

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Fenopine 100 mg/5 ml Oral Suspension Ibuprofen

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

This medicine is available without prescription.

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 doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you/your child does not feel better or if you/your child feel worse after 1 day (infants 3-6 months weighing more than 5 kg) or 3 days (children aged over 6 months).

#### 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 other information

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

Ibuprofen Oral Suspension contains Ibuprofen as the active ingredient. This belongs to a group of medicines called **non-steroidal anti-inflammatory drugs (NSAIDs)**.

Ibuprofen Oral Suspension is used for the treatment of fever and of mild to moderate pain in children aged from 3 months (weighing over 5 kg) to 12 years.

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

##### Do NOT give this medicine if your child:

- is allergic (hypersensitive) to ibuprofen or any of the other ingredients in this medicine (*see Section 6*)
- has had an asthma attack, runny nose, skin reactions (e.g. reddening, hives) after taking aspirin or other non-steroidal anti-inflammatory painkillers
- has (or has had two or more episodes of) a stomach ulcer, perforation or bleeding
- has severe kidney, heart or liver problems
- is suffering from dehydration as there is a risk of renal impairment
- is in the last 3 months of pregnancy
- is under 3 months of age
- has an inherited intolerance to some sugars

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

#### Warnings and precautions

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.

You should discuss your treatment with your doctor or pharmacist before taking Ibuprofen Oral Suspension if your child:

- has 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”).

- has high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- has liver, kidney or bowel problems
- has lupus (SLE) or a mixed connective tissue disease
- has a chronic inflammatory bowel disease such as ulcerative colitis, Crohn's disease
- has asthma or allergic diseases of the lungs
- has chicken-pox (it is advisable to avoid using this medicine during chicken-pox)
- has an infection - please see heading “Infections” below.

#### Skin reactions

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Ibuprofen Oral Suspension and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

#### 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.

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop immediately Ibuprofen Oral Suspension and contact immediately your doctor or medical emergencies if you notice any of these signs.

#### Other medicines and Ibuprofen Oral Suspension

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:

- **Diuretics** (drug to help you pass water)
- Medicines that are **anti-coagulants** (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- Medicines that reduce **high blood pressure**
- **Mifepristone** (drugs to bring about an abortion)
- **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 prednisone)
- **Cardiac glycosides** (drugs used in the treatment of heart problems, such as Digoxin)
- **Ciclosporin** or **Tacrolimus** (used to suppress the body's immune system)
- **Quinolone antibiotics** (used to treat a wide range of infections e.g. Ciprofloxacin)
- any other **Ibuprofen preparations or NSAID painkillers**, including those you can buy without a prescription.

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 doctor or pharmacist before you use Ibuprofen Oral Suspension with other medicines.

The following additional information is relevant to the active ingredient, ibuprofen.

#### Taking Ibuprofen Oral Suspension with food and drink

If possible you should not drink alcohol during treatment with Ibuprofen Oral Suspension, as side effects, particularly those that affect the gastro-intestinal tract or the central nervous system may be increased.

## Pregnancy and breast-feeding

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

### *Pregnancy*

Do not take ibuprofen if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

You should not take ibuprofen during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, ibuprofen can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

### *Breast-feeding*

Only a small amount of ibuprofen and its breakdown products pass into breast milk. As no harmful effects to infants are known to date, it is not usually necessary to stop breast-feeding during **short – term** use of ibuprofen at the recommended doses.

Ibuprofen Oral Suspension 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

Ibuprofen may cause drowsiness and dizziness. Make sure your reactions are normal before driving, operating machinery or doing other jobs which could be dangerous if you are not fully alert.

### **Ibuprofen Oral Suspension contains Maltitol (E965), Sodium methyl hydroxybenzoate (E219), Sodium propyl hydroxybenzoate (E217) and propylene glycol**

- **Maltitol** may have a mild laxative effect (calorific value 2.3 kcal/g). If you have been told by your doctor that you or your child have an intolerance to some sugars, contact your doctor before taking/giving this medicine.
- **Sodium methyl hydroxybenzoate (E219) and Sodium propyl hydroxybenzoate (E217)** may cause allergic reactions (possibly delayed).
- This medicine contains 5.2 mg **propylene glycol** in each 5 ml which is equivalent to 0.832 mg/g.
- This medicine contains less than 1 mmol **sodium** (23 mg) per 5 ml dose, that is to say essentially 'sodium-free'.

## 3. How to give Ibuprofen Oral Suspension

Always take 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.

**Shake the bottle well before measuring the dose.** A double-ended spoon with measures of 2.5 ml and 5 ml is provided to ensure accuracy.

Doses should be given approximately every 6-8 hours.

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

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

This medicine should **NOT** be given if your child weighs less than 5 kg. The usual daily dose in children is 20-30 mg per kg of bodyweight in divided doses.

3 – 6 months (weighing more than 5 kg)	One 2.5 ml dose (50 mg) taken 3 times in 24 hours
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6 – 12 months (weighing 8 – 10 kg)	One 2.5 ml dose (50 mg) taken 3 times in 24 hours
1 – 3 years (weighing 10 – 15 kg)	One 5.0 ml dose (100 mg) taken 3 times in 24 hours
4 – 6 years (weighing 15 – 20 kg)	One 7.5 ml dose (150 mg) taken 3 times in 24 hours
7 - 9 years (weighing 20 - 30 kg)	One 10 ml dose (200 mg) taken 3 times in 24 hours
10 – 12 years (weighing 30 - 40 kg)	One 15 ml dose (300 mg) taken 3 times in 24 hours

**For oral administration and short term use only.** The lowest effective dose should be used for the shortest duration 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).

**WARNING: DO NOT EXCEED THE STATED DOSE**

**If you forget to give Ibuprofen Oral Suspension**

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 Ibuprofen Oral Suspension than you should**

If your child or someone else accidentally takes more Ibuprofen Oral Suspension than the stated dose (an overdose), 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 of overdose 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, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported.

**4. Possible side effects**

Like all medicines, this medicine 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 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
- Aseptic meningitis (stiff neck, headache, nausea, vomiting, fever and disorientation)
- Swelling of the face
- Ringing in the ears (tinnitus)
- Kidney problems
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis)
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome)
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis)
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

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

- 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 (may affect up to 1 in 100 people):**

- Headache, dizziness, sleeplessness, agitation, irritability or tiredness
- Ulcers (sometimes with bleeding)

**Rare (may affect up to 1 in 1,000 people):**

- Flatulence, diarrhoea or constipation

**Very Rare (may affect up to 1 in 10,000 people):**

- 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
- Crohn's disease or ulcerative colitis or other stomach problems may be exacerbated
- 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
- High blood pressure

**Not known (frequency cannot be estimated from the available data):**

- Skin becomes sensitive to light
- A well-defined skin rash that often itches, stings or burns. It tends to occur at the same site each time you take the medicine. It may progress to blistering (Fixed Drug Eruption).

### **Reporting of side effects**

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie).

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 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 or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

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

### **What Ibuprofen Oral Suspension contains**

The **active ingredient** is Ibuprofen. Each 5 ml of oral suspension contains 100 mg of Ibuprofen.

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 (contains propylene glycol).

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

Ibuprofen Oral Suspension is a white oral suspension.

This medicine comes in amber glass or polyethylene bottles containing: 50 ml, 100 ml, 150 ml or 200 ml, with a child-resistant closure. A double ended spoon with measures of 2.5 ml and 5 ml is provided.

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

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

This medical product is authorised in the Member states of the EEA under the following name:

FI: Burana 20 mg/ml Oraalisuspensio

SE: Ibuprofen ABECE 20 mg/ml oral suspension

IE: Fenopine 100 mg/5ml Oral Suspension

NO: Ibux 20 mg/ml mikstur, suspensjon

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