

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Fenopine for Children Six Plus Strawberry 200 mg/5 ml Oral Suspension** ibuprofen

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

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 do not feel better or if you feel worse after 3 days.

#### **What is in this leaflet**

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

#### **1. What Fenopine for Children is and what it is used for**

Fenopine for Children contains ibuprofen. Ibuprofen belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by changing how the body responds to pain, and high body temperature. This product has been specifically formulated for children as it is given by mouth to:

- reduce fever
- relieve symptoms of mild to moderate pain

For use in children from 20 kg body weight (6 years) to 40 kg body weight (12 years).

#### **2. What you need to know before you give/take Fenopine for Children**

##### **Do NOT give/take Fenopine for Children 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
- has bleeding of the brain (cerebrovascular bleeding) or other active bleeding
- has unclarified blood-formation disturbances
- is suffering from dehydration as there is a risk of renal impairment
- Do not take if you are in the last 3 months of pregnancy.

#### **Warnings and precautions**

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### 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 generalised exanthematous pustulosis (AGEP) have been reported in association with Fenopine for Children treatment. Stop taking Fenopine for Children and seek medical attention immediately, if you notice any of these serious skin reactions described in 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.

Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications

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 Fenopine for Children and contact immediately your doctor or medical emergencies if you notice any of these signs.

You should discuss your treatment with your doctor or pharmacist before taking Fenopine for Children 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 kidney, liver or bowel problems
- has lupus (SLE) or a mixed connective tissue disease
- has a chronic inflammatory bowel disease such as ulcerative colitis or Crohn's disease
- has or has had asthma or allergic diseases as shortness of breath may occur
- suffers from hay-fever, nasal polyps or chronic obstructive respiratory disorders as an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (so called analgesic asthma). Quincke's oedema or urticaria
- has chicken-pox
- has just undergone major surgery as medical surveillance is required
- has a disorder of porphyrin metabolism, has certain hereditary blood formation disorders (e.g. acute intermittent porphyria)
- have an infection - please see heading "Infections" below.

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

### Fenopine for Children with alcohol

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

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

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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 for Children

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 for Children 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 for Children. You should therefore always seek the advice of your doctor or pharmacist before you use Fenopine for Children with other medicines.

### 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

Do not take Fenopine for Children 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 Fenopine for Children 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, Fenopine for Children 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 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.

### **Fertility**

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.

### **Fenopine for Children contains Maltitol (E965), Sodium Benzoate (E211) and Propylene glycol**

- **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 medicine.
- This medicine contains 10 mg benzoate salt in each 5 ml which is equivalent to 1.6 mg/g.
- 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, that is to say essentially 'sodium-free'.

### **3. How to give/take Fenopine for Children**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### **The usual dose for pain and fever:**

<b>Child's weight (age)</b>	<b>How much</b>	<b>How often in 24h*</b>
20-29 kg (6-9 years)	5 ml (equivalent to 200 mg ibuprofen)	3 times
30-40 kg (10-12 years)	7.5 ml (equivalent to 300 mg ibuprofen) (one 5 ml spoonful (large end) and one 2.5 ml spoonful (small end))	3 times

\*Doses should be given approximately every 6 to 8 hours.

#### **Not intended for use in children under 6 years of age or under 20 kg.**

For patients with sensitive stomachs it is recommended that Fenopine for Children is taken during a meal.

<b>WARNING:</b> Do not exceed the stated dose
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#### **Method of administration using the spoon**

##### **For oral use**

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1. Shake the bottle well
  2. Use the end of the spoon that corresponds to the required dose
  3. Pour the medicine onto the spoon
  4. Place the spoon in the child's mouth and administer the dose
  5. After use replace the cap. Wash the spoon in warm water and allow to dry.

#### **Duration of treatment**

**This medicine is for short-term use only. If the child's symptoms persist for more than 3 days seek medical advice. If symptoms worsen consult your doctor.**

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).

#### **If you forget to give/take Fenopine for Children**

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 for Children than you should**

If you have given more Fenopine for Children than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital immediately to get an opinion of the risk and advice on action to be taken.

The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding, diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also, agitation, somnolence, disorientation, or coma may occur. Occasionally patients develop convulsions. 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. Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

#### **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
- 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)

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

- 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
- Visual disturbances

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

- Flatulence, diarrhoea or constipation
- Ringing in the ears (tinnitus)
- Kidney damage, increased blood uric acid levels

**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
- 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):**

- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA 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 Fenopine for Children**

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. 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 Fenopine for Children contains**

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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 for Children looks like and contents of the pack**

Fenopine for Children is a colour-free, white oral suspension.

This medicine comes in amber glass bottles containing: 60 ml, 80 ml, 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 1.25 ml, 2.5 ml and 5 ml is provided.

**Marketing Authorisation Holder and Manufacturer**

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

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