

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fenopine 200 mg/5 ml Oral Suspension

Ibuprofen

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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 Fenopine 200 mg/5 ml Oral Suspension is and what it is used for
2. What you need to know before you give/take Fenopine 200 mg/5 ml Oral Suspension
3. How to give/take Fenopine 200 mg/5 ml Oral Suspension
4. Possible side effects
5. How to store Fenopine 200 mg/5 ml Oral Suspension
6. Contents of the pack and other information

1. What Fenopine 200mg/5ml Oral Suspension is and what it is used for

Fenopine 200 mg/5 ml Oral Suspension contains Ibuprofen as the active ingredient. This belongs to a group of medicines called **non-steroidal anti-inflammatory drugs (NSAIDs)**.

Fenopine 200 mg/5 ml Oral Suspension is given to children under 12 as a painkiller for relief of mild to moderate muscular pain, headache, teething pain and toothache. It also reduces the temperature in fever (e.g. colds, influenza and post-immunisation fever). For adults and children over 12 it can also be used for backache, migraines, neuralgia and relief from non-serious arthritic conditions.

2. What you need to know before you give/take Fenopine 200 mg/5 ml Oral Suspension

Do NOT give/take Fenopine 200 mg/5 ml Oral Suspension if you or 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 or wheezing e.g. 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 pain killers (NSAIDs)
- has ever had severe kidney, heart or liver problems
- is suffering from dehydration as there is a risk of renal impairment
- has an inherited intolerance to some sugars
- is less than 3 months old, except on the advice of a doctor
- suffers from a blood disorder

Do not take if you are in the last 3 months of pregnancy or are trying to conceive.

Warnings and precautions

Skin reactions

Serious skin reactions have been reported in association with Fenopine 200 mg/5 ml Oral Suspension treatment. You should stop taking Fenopine 200 mg/5 ml 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.

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 Fenopine 200mg/5ml Oral Suspension 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’).
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- have kidney, liver or bowel problems
- have lupus (SLE) or a mixed connective tissue disease
- have a chronic inflammatory bowel disease such as ulcerative colitis or Crohn's disease
- have asthma or allergic diseases of the lungs
- have chicken-pox
- have a disorder of porphyrin metabolism
- have an infection - please see heading “Infections” below.

Speak to your doctor or pharmacist before taking if 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.

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

Drinking alcohol while taking Ibuprofen may increase your risk of certain side effects.

There is a risk of renal impairment in dehydrated children and adolescents.

Infections

Fenopine 200 mg/5 ml Oral Suspension may hide signs of infections such as fever and pain. It is therefore possible that Fenopine 200 mg/5 ml 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 Fenopine 200 mg/5 ml Oral Suspension

Tell your doctor or pharmacist if you or your child are taking, has recently taken or might take any other medicines, including medicines obtained without a prescription. Fenopine 200mg/5ml Oral Suspension may affect or be affected by some medicines. For example:

- **Diuretics** (drugs 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 (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- **Antihypertensives** (drugs used to treat high blood pressure e.g. Captopril or Propranolol)

- **Lithium, Phenytoin 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)
- **Probenecid and sulfinpyrazone** (used to treat gout)
- **Moclobemide** (used to treat depression)
- **Aminoglycosides** (an antibiotic)
- **Cholestyramine** (used to reduce cholesterol)
- **Baclofen** (used to relax muscles)
- **Sulphonylureas** (used to treat diabetes)
- **Ritonavir** (used to treat HIV infection and AIDS)
- **Bisphosphonates** (used to prevent loss of bone mass)
- **Oxpentifylline** (used to treat poor circulation to arms and legs)
- 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 Fenopine 200 mg/5 ml Oral Suspension. You should therefore always seek the advice of your doctor or pharmacist before you use Fenopine 200 mg/5 ml Oral Suspension with other medicines.

Pregnancy and breast-feeding

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.

Only small amounts of ibuprofen and its break down 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.

Fenopine 200 mg/5 ml Oral Suspension contains Maltitol (E965), benzoate salt (E211), propylene glycol and sodium

- **Maltitol (E965)** 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 medicinal product.
- This medicine contains 10 mg benzoate salt in each 5 ml which is equivalent to 1.6 mg/g. Benzoate salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- This medicine contains 5.2 mg propylene glycol in each 5 ml which is equivalent to 0.832 mg/g. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.
- 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/take Fenopine 200 mg/5 ml Oral Suspension

Always take this medicine exactly 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 measuring device is provided to ensure accuracy.

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. 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. **Leave at least 4 hours between doses.**

For oral 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

Babies under 3 months	Do not give except on the advice of a doctor
3 - 6 months (weighing more than 5 kg)	1.25 ml dose (50 mg) taken up to 3 times in 24 hours
6 - 12 months (weighing 8-10 kg)	1.25 ml dose (50 mg) taken up to 3 to 4 times in 24 hours
1 - 4 years (weighing 10-15 kg)	2.5 ml dose (100 mg) taken up to 3 times in 24 hours
4 - 7 years (weighing 15-20 kg)	3.75 ml dose (150 mg) taken up to 3 times in 24 hours
7 - 12 years (weighing 20-40 kg)	5 ml dose (200 mg) taken up to 3 times in 24 hours
Over 12 years	5 ml to 10ml dose (200 mg – 400 mg) taken 3 times in 24 hours. Do not give more than 30 mls (1200 mg) in any 24 hours.

Post-immunisation fever: One 1.25 ml, followed by another 1.25 ml six hours later if necessary. Not more than 2 doses should be given in 24 hours. If fever is not reduced, consult a doctor.

If you forget to give/take Fenopine 200 mg/5 ml Oral Suspension

If you forget to give/take a dose, give/take 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/take more Fenopine 200 mg/5 ml Oral Suspension than you should

If you have given more Fenopine 200 mg/5 ml 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.

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.

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

- If you or your child's skin start 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 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
- 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.
- Depression or psychotic reactions
- Hair loss
- High blood pressure.

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

- 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 200 mg/5 ml Oral Suspension if you develop these symptoms and seek medical attention immediately. See also section 2.

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- 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 HPRAs Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fenopine 200 mg/5 ml 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. This medicine should be used within 12 months of first opening. Do not store above 25 °C. Store in the original package. Do not throw away any medicines via wastewater. 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 Fenopine 200 mg/5 ml Oral Suspension contains

The **active ingredient** is Ibuprofen 200 mg per 5 ml.

The **other ingredients** are: Glycerol (E422), Xanthan Gum, 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 Fenopine 200 mg/5 ml Oral Suspension looks like and contents of the pack

Fenopine 200 mg/5 ml Oral Suspension is a colour-free, white oral suspension.

This medicine comes in amber glass bottles containing: 60 ml, 80ml, 100 ml, 150 ml or 200 ml with a child-resistant closure. Not all pack sizes may be marketed. A double ended spoon with measures of 1.25ml, 2.5ml and 5ml is provided.

Marketing Authorisation Holder and Manufacturer

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

This medicinal product is authorised in the Member States of the EEA under the following names:

FI: Burana 40mg/ml Oraalisuspenio

LT: IbuViva Forte 200mg/5ml geriamoji suspensija

IE: Fenopine 200 mg/5 ml Oral Suspension

NO: Ibox

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