

**Package leaflet: Information for the user**  
**Ibuprofen Pinewood 200 mg film-coated tablets**  
**Ibuprofen Pinewood 400 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 Ibuprofen Pinewood tablets are and what they are used for
2. What you need to know before you take Ibuprofen Pinewood tablets
3. How to take Ibuprofen Pinewood tablets
4. Possible side effects
5. How to store Ibuprofen Pinewood tablets
6. Contents of the pack and other information

**1. What Ibuprofen Pinewood tablets are and what they are used for**

Ibuprofen Pinewood 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 Ibuprofen Pinewood tablets**

**Do NOT take Ibuprofen Pinewood tablets:**

- if you are allergic (hypersensitive) to ibuprofen or any of the other ingredients of this medicine (*listed in Section 6*)
- if you 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.
- if you have a history of gastrointestinal bleeding related to previous NSAID use (symptoms include blood in your stools or black stools)
- if you suffer from recurrent stomach ulcers or gastrointestinal bleeding (two or more attacks)
- if you have severe kidney, heart or liver problems.

**Warnings and Precautions**

## Skin reactions

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

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.

During chicken pox (varicella) it is advisable to avoid use of ibuprofen.

You should discuss your treatment with your doctor or pharmacist before taking Ibuprofen Pinewood 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.
- have an infection - please see heading “Infections” below.

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**

Ibuprofen Pinewood tablets may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen Pinewood 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.

### **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 (2400 mg) 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 Ibuprofen Pinewood tablets.
- Ibuprofen Pinewood tablets 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 Ibuprofen Pinewood tablets.
- There is a risk of kidney impairment in dehydrated children and adolescents.

### **Other medicines and Ibuprofen Pinewood 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 gastrointestinal 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 Ibuprofen Pinewood tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen Pinewood tablets with other medicines.

### **Ibuprofen Pinewood tablets with food and drink**

Tablets should be swallowed with a drink of water.

### **Pregnancy, breast-feeding and fertility**

Do NOT take Ibuprofen Pinewood tablets if you are in the last 3 months of pregnancy. You should only take Ibuprofen Pinewood tablets if your doctor considers it necessary. You should not take Ibuprofen Pinewood 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 Ibuprofen Pinewood tablets if you are breast-feeding.

If you are pregnant or breast-feeding, 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**

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.

### **Ibuprofen Pinewood 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 Ibuprofen Pinewood 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 Ibuprofen Pinewood tablets than you should**

If you have taken more Ibuprofen Pinewood 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.

*Symptoms of overdose are:* 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 Ibuprofen Pinewood 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, Ibuprofen Pinewood tablets can cause side effects, although not everybody gets them.

**STOP** taking Ibuprofen Pinewood 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** (may affect up to 1 in 1,000 people) or **very rare** (may affect up to 1 in 10,000 people) 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 Ibuprofen Pinewood tablets 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** (may affect up to 1 in 10 people) 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** (may affect up to 1 in 100 people) 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** (may affect up to 1 in 1,000 people) side effects include:

- difficulty in hearing.

**Very rare** (may affect up to 1 in 10,000 people) side effects include:

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

**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 Pinewood tablets if you develop these symptoms and seek medical attention immediately. See also section 2.
- Skin becomes sensitive to 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 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 Pinewood 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, carton and blister.

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 Ibuprofen Pinewood tablets contain:**

- the **active substance** is ibuprofen (200 mg or 400 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 Ibuprofen Pinewood tablets look like and contents of the pack**

- Ibuprofen Pinewood 200 mg 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 the following packs:
  - plastic containers with caps or child-resistant closures, in pack sizes of 12, 24, 40, 50, 100, 250, 500 and 1000 tablets
  - blister packs of PVC - Aluminium foil, in pack size of 96 tablets.
- Ibuprofen Pinewood 400 mg 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 the following packs:
  - plastic containers with caps or child-resistant closures, in pack sizes of 30, 50, 100, 250, 500 and 1000 tablets
  - blister packs of PVC - Aluminium foil, in pack size of 96 tablets.

Not all pack sizes may be marketed.

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

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

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