

**PATIENT INFORMATION LEAFLET**  
**FENOPINE 200MG, 400MG, & 600MG FILM-COATED TABLETS**  
**Ibuprofen**

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

**In this leaflet:**

1. What Fenopine tablets are and what they are used for
2. What you need to know before you take Fenopine tablets
3. How to take Fenopine tablets
4. Possible side effects
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**1. WHAT FENOPINE TABLETS ARE AND WHAT THEY ARE USED FOR**

Fenopine tablets contain the active ingredient ibuprofen which is a non-steroidal anti-inflammatory drug (NSAID). They are used for the treatment of mild to moderate pain and inflammation associated with the following conditions:

- post-operative pain
- toothache
- period pain
- soft tissue injury (muscles and ligaments)
- stiffness and pain in the back and muscles
- types of arthritis e.g. rheumatoid, osteoarthritis

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FENOPINE TABLETS**

**Do NOT take the tablets if you:**

- are allergic (hypersensitive) to ibuprofen or any of the other ingredients in the tablets (*see Section 6*)
- are allergic to aspirin or any other NSAIDs (e.g. diclofenac), seen as a red skin rash, wheezing, asthma, face swelling or runny nose. If you are not sure, ask your doctor or pharmacist.
- have a history of gastrointestinal bleeding related to previous NSAID use (symptoms include blood in your stools or black stools)
- suffer from recurrent stomach ulcers or gastrointestinal bleeding (two or more attacks)
- have severe kidney, heart or liver problems.

**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 Fenopine Tablets if you or your child:

- 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.
- develop serious skin rashes or flaking skin, face swelling, vomiting, abdominal pain, have dark urine/stools in the early part of treatment. **Stop taking the tablets and see a doctor immediately**
- have ever had gastrointestinal problems such as stomach ulcer, ulcerative colitis or Crohn's disease, bleeding or black stools. If you have had stomach discomfort or heartburn or any allergic reaction after taking pain relievers or anti-inflammatory medicines in the past or if this occurs while you are taking these tablets, **stop taking the tablets and see a doctor immediately**
- are elderly, as you may be more at risk of side effects from NSAIDs. If you notice any gastrointestinal problems, **stop taking the tablets and see a doctor immediately**
- have asthma, seasonal hayfever or eczema. You may be at risk of an allergic reaction, seen as red skin rash, wheezing, asthma, face swelling or runny nose. If any of these happen, **stop taking the tablets and see a doctor immediately**
- are taking other **pain relievers** or **anti-inflammatory** medicines
- are at risk of being **dehydrated** (e.g. by sickness, diarrhoea, or before or after major surgery)
- have **kidney** or **liver** problems or are taking **diuretic** medicines. You should be monitored carefully and the dose kept as low as possible
- have **heart** problems or **high blood pressure** as fluid retention may occur
- are suffering from **Systemic Lupus Erythematosus (SLE)** a condition of the immune system affecting connective tissue resulting in joint pain, skin change and disorder of other organs.
- have a **bleeding disorder** or other blood disorders, including a rare liver condition called **hepatic porphyria** or are taking **anticoagulants** such as aspirin or warfarin. You should be monitored carefully.

These tablets should be taken for the shortest possible time. Your doctor may monitor you with tests to check your blood, liver, kidney and heart function, especially if you are elderly. If no benefit is seen then the treatment should be stopped.

### Other precautions

- Medicines such as ibuprofen may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses (2400mg) and prolonged treatment.
- If you have heart problems, or have had a stroke or think that you might be at risk of these conditions (for example, if you have high blood pressure, diabetes, high cholesterol or if you are a smoker), tell your doctor or pharmacist before you take Fenopine.
- Fenopine may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make detection more difficult. If you feel unwell and need to see a doctor, remember to tell him/her that you are taking Fenopine.

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

### Other medicines and Fenopine Tablets

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, but particularly if you are taking:

- **SSRI antidepressants** (selective serotonin reuptake inhibitors) such as fluoxetine or paroxetine (used to treat mania and depression); – you may be more prone to gastro-intestinal bleeding (*see Section 2 “Take special care”*)
- **digoxin** or other heart glycosides (medicines used for heart problems)
- 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, betablockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- **ciclosporin** (for patients who have received organ transplants)
- **methotrexate** (used to treat inflammatory conditions and some types of cancer); take care if you are taking within 24 hours of each other
- Other **anti-inflammatory medicines** or **pain relievers** such as aspirin or diclofenac
- Any medicines to treat heart conditions (e.g. **diuretics** such as **furosemide**)
- **antibiotics** such as aminoglycosides or quinolones (to treat bacterial infections); special care should be taken if you are prone to epileptic seizures (fits)
- **probenecid** (used to treat gout or kidney stones)
- **ACE inhibitors** or **beta-blockers** (for high blood pressure and heart failure)
- **corticosteroids** (for relief of inflammation)
- **ginkgo biloba** (there is a chance you may bleed more easily if you are taking this and ibuprofen at the same time)
- **Zidovudine** (to treat HIV)
- **Losartan** (to treat high blood pressure).

If you are taking medicine to treat bipolar disorder such as lithium, it is likely that the lithium levels will increase when used together with Ibuprofen.

Some other medicines may also affect or be affected by the treatment of Fenopine Tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Fenopine Tablets with other medicines.

### Taking with food and drink

Tablets should be swallowed with a drink of water.

### Pregnancy and breast-feeding

Do NOT take Fenopine tablets if you are in the last 3 months of pregnancy. You should only take Fenopine tablets if your doctor considers it necessary. You should not take Fenopine tablets if you are trying to become pregnant. As with other anti-inflammatory medicines, the use of ibuprofen (the active substance in these tablets) may make it more difficult to become pregnant. This is reversible on stopping the medicine.

Do NOT take Fenopine tablets if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy, or if you are breast-feeding.

### **Driving and using machines**

Usually these tablets have no influence on ability to drive or use machines. However, if you notice any side effects, do not drive or use machines.

### **3. HOW TO TAKE FENOPINE TABLETS**

Always take the tablets exactly as your doctor has told you. You should check with your doctor if you are not sure about the dose you should take. These tablets should be taken for the shortest possible time, at the lowest dose to reduce the risk of any side effects. Your doctor may monitor you to check your liver, kidney and heart function.

This medicine should be taken with liquid by mouth, preferably after food to reduce the risk of side effects.

- **Adults:** the usual dose is 1200mg to 1600mg daily in divided doses. Some patients may be maintained on 600mg to 1200mg daily. The maximum daily dose should not exceed 2400mg.
- **Elderly:** same as the adult dose, unless you suffer from liver or kidney problems. You may be more sensitive to the effects of these tablets. Therefore always follow your doctor's instructions carefully and take the minimum number of tablets that provide relief of symptoms. Tell your doctor immediately if you have any side effects (*see Section 4*).
- **Children:** the exact dosage will depend on body weight. The usual dose is 20 mg/kg of body weight, which should be given in divided doses throughout the day. Do not give to children weighing less than 20 kg. Do not give more than 2 x 200 mg tablets in 24 hours to children weighing less than 30 kg.

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

### **If you take more tablets than you should**

If you have taken more tablets than you should, or someone else has taken the tablets, go to your nearest hospital accident and emergency department. Take this leaflet and/or the pack with you.

*Symptoms of overdose are:* headache, being sick, drowsiness, low blood pressure and loss of consciousness.

### **If you forget to take Tablets**

If you miss a dose, take a tablet as soon as you remember unless it is nearly time for your next tablet. Carry on taking the rest of your tablets at the correct time. Do not take a double dose to make up for a forgotten dose.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Fenopine tablets can cause side effects, although not everybody gets them.

**STOP** taking Fenopine tablets and **seek medical help immediately** if you have any of the following which may be signs of an **allergic reaction**:

- difficulty in breathing or swallowing,
- swelling of the face, lips, tongue or throat.
- severe itching of the skin, with a red rash or raised bumps.

Some **rare** (between 1 in 10,000 and 1 in 1,000) or **very rare** (less than 1 in 10,000) side effects could be **serious**, especially if you suffer from ulcers, bleeding or are elderly. **If you notice any of the following, STOP taking these tablets and tell a doctor immediately:**

- severe stomach pain, blood in the stools or black “tarry” stools, vomiting blood
- wheezing and feelings of tightness in the chest
- chest pain, fainting, high blood pressure
- sudden and severe headache, stiff neck, difficulty in speaking, convulsions
- skin rash with blisters, peeling of the skin, purple skin, lesions, blistering of the mouth or eyes
- swelling of arms, hands, legs and feet (oedema)
- any change in the appearance or amount of urine
- yellowing of the skin or eyes
- unusual bleeding or bruising, high fever or persistent sore throat.

Medicines such as Fenopine may be associated with a small increased risk of heart attack (also called "myocardial infarction") or stroke.

The following side-effects may occur:

The **common** (between 1 in 100 and 1 in 10) side effects reported are those affecting the stomach:

- diarrhoea, flatulence (wind), constipation, heartburn, excessive acid production caused by inflammation of the stomach or large intestine, nausea and stomach pain or upset.

**Uncommon** (between 1 in 1,000 and 1 in 100) side effects include:

- impaired kidney function, other kidney disorders and rarely kidney failure; abnormal liver function (usually identified by your doctor) including jaundice (identified as yellowing of the skin and eyes) and hepatitis
- blurred or disturbed vision, inflammation of the optic nerve causing loss of vision
- headaches, tingling, pricking, or numbness of the skin
- depression, confusion, seeing and hearing things (hallucinations)
- ringing in the ears (tinnitus), vertigo, dizziness
- a general feeling of being unwell, tiredness, drowsiness
- blood disorders such as clotting problems which may result in bruising or bleeding, certain types of anaemia (deficiency of red blood cells)
- severe skin reactions.

**Rare** (between 1 in 10,000 and 1 in 1,000) side effects

- difficulty in hearing.

**Very rare** (less than 1 in 10,000) side effects:

- aseptic meningitis; symptoms of this condition are severe headache, high temperature, stiffness of the neck and intolerance to bright light.

**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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE FENOPINE TABLETS**

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original container.

Do not use the tablets after the expiry date (EXP.) which is stated on the label. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What FENOPINE film-coated tablets contain:**

- the **active substance** is ibuprofen (200mg, 400mg or 600mg per tablet)
- **other ingredients:** maize starch, pregelatinised maize starch, colloidal anhydrous silica, sodium starch glycollate, stearic acid, hypromellose (E464), talc, titanium dioxide (E171) and erythrosine (E127)

### **What Fenopine tablets look like and contents of the pack**

- Fenopine 200mg tablets are pink, round film-coated tablets with markings “IBU 200” on one side and plain on the other side. This strength is available in pack sizes of 12, 24, 40, 50, 100, 250, 500 and 1000 tablets in plastic containers with caps or child-resistant closures.
- Fenopine 400mg tablets are pink, round film-coated tablets with markings “IBU 400” on one side and plain on the other side. This strength is available in pack sizes of 30, 50, 100, 250, 500 and 1000 tablets in plastic containers with caps or child-resistant closures.
- Fenopine 600mg tablets are pink, capsule shaped, film-coated tablets with markings “IBU 600” on one side and plain on the other side. This strength is available in pack sizes of 100, 250, 500 and 1000 tablets in plastic containers with caps or child-resistant closures.

Not all pack sizes may be marketed.

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

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

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