

## Ibulek Children 100 mg/5 ml oral suspension (ibuprofen)

### Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If your child after 3 days does not feel better or feels worse, you must talk to a doctor. If this medicine is used in babies 3 to 5 months of age and their condition is not improved or it gets worse during the first 24 hours of administration, seek immediate medical advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What Ibulek Children is and what it is used for
2. What you need to know before you take Ibulek Children
3. How to use Ibulek Children
4. Possible side effects
5. How to store Ibulek Children
6. Contents of the pack and other information

#### 1. What Ibulek Children is and what it is used for

Ibulek Children contains ibuprofen. It belongs to a group of medicines called non-steroidal antiinflammatory drugs. They relieve pain, decrease inflammation and reduce fever.

Ibulek Children is used in the short term treatment of fever including fever after vaccination. It is suitable for pain relief associated with dentition, toothache, throat and ear inflammation, mild pain after sprains and injuries.

#### 2. What you need to know before you use Ibulek Children

##### Do not use Ibulek Children:

- if your child is allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- if your child has ever had allergic reaction such as difficulty breathing and wheezing (asthma), runny nose, rash, swelling in the face, tongue, lips and throat after taking ibuprofen, acetylsalicylic acid or other non-steroidal antiinflammatory drugs;
- if your child is under 3 months old;
- if your child weighs less than 5 kg;
- if your child is taking other non-steroidal antiinflammatory drugs, analgesics, fever-lowering drugs, acetylsalicylic acid in a daily dose of over 75 mg;
- if your child has (or has had two or more episodes) a stomach ulcer, perforation or bleeding from the stomach or intestines;
- if your child suffers from severe heart, liver or kidney disease;
- if your child has hereditary intolerance to fructose (fruit sugar).

This medicine should not be given to children under the age of 3 months unless expressly prescribed by a doctor.

This medicine should not be used in the last three months of pregnancy.

### Warnings and precautions

Talk to your doctor:

- if your child has high blood pressure, heart disease or other problems associated with blood circulation as there is a certain risk of developing heart problems during ibuprofen treatment;
- if your child has diabetes or elevated cholesterol levels which may increase the risk of developing heart problems;
- if your child suffers from asthma or any allergic disease involving the lungs;
- if your child has or has had kidney, liver, heart problems or gastrointestinal problems as there is a risk of kidney impairment in case of dehydration;
- if your child has immune system disorders, systemic lupus or another similar disease;
- if your child suffers from Crohn's disease, ulcerative colitis or another inflammatory intestinal disease;

If you are an adult and take this product, you should know that the information in Warnings and precautions applies to you as well but in addition to it you should consider the following:

- if you have heart problems, have undergone a stroke, have high blood pressure, diabetes, increased cholesterol level, or smoke, you should talk to a doctor or pharmacist about your treatment with this medicine.
- the use of ibuprofen, similar to other non-steroidal antiinflammatory drugs, may be associated with a slightly increased risk for a heart event (heart attack) or stroke. This risk is higher if you take high doses or have a prolonged treatment therefore the recommended doses and treatment duration should not be exceeded.
- if you are over 65 years of age, you should talk to your doctor about whether it is appropriate for you to take this medicine.
- there is evidence which, although limited, shows that ibuprofen is detected in very low levels in breast milk therefore it is unlikely that it may exert harmful effects on the infant.

### Other medicines and Ibulek Children

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is particularly important if it refers to the following medicines:

- other medicines containing ibuprofen or other non-steroidal antiinflammatory drugs including non-prescription ones as the risk for gastrointestinal impairment increases;
- low doses (less than 75 mg daily) of acetylsalicylic acid - possible change in the effect;
- medicines to increase the production of urine (diuretics) - increased risk for kidney impairment;
- medicines to thin blood (anticoagulants such as warfarin and antiplatelet drugs such as dipyridamole and clopidogrel) - increased risk of bleeding;
- medicines for treatment of high blood pressure (captopril, atenolol, losartan) - potential reduction in their effect;
- lithium (to treat mood disorders and depression) - its effect may be enhanced;
- methotrexate (to treat psoriasis, arthritis or some types of cancer) - its effect may be enhanced;
- zidovudine (for HIV infection) - a potential risk of haemorrhages in the joints and skin);
- corticosteroids (antiinflammatory drugs to treat arthritis, asthma, etc.) - increased risk of gastrointestinal impairment;
- cardiac glycosides (to treat heart diseases);
- cyclosporine and tacrolimus (to prevent organ rejection after transplant) - potential kidney impairment;
- mifepristone (for pregnancy termination)
- quinolone antibiotics (type of antibiotics) - increased risk of seizures;

### Ibulek Children with food and drink

This medicine may be taken with or without food. Food decreases the likelihood of developing gastrointestinal problems; however, it may delay its effect.

Alcohol consumption and tobacco smoking are inappropriate during treatment.

### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Pregnancy

During the first 6 months of pregnancy this product can be used only if prescribed by a doctor.

During the last 3 months of pregnancy this medicinal product should not be used.

#### Breast - feeding

This medicinal product may be used during breast-feeding for a short period as ibuprofen passes into breast milk in small amounts. If a prolonged treatment is required, talk to your doctor.

#### Fertility

Non-steroidal antiinflammatory drugs including ibuprofen may impair fertility (ability to become pregnant) in women. This effect is reversible upon stopping the medicine. In case of irregular use, it is not likely that Ibulek Children influence your chances of becoming pregnant.

Nevertheless, before taking this medicine, speak to your doctor if you are attempting to conceive.

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

Ibulek Children is not expected to influence the ability to drive and use machines in the recommended doses and treatment duration.

#### **Ibulek Children contains maltitol**

This medicinal product contains maltitol (malt syrup). If your doctor has told you that you have intolerance to some sugars, talk to him before taking this product. Malt syrup may have mild laxative effects. Its energy value is 2,3 kcal/g.

### **3. How to use Ibulek Children**

**Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.**

#### Dosage

You should know that this medicine is intended for short term use only. Ibulek Children should be used in the lowest possible dose to achieve effect. For easy reference, the recommended daily doses are presented in the table below:

Age group	Body weight (kg)	Recommended daily dose
Infants aged 3 – 6 months and weighing over 5 kg	5 – 7,6	2,5 ml (50 mg) up to 3 times daily
Infants aged 6 – 12 months	7,7 – 9	2,5 ml (50 mg) up to 3 - 4 times daily
Children 1 – 3 years	10 – 16	5 ml (100 mg) up to 3 times daily
Children 4 – 6 years	17 – 20	7,5 ml (150 mg) up to 3 times daily
Children 7 – 9 years	21 – 30	10 ml (200 mg) up to 3 times daily
Children 10 – 12 years	31 - 40	15 ml (300 mg) up to 3 times daily

The recommended daily dose for children with juvenile arthritis is up to 40 mg/kg body weight distributed into several doses.

For fever following vaccination (children aged 2 -6 months) the recommended dose is 2,5 ml (50 mg), to be repeated if required, after a 6 hour interval. More than two single doses of 2,5 ml (50 mg) should not be administered within a 24 hour period. If the fever is not influenced, a doctor should be consulted.

Ibulek Children may be given to infants below 3 months of age only if prescribed by a doctor. It should not be given to infants weighing less than 5 kg.

The maximum treatment duration without doctor's advice for infants and children  $\geq$  6 months to 12 years and adolescents aged 12 -18 years should not be longer than 3 days. If the symptoms worsen or last more than 3 days you should seek medical advice.

For infants aged  $\geq$  3 months to  $\leq$  5 months and weighing over 5 kg, if the symptoms worsen or persist for more than 24 hours, a doctor should be consulted.

#### Method of administration

Ibulek Children is intended for use through the mouth. In case of a sensitive stomach the medicine may be taken during meals.

The required amount of suspension is measured by the dosing device supplied in the carton package. The dosing device is a 5 ml oral dosing syringe marked in gradations of half milliliters up to 5 ml. To administer the medicine, place the end of the syringe into the child's mouth and press the plunger down to slowly and gently release the suspension. After use, wash the syringe in warm water and allow to dry.

#### **If you use more Ibulek Children than you should**

The main symptoms of overdosing include vomiting, nausea, stomach pain, stomach or intestinal bleeding, diarrhea, headache, dizziness or sleepiness. More rarely, low blood pressure, slow breathing or loss of consciousness may occur.

If you have given more of this medicine than you should, contact a doctor or go to the nearest hospital straight away. Take the pack with you to show to the doctor which medicine you have used.

#### **If you forget a dose of Ibulek Children**

If you forget a dose, give the next dose as soon as you remember.

You can then carry on with the normal dose at the correct time. Do not give a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If your child experiences any of the following side effects or symptoms, stop giving this medicine and tell your doctor immediately:**

- Allergic reactions such as skin rash, itching, urticaria (hives), worsening of asthma, difficulty breathing and unexplained wheezing, swelling of the face, lips or throat, low blood pressure;
- Gastrointestinal complications incl. perforation or bleeding with symptoms such as abdominal pain and discomfort, vomiting blood or dark particles that look like coffee grounds, change in the colour of stools (bright red or black tarry);
- Skin redness, blistering or impaired skin or mucous membrane integrity that may be symptoms of severe skin damage;
- Stiff neck, headache, nausea, vomiting, fever and confusion.

**Stop giving this medicine and tell your doctor in case of the following side effects:**

- Unexplained stomach pain, indigestion, heartburn, nausea or vomiting;
- Yellowing of the eyes, pale stools, dark urine;
- Severe sore throat with high fever;
- Unexplained bruising, tiredness or getting infections such as colds more often than normal.

**Other side effects that may occur are:**

*Uncommon:* headache

*Rare:* diarrhea, constipation;

*Very rare:* kidney problems, slightly increased risk of heart attack or stroke; that is unlikely to happen at the recommended dose level given to children, worsening of colitis and Crohn's disease, high blood pressure.

#### **Reporting of suspected side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### **5. How to store Ibulek Children**

Store below 30 °C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening of the pack: 6 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6. Contents of the pack and other information**

##### **What Ibulek Children contains**

- The active substance is ibuprofen. Each 5 ml suspension contain 100 mg ibuprofen; 1 ml suspension contains 20 mg ibuprofen;
- The other ingredients are: liquid maltitol, glycerol, citric acid, anhydrous, sodium citrate, sodium chloride, saccharin sodium, sodium benzoate, polysorbate 80, xanthan gum, strawberry flavour (mixture of aromatic substances and glucose).

##### **What Ibulek Children looks like and contents of the pack**

Ibulek Children oral suspension is an almost white viscous syrupy suspension with strawberry flavour and sweet taste.

120 ml oral suspension in dark coloured glass bottles.

Dosing device: 5 ml oral dosing syringe marked in gradations of half milliliters up to 5 ml.

##### **Marketing Authorisation Holder and Manufacturer**

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