisolone), medicines for thinning the blood (such as warfarin), selective serotonin-reuptake inhibitors (medicines for treatment of depression) or anti-platelet medicines (such as aspirin).
- you or your child are taking another NSAID medicine (including COX-2 inhibitors such as celecoxib or etoricoxib) as taking these together should be avoided (see section 'Drug interactions').
- you or your child have or have had asthma or allergic diseases as shortness of breath may occur.
- you or your child suffer from hayfever, nasal polyps or chronic obstructive respiratory disorders as an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (analgesic asthma), Quincke's oedema or urticaria.
- you or your child have just undergone major surgery as medical surveillance is required.
- you or your child are dehydrated as there is a risk of kidney problems.
- **the patient has an infection** - as this medicine may hide signs of infections such as fever and pain. It is therefore possible that 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 chickenpox. If you or your child take this medicine while you have an infection and the symptoms of the infection persist or worsen, consult a doctor without delay.
- during chicken pox (varicella) it is advisable to avoid use of this medicine.
- **skin reactions** - serious skin reactions have been reported in association with this medicine. You should stop taking/giving this medicine and seek medical attention immediately, if you or your child develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy, since this can be the first signs of a very serious skin reaction. (See section 4).
- you or your child have heart problems, including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack (TIA)).
- you or your child have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Additional warnings
- Side effects may be minimized by using the minimum effective dose for the shortest duration.
- In general terms, the habitual use of (several sorts of) analgesics can lead to severe kidney problems. The risk may be increased under physical strain associated with loss of salt and dehydration. Therefore it should be avoided.
- Prolonged use of any type of painkiller to relieve headaches can make them worse. If you experience or suspect this situation, you should seek medical advice, and treatment should be discontinued. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medicines.
- Gastrointestinal bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of serious gastrointestinal events. When gastrointestinal bleeding or ulceration occurs, the treatment should be stopped immediately. The risk of gastrointestinal bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation (see section 2 'Do not use this medicine if you or your child') and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective medicines (e.g. misoprostol or proton pump inhibitors) should be considered for those patients, and also those requiring concomitant treatment with low-dose aspirin or other medicines likely to increase gastrointestinal risk.
- Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

Elderly
The elderly have an increased risk of side effects when taking NSAIDs, particularly those relating to the stomach and bowel. (For further information, see section 4 'Side effects').
Patients with a history of gastrointestinal toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially gastrointestinal bleeding) particularly in the initial stages of treatment.

Interactions with other medicines
If you or your child are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. Especially if you or your child are taking:
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin (acetylsalicylic acid), warfarin, ticlopidine)
- medicines for treatment of high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan). Some other medicines may also affect or be affected by the treatment with this medicine. You should therefore always consult with your doctor or pharmacist before using this medicine with other medicines.
- other NSAIDs including COX-2 inhibitors - this may increase the risk of side effects.
- digoxin (for heart failure) - the effect of digoxin may be enhanced.
- glucocorticoids medicines containing cortisone or cortisone-like substances - this may increase the risk of gastrointestinal ulcers or bleeding.
- anti-platelet medicines - the risk of bleeding may increase.
- aspirin (low dose) - the blood-thinning effect may be impaired.
- medicines for thinning the blood (such as warfarin) - ibuprofen may enhance the effects of these medicines.
- phenytoin (for treatment of epilepsy) - the effect of phenytoin may be enhanced.
- selective serotonin reuptake inhibitors (medicines used for depression) - these may increase the risk of gastrointestinal bleeding.
- lithium (a medicine for manic depressive illness and depression) - the effect of lithium may be enhanced.
- probenecid and sulfinpyrazones (medicines for gout) - the excretion of ibuprofen may be delayed.
- medicines for high blood pressure and diuretics - ibuprofen may diminish the effects of these medicines and there could be a possible increased risk for the kidneys.
- potassium sparing diuretics (e.g. amiloride, potassium canreoate, spironolactone, triamterene) - may lead to hyperkalaemia (high level of potassium in the blood).
- methotrexate (a medicine for treatment of cancer or rheumatism) - the effect of methotrexate may be enhanced.
- tacrolimus and cyclosporine (immunosuppressive medicines) - kidney damage may occur.
- zidovudine (a medicine for treating HIV/AIDS) - the use of this medicine may cause an increased risk of bleeding into a joint or a bleeding that leads to swelling in HIV (+) haemophiliacs.
- sulfonylureas (medicines for the treatment of diabetes) - the blood sugar levels can be affected.
- quinolone antibiotics - the risk for convulsions may be increased.
- voriconazole and fluconazole (CYP2C9 inhibitors) (for treatment of fungal infections) - the effect of ibuprofen may increase. Reduction of the ibuprofen dosage should be considered, particularly when high-dose ibuprofen is administered with either voriconazole or fluconazole.
- baclofen - baclofen toxicity may develop after starting ibuprofen.
- ritonavir – it may increase the plasma concentrations of NSAIDs.
- aminoglycosides - NSAIDs may decrease the excretion of aminoglycosides.

Using this medicine and alcohol consumption
You should not drink alcohol while using this medicine. Some side effects, such as those affecting the gastrointestinal tract or the central nervous system can be more likely when alcohol is consumed at the same time as this medicine.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Pregnancy
This medicine has the potential side effect of kidney damage in unborn babies and low amniotic fluid as of the 20th week of pregnancy. It is recommended to refrain from using NSAIDs from the 20th week of pregnancy and to consult with a healthcare professional if necessary.
Do not use iBOO 4% for Children if you are in the last three months of pregnancy. Avoid the use of this medicine in the first 6 months of pregnancy unless your doctor instructs you otherwise.

Breastfeeding
Only small amounts of ibuprofen and its decomposition products pass into breast milk. This medicine may be used during breastfeeding, if it used at the recommended dosage and for the shortest possible time.

Fertility
This medicine belongs to a group of medicines (NSAIDs) which may impair fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines
For short-term use, this medicine has no or negligible influence on the ability to drive and use machines.

Important information about some of this medicine's ingredients
- **Maltitol** - If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
  Maltitol may cause mild diarrhoea.
  The caloric value of maltitol: 2.3 kilocalories/gram.
- **Sodium** - This medicine contains 28.95 mg sodium (the main component in table salt) in 5 ml, equivalent to 1.45% 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 (gasping 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 years), 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 side effects (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 dose is usually:
5-10 mg/kg every 6 to 8 hours up to maximum 4 times per 24 hours at intervals of at least 4 hours between doses. Do not exceed the dosage of 40 mg/kg per 24 hours. The maximal dosage above the age of 12 years is 1200 per 24 hours.

Dosage chart by weight

Weight (kg)	Dose in ml for use with a measuring syringe	No. of doses in 24 hours
Below 5 kg	According to a doctor's prescription	
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 chart by age

Age (years)	Dose measured in a measuring syringe	No. of doses in 24 hours
3-6 months	According to a doctor's prescription	
6-11 months	1.25 ml	3-4 times a day
12-23 months	2 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

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 chart by weight. Only if you cannot establish the weight of the child, can the dosage 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.
- **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** – will the dosage 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 use this medicine for more than 24 hours in infants between 3-6 months of age. If the symptoms persist longer than 24 hours or worsen, consult the doctor.
Do not use this medicine for more than 3 days in children over the age of 6 months. If the symptoms persist longer than 3 days or worsen, consult the doctor.
Take the lowest dose for the shortest time to relieve symptoms.
Consult a doctor without delay if your child is taking this medicine while having an infection and the symptoms of their infection persist or worsen.

Method of administration
Always shake the bottle well before use.

Instructions for use:
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.
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. While holding the syringe in place, gently pull the plunger down to draw the medicine to the correct mark on the syringe. See dosage charts.
4. At the end of filling, turn the bottle right side up and gently release the syringe.
5. Insert the end of the syringe into the mouth (towards the cheek) and empty its content slowly and gently.
6. After use, close the bottle tightly. Separate the syringe parts, wash them in lukewarm water and soap and let them dry.

If you used or administered a higher dose to your child
If you or your child have taken a higher dose than necessary or if a child has accidentally swallowed some medicine, immediately see a doctor or go to the closest hospital emergency room to get an opinion of the risk and consult about the action to be taken.
The symptoms can include nausea, stomach pain, vomiting (there may be a small amount of blood), or more rarely diarrhoea. In addition, headache, gastrointestinal bleeding, blurred vision, ringing in the ears, confusion and shaky eye movement, exacerbation of asthma in asthmatics.
At high dosages, drowsiness, excitation, disorientation, chest pain, palpitations, loss of consciousness, coma, convulsions (mainly in children), vertigo, weakness and dizziness, blood in urine, low blood pressure, high level of potassium in the blood, metabolic acidosis, increased prothrombin time/INR, acute renal failure, liver damage, respiratory depression, cyanosis, cold body feeling, and breathing problems have been reported.

If you forgot to take the medicine
Do not take a double dose to make up for the forgotten dose. If you do forget to take or give a dose, take or give it as soon as you remember and then take the next dose according to the dose interval detailed in section 3.

Do not take medicines in the dark! Check the label and 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

As with any medicine, using iBOO 4% 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.

Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms.
Although side effects are uncommon, you or your child may get one of the known side effects of NSAIDs. If they do, or if you have concerns, stop giving this medicine and contact your doctor as soon as possible.
Elderly people using this medicine are at increased risk of developing problems associated with side effects.

STOP USING this medicine and seek immediate medical help if you or your child develop:
- **signs of intestinal bleeding** such as: severe pain in the abdomen, black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- **signs of rare but serious allergic reaction** such as worsening of asthma, unexplained wheezing or shortness of breath, swelling of the face, tongue or throat, difficulty breathing, racing heart, drop in blood pressure leading to shock. These can happen even on first use of this medicine. If any of these symptoms occur, call a doctor at once.
- **severe skin reactions** such as rashes covering the whole body, peeling, blistering or flaking skin.
- a severe skin reaction known as DRESS (Drug reaction with eosinophilia and systemic symptoms) syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase in eosinophils (a type of white blood cells).
- 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 generalised exanthematous pustulosis - AGEP) (frequency not known). See section 2.

Tell your doctor if you or your child have any of the following side effects, they become worse or you notice any effects not listed.

Common side effects (affect up to 1-10 in 100 users)
Stomach and intestinal complaints such as acid burn, stomach pain and nausea, indigestion, diarrhoea, vomiting, flatulence and constipation and slight blood losses in stomach and/or bowel that may cause anaemia in exceptional cases

Uncommon side effects (affect 1-10 in 1,000 users):
- gastrointestinal ulcers, perforation or bleeding, inflammation of the mucous membrane of the mouth with ulceration, worsening of existing bowel disease (colitis or Crohn's disease), inflammation of the stomach (gastritis)
- headache, dizziness, sleeplessness, agitation, irritability or tiredness
- visual disturbances
- various skin rashes
- hypersensitivity reactions with hives and itch

Rare side effects (affect 1-10 in 10,000 users):
- tinnitus (ringing in the ears)
- increased urea concentrations in blood, pain in the flanks and/or the abdomen, blood in the urine and a fever may be signs of damage to kidneys (papillary necrosis)
- increased uric acid concentrations in the blood
- decreased haemoglobin levels

Very rare side effects (affect less than 1 in 10,000 users):
- oesophagitis, pancreatitis, and formation of intestinal diaphragm-like strictures
- heart failure, heart attack and swelling in the face or hands (oedema)
- passing less urine than normal and swelling (especially in patients with high blood pressure or reduced kidney function), swelling (oedema) and cloudy urine (nephrotic syndrome); inflammatory kidney disease (interstitial nephritis) that may lead to acute kidney failure. If one of the above-mentioned symptoms occur or if you have a general miserable feeling, stop taking this medicine and consult your doctor immediately as these could be first signs of kidney damage or kidney failure.
- psychotic reactions, depression
- high blood pressure, vasculitis
- palpitations
- liver dysfunction, damage to the liver (first signs could be discoloration of the skin), especially during long-term treatment, liver failure, acute inflammation of the liver (hepatitis)
- problems in the blood cell production - first signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding and unexplained bruising. In these cases, you must stop taking the medicine immediately and consult a doctor. Do not use other medicines to relieve pain or reduce fever.
- severe skin infections and soft tissue complications during chicken pox (varicella) infection.
- exacerbation of infection-related inflammations (e.g. necrotizing fasciitis) associated with the use of certain painkillers (NSAIDs) has been described. If signs of an infection appear or get worse, you must go to the doctor without delay. It is to be investigated whether there is an indication for an anti-infective/antibiotic therapy.
- symptoms of aseptic meningitis with stiff neck, headache, nausea, vomiting, fever or clouding of consciousness have been observed when using ibuprofen. Patients with autoimmune disorders (SLE, mixed connective tissue disease) may be more likely to be affected. Contact a doctor at once, if these occur.
- severe forms of skin reactions such as skin rash with redness and blistering (e.g. Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis (TEN)/Lyell's syndrome), hair loss (alopecia).

Side effects of unknown frequency (the frequency of these effects has not been established yet):
- respiratory tract reactivity comprising asthma, bronchospasm or dyspnoea
- skin becomes sensitive to light

Medicines such as this may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

If you experience any 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 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (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! This and all other medicines should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. 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 appears on the bottle and package. The expiry date refers to the last day of that month.
- **Store below 25˚C.**
- **After first opening of the bottle, the medicine may be used for up to six months, but no later than the expiry date.**
- Do not dispose of the medicine via wastewater or household waste. Ask the pharmacist about how to dispose of this medicine (medicines you no longer use). These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Liquid maltitol, glycerol (E-422), sodium chloride, sodium citrate, citric acid anhydrous, hypromellose 15cP, xanthan gum, sodium benzoate, strawberry flavor, saccharin sodium, thaumatin, 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 package:
Viscous suspension, white/cream color, strawberry scented.
Each pack contains a bottle of suspension and a syringe for dose precision.
Amount in pack: 30 ml

Name and address of the license holder:
Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020

Name and address of the manufacturer: Farmalider S.A., Alcobendas 28108, Madrid, Spain

This leaflet was revised in July 2023 in accordance with Ministry of Health guidelines

Registration number of the medicine in the Ministry of Health's National Drug Registry: 160-27-34833

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