

PATIENT INFORMATION LEAFLET
IBUPROFEN 100 mg/5 ml Oral Suspension
Ibuprofen 100 mg/5 ml

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to give Ibuprofen Oral Suspension to your child carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your child's symptoms worsen or do not improve after a few days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

1. WHAT IBUPROFEN IS AND WHAT IT IS USED FOR

Ibuprofen 100 mg/5 ml Oral Suspension ("Ibuprofen") contains ibuprofen as the active ingredient. This belongs to a group of medicines called **non-steroidal anti-inflammatory drugs (NSAIDs)**. Ibuprofen is given to children as a pain reliever for relief of mild to moderate muscular pain, headache, earache, sore throat, dental pain and backache. This medicine can also be used in minor injuries such as sprains and strains. It also reduces temperature in fever (e.g. post-immunisation fever), as well as other symptoms of cold and influenza.

2. WHAT YOU NEED TO KNOW BEFORE YOU GIVE IBUPROFEN

Do NOT give this medicine if your child:

- has an allergy or hypersensitivity to ibuprofen or any of the other ingredients in this medicine (see Section 6 and end of Section 2: *Important information about ingredients*).
- has had an allergic reaction or wheezing after taking aspirin or other non-steroidal anti-inflammatory painkillers. (*Symptoms of a rare allergic reaction are given under Section 4: Possible side effects*).
- has ever had a stomach ulcer or a history of bleeding into, or perforation of, the intestine especially after previous NSAID treatment
- is taking any other non-steroidal anti-inflammatory painkillers (NSAIDs)
- has ever had severe kidney, heart or liver problems
- has an inherited intolerance of some sugars
- is less than 3 months old

If any of these apply, ask for advice from a doctor or pharmacist before giving this medicine.

Warnings and Precautions

There is a risk of renal (kidney) impairment in dehydrated children.

You should discuss your child's treatment with your doctor or pharmacist before giving Ibuprofen 100mg/5ml Oral Suspension if your child:

- has high blood pressure, kidney or liver problems
- has asthma or diabetes
- has lupus or mixed connective tissue disease
- has a chronic inflammatory intestinal disease such as ulcerative colitis or Crohn's disease or gastrointestinal bleeding
- has chicken pox

Other medicines and Ibuprofen 100mg/5ml Oral Suspension

Please tell your doctor or pharmacist if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription. Ibuprofen 100mg/5ml Oral Suspension may affect or be affected by some medicines. For example:

- **Diuretics** (drugs to help you pass water)
- Medicines that are anticoagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- **Lithium** or **Selective serotonin reuptake inhibitors** (SSRI's e.g. Fluoxetine) (used to treat mood disorders)
- **Methotrexate** (used to treat rheumatoid arthritis, psoriasis and some cancers)
- **Zidovudine** (used to treat HIV)
- **Corticosteroids** (anti-inflammatory drugs, such as Hydrocortisone)
- **Cardiac glycosides** (drugs used in the treatment of heart problems, such as Digoxin)
- **Ciclosporin** or **Tacrolimus** (used to suppress the body's immune system)
- **Mifepristone** (used to terminate a pregnancy)
- **Quinolone antibiotics** (used to treat a wide range of infections e.g. Ciprofloxacin)
- any other **Ibuprofen preparations**, including those you can buy without a prescription.

Some other medicines may also affect or be affected by the treatment of Ibuprofen 100mg/5ml. You should therefore always seek the advice of your child's doctor or pharmacist before you give Ibuprofen 100 mg/5ml Oral Suspension with other medicines.

This product is intended for children aged between 3 months and 12 years. If you are an adult taking this product; The above warnings and information apply, and in addition the following also applies:

- **Do NOT** take this product if you are taking aspirin at doses above 75 mg daily. If you are on low dose aspirin (up to 75 mg daily) speak to your doctor or pharmacist before you take this product.
 - if you 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 legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack ('TIA')).
 - if you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker
 - Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.
 - Do not take if you are in the **last three months** of pregnancy.
- Speak to your doctor or pharmacist before taking if;
- you are in the **first six months** of pregnancy
 - you are elderly
 - you are trying to get pregnant. Ibuprofen belongs to a group of medicines which may **impair fertility** in women. This effect is reversible on stopping the medicine. It is unlikely that Ibuprofen, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.

Pregnancy and breast-feeding

Ibuprofen should NOT be taken in the last 3 months of pregnancy, as it may be harmful to the unborn child.

Pregnant women intending to use this product should seek medical advice before use as it should only be taken on doctor's advice during the first 6 months of pregnancy.

Important information about some of the ingredients of this medicine

- **Maltitol (E965)**, may have a mild laxative effect (a 5 ml dose contains 1.335 g of maltitol). If your child has an intolerance to some sugars, contact your doctor before giving this medicine.
- **Sodium methyl hydroxybenzoate (E219)** and **Sodium propyl hydroxybenzoate (E217)**, may cause allergic reactions (possibly delayed).

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3. HOW TO GIVE IBUPROFEN

Shake the bottle well before measuring the dose. A double-ended measuring spoon is provided to ensure accuracy. The small spoon measures a 2.5 ml dose and the larger spoon measures 5 ml.

This medicine should **NOT** be given if your child weighs less than 5 kg. The usual daily dose in children is 20 mg per kg of bodyweight in divided doses, **every 6 to 8 hours if required. Leave at least 4 hours between doses. For short term use only.** Consult a doctor promptly if symptoms persist or worsen.

WARNING: DO NOT EXCEED THE STATED DOSE

DOSAGE: Children (A spoon is provided to measure doses of 2.5 ml or 5 ml)		
3 - 6 months (weighing over 5 kg)	2.5 ml 3 times a day	Do not give for more than 24 hours.
6 months – 1 year	2.5 ml 3 to 4 times a day	Do not give to children aged 6 months and older for more than 3 days.
1 year – 4 years	5 ml 3 times a day	
4 years – 7 years	7.5 ml 3 times a day	
7 years – 12 years	10 ml 3 times a day	
Do not give to babies under 3 months		

For infants aged 3-5 months medical advice should be sought if symptoms worsen or not later than 24 hours if symptoms persist.

If in children aged from 6 months and in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Post-immunisation fever: One small spoonful (2.5 ml), followed by another small spoonful (2.5 ml) 6 hours later if necessary. No more than 2 doses should be given in 24 hours. If fever is not reduced, consult a doctor.

If you forget to give this medicine

If you forget to give a dose, give it as soon as you remember, unless it is almost time for the next dose. Never give a double dose to make up for the missed dose.

If you give more medicine than you should

If your child or someone else accidentally takes a lot more than the stated dose (an overdose), you should contact a doctor immediately, or go to the nearest hospital casualty department, and take the bottle with you if you can.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ibuprofen can cause side-effects although not everybody gets them.

You should STOP giving Ibuprofen and seek advice from your doctor if your child experiences a very rare allergic reaction, including skin rashes, increased sensitivity to light, swelling of the face and tongue, inflammation of the blood vessels, fever or shock. Skin and mucous membrane reactions may also occur.

The most common side-effect is irritation of the stomach which can cause problems in some patients.

If your child suffers from the following, stop giving the medicine and seek immediate medical help:

- Passing blood in their faeces (stools/motions)
- Passing black tarry stools
- Vomiting blood or dark particles that look like ground coffee
- Unexplained wheezing, shortness of breath, skin rash (which may be severe and include blistering or peeling of the skin), itching or bruising, lightheadedness, racing of the heart or fluid retention e.g. swollen ankles, not passing enough urine
- stiff neck, headache, nausea, vomiting, fever and disorientation.

If your child experiences any of the following, stop giving the medicine and tell your doctor:

- If your child's skin starts to turn red or they develop a varied skin reaction or their skin starts to blister or peel, this is very rare
- Unexplained stomach pain, indigestion, heartburn, feeling sick and/or vomiting
- Yellowing of the eyes and/or skin
- Severe sore throat with high fever or unexplained bleeding, bruising and tiredness.

Other unusual effects may include:

Uncommon:

- Headache.

Rare:

- Ibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment
- Flatulence, diarrhoea or constipation.

Very Rare:

- Occasionally hypersensitivity reactions may occur which can cause skin rashes
- Liver and kidney problems may occur with Ibuprofen
- Crohn's disease or ulcerative colitis or other stomach problems may be exacerbated.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE IBUPROFEN

Keep this medicine out of the sight and reach of children. Do not use after the expiry date shown on the bottle. Do not store above 25°C.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ibuprofen contains:

The **active ingredient** is ibuprofen 100 mg per 5 ml

The **other ingredients** are: glycerol (E422), xanthan gum, maltitol (E965), polysorbate 80, saccharin sodium (E954), citric acid monohydrate, sodium methyl hydroxybenzoate (E219), sodium propyl hydroxybenzoate (E217), purified water and strawberry flavour.

What Ibuprofen looks like and contents of the pack:

Ibuprofen is a sugar free, colour-free and strawberry flavoured oral suspension.

This medicine comes in amber glass bottles or polyethylene bottles of: 50 ml, 100 ml, 150 ml or 200 ml with a child-resistant closure.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

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