

## Package leaflet: Information for the user

### Ibuprofen 200 mg/5 ml Oral Suspension

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you and your child.**

Your medicine is called Ibuprofen 200 mg/5 ml Oral Suspension. It will be referred to throughout this leaflet as "Ibuprofen Oral Suspension".

This medicine is available without prescription, but you still need to give Ibuprofen Oral Suspension carefully to get the best results from it. Always use 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 you get any side effects, talk to your pharmacist. This includes any possible side effects not listed in this leaflet. (See section 4).
- You must talk to your doctor if your child does not feel better or feels worse after three days.

What is in this leaflet:

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

#### 1. What Ibuprofen Oral Suspension is and what it is used for

Ibuprofen Oral Suspension contains ibuprofen as the active ingredient. Each 5 ml of oral suspension contains 200 mg of ibuprofen. **This is twice the strength of normal ibuprofen suspension and you should be careful that you use the correct dose.**

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Ibuprofen Oral Suspension is given to children aged 7 - 12 years as a painkiller for relief of mild to moderate muscular pain, headache and dental pain. It also reduces the temperature in fever and relieves the symptoms of colds and influenza.

This medicine should not be used for more than 3 days.

#### 2. What you need to know before you give Ibuprofen Oral Suspension

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 Section 2: Important information about ingredients)
- has had an allergic reaction such as wheezing, an asthma attack, runny nose, skin reaction or swelling after taking aspirin or other non-steroidal anti-inflammatory painkillers
- 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) such as naproxen.
- is taking aspirin at doses above 75 mg daily
- has ever had severe kidney, heart or liver problems
- is suffering from severe dehydration
- has an inherited intolerance to some sugars
- is less than seven years of age or weighs less than 20 kg.

#### Warnings and precautions

##### Skin reactions

Serious skin reactions have been reported in association with Ibuprofen Oral Suspension treatment. You should stop taking Ibuprofen Oral Suspension and seek medical attention immediately, if you 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 should discuss your child's treatment with your doctor or pharmacist before giving this medicine if your child:

- has kidney, liver or bowel problems
- has lupus (SLE) or mixed connective tissue disease
- has a chronic inflammatory bowel disease such as ulcerative colitis or Crohn's disease
- has asthma or allergic diseases of the lungs
- has chickenpox
- has an infection - please see heading "Infections" below.

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

Medicines such as Ibuprofen Oral Suspension 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.

Do not exceed the recommended dose or duration of treatment.

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

Drinking alcohol while taking ibuprofen may increase the risk of certain side effects.

##### Infections

Ibuprofen Oral Suspension may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen Oral Suspension 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 take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

##### Other medicines and Ibuprofen Oral Suspension

Please tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription.

Ibuprofen Oral Suspension may affect or be affected by some medicines. For example:

- any other ibuprofen preparations or NSAID painkillers, including those you can buy without a prescription.
- aspirin
- medicines that are anticoagulants (i.e. thin blood/ prevent clotting, e.g. aspirin, warfarin)
- medicines that reduce high blood pressure (ACE inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan)
- cardiac glycosides (used in the treatment of heart problems, such as digoxin)
- ciclosporin or tacrolimus (used to suppress the body's immune system)
- corticosteroids (anti-inflammatory drugs, such as prednisolone or beclomethasone.)
- diuretics (to help pass water such as furosemide or bendroflumethiazide)
- lithium, or selective serotonin reuptake inhibitors (SSRIs such as fluoxetine - used to treat mood disorders)
- methotrexate (used to treat rheumatoid arthritis, psoriasis and some cancers)
- mifepristone (used to terminate pregnancy)
- quinolone antibiotics (used to treat a wide range of infections e.g. ciprofloxacin)
- zidovudine (used to treat HIV)

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

##### Important information about some of the ingredients of this medicine:

- maltitol (E965) may have a mild laxative effect (calorific value 2.3 kcal/g). If you have been told that you or your child has an intolerance to some sugars, contact your doctor before taking/giving this medicine.

The following warnings are less likely to apply to children but should be considered before giving this medicine.

- ibuprofen belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. It is unlikely that this medicine, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant
- you should only take this product on a doctor's advice during the first 6 months of pregnancy
- DO NOT take this medicine if you are in the last 3 months of your pregnancy
- in limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely
- medicines such as Ibuprofen Oral Suspension 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. Do not exceed the recommended dose or duration of treatment
- you should discuss your treatment with your doctor or pharmacist if you have diabetes, high cholesterol, high blood pressure, 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'), or if you have a family history of heart disease or stroke, or if you are a smoker.

##### Driving and using machines

Ibuprofen Oral Suspension is not expected to affect your ability to drive or operate machinery.

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### 3. How to give Ibuprofen Oral Suspension

**This product is twice the strength of normal ibuprofen suspension and you should be careful that you use the correct dose.**

Always use Ibuprofen Oral Suspension exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or a pharmacist if you are unsure. Shake the bottle well before measuring the dose. A measuring device is provided to ensure accuracy.

This product is intended for short term use only. You should use the lowest dose for the shortest time necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

Age	How Much
Under seven years	Do not use
Seven - nine years	One 5 ml spoonful up to three times in 24 hours
Ten - twelve years	One 5 ml spoonful and one 2.5 ml spoonful up to three times in 24 hours

- Do not give to children under 7 years of age, or those weighing less than 20 kg
- Separate the doses evenly (every 6-8 hours). Leave at least 4 hours between doses.
- Do not give more than 3 doses in any 24 hour period.

**Warning: Do not exceed the stated dose**

**You must talk to your doctor or pharmacist if your child does not get better or feels worse after three days.**

If you have given more Ibuprofen Oral Suspension than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken and take the bottle with you if you can.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

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. Do not give a double dose to make up for the missed dose.

For oral use only.

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

### 4. Possible Side Effects

Like all medicines, ibuprofen can cause side effects, although not everybody gets them. The most common side effect is irritation of the stomach which can cause problems in some patients.

If any of the following occur, stop giving the medicine and seek immediate medical help:

- passing blood in the stools (faeces/motions)
- passing black tarry stools
- vomiting blood or dark particles that look like coffee grounds
- unexplained wheezing, shortness of breath, skin rash (which may be severe and include blistering or peeling of the skin), itching or bruising, light-headedness, racing of the heart or fluid retention e.g. swollen ankles, not passing enough water
- stiff neck, headache, nausea, vomiting, fever and disorientation
- swelling of the face.

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

- if your child's skin starts to turn red or if they develop a painful 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 the following:

Uncommon:

- headache, dizziness, sleeplessness, agitation, irritability or tiredness
- visual disturbances.

Rare:

- flatulence, diarrhoea or constipation
- ringing in the ears (tinnitus)
- kidney damage, increased blood uric acid levels.

Very Rare:

- occasionally hypersensitivity reactions may occur which can cause skin rashes as well as asthma attacks, swelling of the tongue and breathlessness
- liver problems may occur with ibuprofen
- passing less urine than normal, increased proteins in the blood (detected by tests)
- Crohn's disease or ulcerative colitis or other stomach problems may be exacerbated
- depression or psychotic reactions
- hair loss
- high blood pressure.

Unknown:

- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Ibuprofen Oral Suspension if you develop these symptoms and seek medical attention immediately. See also section 2.
- Skin becomes sensitive to light.

**Reporting of 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. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://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 Oral Suspension

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date, which is shown on the bottle. The expiry date refers to the last day of that month. Do not store above 25°C. Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

### 6. Contents of the pack and further information

**What Ibuprofen Oral Suspension contains**

Each 5 ml contains 200 mg of the active ingredient ibuprofen. The other ingredients are: glycerol (E422), xanthan gum, liquid maltitol (E965), polysorbate 80, saccharin sodium (E954), citric acid monohydrate, sodium benzoate (E211), magnesium aluminium silicate, purified water and strawberry flavour (contains propylene glycol).

**What Ibuprofen Oral Suspension looks like and contents of the pack**

Ibuprofen Oral Suspension is a colour-free, white oral suspension. This medicine comes in amber glass bottles containing 60 ml, 80 ml or 100 ml with a child-resistant closure. Not all pack sizes may be marketed. A double ended spoon with measures of 1.25 ml, 2.5 ml and 5 ml is provided.

This medicine should be used within 3 months of first opening.

**Marketing Authorisation Holder**

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

**Manufacturer**

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

PL Number: 04917/0099

**Other sources of information**

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only).

Please be ready to give the following information:

**Product name: Ibuprofen 200 mg/5 ml Oral Suspension**

**Reference number: PL 04917/0099**

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last updated in November 2021