

Package leaflet: Information for the user
Fenopine 600 mg film-coated tablets
ibuprofen

Read all of this leaflet carefully before you start taking 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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is 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
5. How to store Fenopine tablets
6. Contents of the pack and other information

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:

- soft tissue injury (muscles and ligaments)
- types of arthritis e.g. rheumatoid, osteoarthritis, seronegative arthropathies
- non-articular rheumatism (soft tissue)

2. What you need to know before you take Fenopine tablets

Do not take Fenopine tablets:

- if you are allergic to ibuprofen or any of the other ingredients in the tablets (listed in section 6)
- if you previously experienced stomach bleeding or perforation after taking ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs)
- if you currently have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation in the past
- if you suffer from severe heart failure, liver failure or kidney failure
- if you have a condition which increases your tendency to bleeding
- if you are sensitive (allergic) or previously had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers
- if you are in the last 3 months of pregnancy.

Do not take Fenopine tablets if any of the above applies to you. If you are not sure, talk to your doctor.

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before taking Fenopine tablets

- if you have, or previously suffered from bronchial asthma, chronic rhinitis or allergic diseases, you may be at risk of an allergic reaction seen as red skin rash, wheezing, asthma, face swelling or runny nose
- if you suffer from liver, kidney or heart disease
- if you suffer from high blood pressure (hypertension)
- if you are elderly – elderly people are more prone to side effects to NSAIDs, particularly stomach bleeding and perforation which can be fatal
- if you have, or you previously had a stomach ulcer, stomach bleeding or other gastric complaint
- if you are at risk of being dehydrated (e.g. by sickness, diarrhoea or before major surgery) – there is a risk of renal impairment (kidney not functioning as it should) in dehydrated children, adolescents and the elderly
- if you are taking other pain relievers or anti-inflammatory medicines
- if you have a condition which increases your tendency to bleeding or have bleeding in the skull – please see above
- if you have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- if you have lupus or a connective tissue disease (autoimmune diseases affecting connective tissue)
- if you have an infection – please see heading “infections” below
- during chicken pox (varicella) it is advisable to avoid the use of ibuprofen.

You must immediately seek medical advice, if your symptoms get worse or if you experience severe or unexpected side effects e.g. unusual bleeding symptoms, serious skin reactions or any other sign of serious allergy (see section “Possible side effects”).

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.

Infections

Fenopine Tablets may hide signs of infections such as fever and pain. It is therefore possible that Fenopine Tablets 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.

Heart attack and stroke

Anti-inflammatory/pain-killer medicines like Fenopine tablets 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 before taking Fenopine tablets if you:

- have heart problems including heart failure, angina (chest pain) or you have had a heart attack, bypass surgery or 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.

Skin reactions

Serious skin reactions have been reported in association with Fenopine tablets treatment. You should stop taking Fenopine tablets 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.

Children and adolescents

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

Other medicines and Fenopine Tablets

Tell your doctor if you are taking, have recently taken or might take any other medicines

This is because Fenopine tablets may affect or be affected by some medicines. For example:

- medicines that are anticoagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, heparin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, betablockers such as atenolol, or angiotensin-II receptor antagonists such as losartan).

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

In particular, you should tell your doctor if you are taking any of the following medicines in addition to those mentioned above:

- any medicines used to treat high blood pressure (see above)
- any medicines to treat heart conditions (e.g. diuretics such as bendroflumethiazide or furosemide or cardiac glycosides such as digoxin)
- any anti-coagulants or anti-platelet medicines (see above)
- lithium or selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine or paroxetine (used to treat depression)
- a medicine called zidovudine (an anti-viral drug)
- a medicine called methotrexate (used to treat some forms of cancer)
- medicines called cyclosporin or tacrolimus (immunosuppressants used following organ transplant or in autoimmune conditions such as psoriasis, eczema)
- any other NSAIDs or anti-inflammatory pain killers, including aspirin or diclofenac and the group of drugs known as COX-2 inhibitors such as celecoxib and lumiracoxib
- any corticosteroids (e.g. hydrocortisone, betamethasone, prednisolone, used to treat inflammatory conditions)
- a certain type of antibiotic, known as quinolone antibiotics (e.g. ciprofloxacin and levofloxacin); special care should be taken if you are prone to epileptic seizures
- a certain type of antibiotic known as aminoglycosides
- mifepristone (used for the medical termination of pregnancy)
- probenecid (used to treat gout or kidney stones)
- any oral medicines used to treat diabetes (e.g. metformin, or any sulphonylurea medicines)

- a herbal remedy called ginkgo biloba (there is a chance that you may bleed more easily if you are taking ibuprofen and ginkgo biloba at the same time)
- cholestyramine (used to treat high cholesterol levels)
- voriconazole or fluconazole (anti-fungal drugs).

Fenopine tablets with food, drink and alcohol

Tablets should be swallowed with a drink of water.

If you drink alcohol while taking this medicine you may be more likely to get side effects.

Pregnancy, breast-feeding and fertility

Do NOT take Fenopine tablets 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 baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Fenopine tablets 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 tablets 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.

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.

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

Driving and using machines

Medicines such as Fenopine tablets may cause dizziness, drowsiness, tiredness and problems with vision. If affected, you should not drive or operate machines. Also you should not do anything else where you need to be alert. This particularly applies in combination with alcohol.

Fenopine tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Fenopine tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. These tablets should be taken for the shortest possible time, at the lowest dose to reduce the risk of any side effects. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2). 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 recommended dose is 1200 mg to 1600 mg daily in divided doses. Some patients may be maintained on 600 mg to 1200 mg daily. The maximum daily dose should not exceed 2400 mg.
- **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 recommended 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 Fenopine tablets than you should

If you have taken more Fenopine tablets 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.

If you forget to take Fenopine 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, this medicine can cause side effects, although not everybody gets them. If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor, pharmacist or nurse. You can minimise the risk of side effects by taking the least amount of tablets for the shortest amount of time necessary to control your symptoms.

Serious side effects

Stop taking Fenopine tablets and see your doctor straight away if you notice any of the following serious side effects – you may need urgent medical attention:

Common (may affect up to 1 in 10 people):

- signs of bleeding from the stomach or gut such as passing blood in your faeces (stools/motions), passing black tarry stools or vomiting any blood or dark particles that look like coffee grounds

Uncommon (may affect up to 1 in 100 people):

- swelling of the face, tongue or throat (larynx) which can cause great difficulty in swallowing and breathing (angioedema)
- difficulty breathing, wheezing or coughing, asthma or worsening of asthma

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

- rapid heartbeat, severe fall in blood pressure or life-threatening shock
- signs of aseptic meningitis such as neck stiffness, headache, feeling sick, being sick, fever or altered consciousness. Patients with autoimmune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected

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

- severe rash, peeling, blistering or flaking skin
- severe infection with destruction (necrosis) of skin, subcutaneous tissue and muscle; this may occur in exceptional cases during chicken pox

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 localised on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Ibuprofen Pinewood tablets if you develop these symptoms and seek medical attention immediately. See also section 2.

Stop taking this medicine and see your doctor straight away if you notice any of the side effects above.

Stop taking this medicine and tell your doctor if you notice any of the following:

Common (may affect up to 1 in 10 people):

- indigestion or heartburn
- abdominal (stomach) pains or other abdominal stomach symptoms

Stop taking this medicine and tell you doctor if you notice any of the side effects above.

Other side effects

Common (may affect up to 1 in 10 people):

- rash
- feeling dizzy or tired
- loss of appetite, diarrhoea, feeling sick, being sick, wind, constipation
- headache – if this happens while you are taking this medicine it is important not to take any other medicines for pain to help with this.

Uncommon (may affect up to 1 in 100 people):

- feeling drowsy

- feeling anxious
- feeling a tingling sensation or ‘pins and needles’
- difficulty sleeping
- hives, itching
- skin becomes sensitive to light
- visual disturbances, hearing problems
- ringing in the ears (tinnitus)
- sensation of feeling dizzy or spinning (vertigo)
- hepatitis, yellowing of your skin or eyes, reduced liver function
- reduced kidney function, inflammation of the kidneys, kidney failure
- sneezing, blocked, itchy or runny nose (rhinitis)
- stomach or gut ulcer, hole in the wall of the digestive tract
- inflammation of your stomach lining
- small bruises on your skin or inside your mouth, nose or ears
- hypersensitivity reactions such as unexplained wheezing, shortness of breath, skin rash, itching or bruising.

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

- feeling depressed or confused
- fluid retention (oedema)
- loss of vision
- changes in blood count – the first signs are: high temperature, sore throat, mouth ulcers, flu-like symptoms, feeling very tired, bleeding from the nose and the skin
- reduction in blood cells (anaemia).

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

- heart failure, heart attack, high blood pressure
- liver failure
- inflammation of the pancreas
- skin problems (which can also affect inside your mouth, nose or ears) such as ‘Stevens-Johnson syndrome’, ‘toxic epidermal necrolysis’ or ‘erythema multiforme’.

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

- prolonged bleeding time
- worsening of ulcers in the large intestine (colitis) or Crohn’s Disease (bowel disease).

The following side effects have also been reported with other NSAIDs:

- high blood pressure or heart failure. See also section 2 “Warnings and precautions”
- a small increased risk of heart attack or stroke. See also section 2 “Warnings and precautions”.

If any of the side effects get serious or you notice any side effects not listed in this leaflet please contact your doctor or pharmacist.

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 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 tablets

Keep this medicine out of the sight and reach of children.

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

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. 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 protect the environment.

6. Contents of the pack and other information

What Fenopine tablets contain:

- the **active substance** is ibuprofen (600 mg per tablet)
- the **other ingredients** are maize starch, pregelatinised maize starch, colloidal anhydrous silica, sodium starch glycolate, stearic acid, hypromellose (E464), talc, titanium dioxide (E171) and erythrosine aluminium lake (E127)

What Fenopine tablets look like and contents of the pack

- Fenopine 600 mg 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.

PA 281/088/3

This leaflet was last revised in December 2022