

**Package leaflet: Information for the patient**  
**Ibuprofen 200 mg soft capsules**

**Ibuprofen**

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse 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, pharmacist or nurse. 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.

**What is in this leaflet**

1. What Ibuprofen 200 mg soft capsules is and what it is used for
2. What you need to know before you take Ibuprofen 200 mg soft capsules
3. How to take Ibuprofen 200 mg soft capsules
4. Possible side effects
5. How to store Ibuprofen 200 mg soft capsules
6. Contents of the pack and other information

**1. What Ibuprofen 200 mg soft capsules is and what it is used for**

The active ingredient (which makes the medicine work) is Ibuprofen. It belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to pain, swelling, and high temperature.

Ibuprofen 200mg soft capsules is used for the relief of:

- Headaches and migraine pain
- Dental pain and neuralgia
- Period pain
- Rheumatic, muscular and back pain
- Feverishness and symptoms at cold and flu.

**2. What you need to know before you take Ibuprofen 200 mg soft capsules**

**Do not take Ibuprofen 200 mg soft capsules:**

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).

- have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding
- have had a shortness of breath, worsening of asthma, allergic rash or itchy, runny nose or swelling of the lips, face, tongue or throat when taking ibuprofen, codeine, aspirin or other similar medicines
- have had stomach bleeding or perforation after taking ibuprofen, aspirin or other similar medicines
- are taking other NSAID painkillers or more than 75mg aspirin a day
- suffer from severe liver or kidney problems
- have severe heart failure, high blood pressure or blood coagulation disorder
- have breathing difficulties
- are in the last 3 months of pregnancy
- are under 12 years old.

### **Warnings and precautions**

Talk to your doctor or pharmacist or nurse before taking Ibuprofen 200 mg soft capsules if you:

- have asthma or have suffered from asthma
- have kidney, heart, liver or bowel problems
- 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 a family history or heart disease or stroke, or if you are a smoker
- have a head injury, unexplained bleeding or raised intracranial pressure
- have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- suffer from a connective tissue disease such as Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes and other organ disorders)
- are elderly. Elderly patients are more prone to side effects such as stomach bleeding and perforation which may be fatal.
- are receiving regular treatment from your doctor
- have previously experienced stomach bleeding or perforation after taking ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs)
- are in the first 6 months of pregnancy
- have chicken pox as it is advisable to avoid the use of Ibuprofen 200mg soft capsules.

- you have an infection – please see heading “Infections” below

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

### **Take special care with Ibuprofen soft capsules**

#### **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 generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Ibuprofen 200mg soft capsules and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

#### **Infections**

Ibuprofen may hide signs of infections such as fever and pain. It is therefore possible that ibuprofen 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 warnings**

- Ibuprofen 200mg soft Capsules belongs to a group of medicines, which may impair fertility in women. This is reversible on stopping the medicine.
- It is unlikely that Ibuprofen 200mg soft capsules, used occasionally will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.
- Anti-inflammatory/pain-killer medicines such as 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 Ibuprofen 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
- There is a risk of renal impairment in dehydrated children and adolescents.

### **Other medicines and Ibuprofen 200 mg soft capsules**

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

To reduce the risk of side effects, do not take this product with other NSAID containing products (e.g, aspirin, ibuprofen). Ibuprofen may affect or be affected by some other medicines. For example:

Avoid taking this product with corticosteroid tablets, quinolone antibiotics or medicines that are:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- drugs for heart failure such as digoxin aspirin or other NSAIDs (e.g. COX-2 inhibitors)
- corticosteroids (such as prednisolone) since this may increase the risk of gastrointestinal ulceration or bleeding
- to reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-11 receptor antagonists such as losartan)
- water tablets (diuretics) since NSAIDs may diminish the effects of these
- methotrexate (a medicine for cancer or rheumatism) since there is evidence for a potential increase in plasma levels of methotrexate
- ciclosporin or tacrolimus (a medicine to suppress the immune reaction) since there is limited evidence of an increased risk for kidney toxicity
- lithium (a medicine for depression) since there is evidence for a potential increase in plasma levels of lithium
- selective serotonin-reuptake inhibitors (a medicine for depression) since these may increase the risk of gastrointestinal side effects
- for pregnancy termination (e.g., mifepristone)
- Zidovudine: there is evidence of an increased risk of haemathroses and haematoma in HIV (+) haemophiles receiving concurrent treatment with Zidovudine and ibuprofenprobenecid (to treat gout)
- oral hypoglycaemic agents (oral medicines to treat diabetes)
- aminoglycosides (a type of antibiotic)
- Quinolone antibiotics since patients taking NSAIDs and quinolone antibiotics may have an increased risk of developing convulsions

Some other medicines may also affect or be affected by the treatment at Ibuprofen. You should therefore always seek the advice at your doctor or pharmacist before you use Ibuprofen 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. Do not take Ibuprofen 200 mg soft capsules 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 child. 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 200 mg soft capsules 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, it 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.

Ibuprofen 200mg soft Capsules belong to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. Patients should be aware that this product may make it more difficult to become pregnant and should inform their doctor if planning to become pregnant or having problems becoming pregnant. Consult your doctor before use if you are in the first 6 months of pregnancy. Do not use Ibuprofen in the last 3 months of pregnancy. Ibuprofen can pass in very small concentrations into breast milk with no harmful effects to the infant. It is not necessary to interrupt breastfeeding for short term treatment at the recommended dose.

## **Driving and using machines**

Ibuprofen does not have any effect on the ability to drive and use machines.

## **Ibuprofen soft capsules contains Potassium**

This medicine contains 18.75 mg of Potassium per capsule. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

### **3. How to take Ibuprofen 200 mg soft capsules**

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

This product is for short term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms.

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).

**Adults, the elderly and children over 12 years:**

200 - 400mg taken with water up to three times a day as required. Leave at least four hours between doses with a maximum of 1200mg in any 24 hour period. Do not chew the capsules.

**Do not give to children under 12 years.**

**In children and adolescents between 12 and 18 years:**

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

**In adults:**

**Do not take for longer than 10 days** unless your doctor tells you to. If symptoms persist or the pain or fever worsen, or if any new symptoms occur, consult your doctor or pharmacist.

**If you take more of Ibuprofen 200 mg soft capsules than you should**

If you have taken more Ibuprofen 200 mg soft capsules 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 advise 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 Ibuprofen 200 mg soft capsules**

If you forget to take Ibuprofen 200 mg soft capsules. Take your tablets as usual. 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.

**STOP TAKING the medicine and seek immediate medical help if you develop:**

- **signs of intestinal bleeding** such as: bright red faeces (stools/motions), black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- allergic reactions such as unexplained wheezing, shortness of breath, swelling of the face, tongue or throat, palpitations, skin rash or itching ('nettle rash').
- dizziness or faster heartbeat, heart failure
- severe skin reaction such as skin peeling e.g. Stevens-Johnson syndrome.
- swelling of your face, tongue or throat
- severe sore throat, flu-like symptoms, severe exhaustion, nose or skin bleeding, mouth ulcers
- any sign of bleeding from the stomach or bowels (vomiting blood and/or passing black stools) or worsening of colitis or Crohn's disease
- blood disorders, swelling, high blood pressure, heart failure, blurred vision
- stomach problems such as unexplained, stomach pain, indigestion, feeling sick and/or vomiting, diarrhoea or constipation, flatulence
- **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).
- 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].
- any sign of bleeding from the stomach or bowels (vomiting blood and/or passing black stools) or worsening of colitis or Crohn's disease
- asthma, aggravation of asthma or wheezing
- stomach ulcers
- liver or kidney problems
- a severe headache, stiff neck, nausea, vomiting, fever or confusion.
- bruising easily, or bleeding (thrombocytopaenia)
- severe skin infections and soft tissue complications during chicken pox (varicella) infection.
- **Frequency Not known:**
  - 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. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using this medicine if you develop these symptoms and seek medical attention immediately. See also section 2.
  - Skin becomes sensitive to light.

- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

**STOP TAKING the medicine and tell your doctor if you experience:**

- fever, flu-like symptoms, sore throat, mouth ulcers, headache, a stiff neck. Nausea, vomiting, unexplained bleeding and bruising, severe exhaustion.
- indigestion, unexplained stomach or abdominal pain, constipation, diarrhoea, vomiting, flatulence or if you feel sick, chest pain or fast, irregular heart beat, high blood pressure
- liver and kidney problems associated with swelling in your arms and legs
- severe skin infections and soft tissue complications during chicken pox (varicella) infection

Side effects may be minimized by using the minimum effective dose for the shortest duration. **Medicines such as ibuprofen may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke.** The elderly are at an increased risk of side effects. Shortness of breath may occur if you suffer from or have a history of allergic disease. Tell your doctor if you notice any unusual symptoms – especially dark bowel motions, vomiting blood or stomach pains. Serious skin reactions (such as Stevens-Johnson syndrome) have been reported very rarely in association with the use of NSAIDs. The use of Ibuprofen 200 mg soft capsules should be stopped immediately at the first appearance of skin rash, mouth ulcers or any other signs of allergic reactions. There is increased risk of bleeding of the stomach, ulceration, perforation with increasing NSAID doses, in patients with a history of ulcers, and the elderly. It is recommended to commence treatment at the lowest dose. The option of adding a protective agent should also be discussed with your doctor. **If any of the side effects gets serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.**

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRRA 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 200 mg soft capsules**

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- Do not use this medicine after the expiry date which is stated on the blister and carton 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 Ibuprofen 200 mg soft capsules contains**

- Each capsule contains 200 mg of active substance ibuprofen.
- The other ingredients are gelatin, polysorbate, purified water. The capsule fill contains macrogol 600, polysorbate 80, potassium hydroxide and purified water.

### **What Ibuprofen 200 mg soft capsules looks like and contents of the pack**

- The capsules are transparent, oval shaped soft gelatin capsule printed 'BL200' in white ink, containing clear solution.
- This medicine is available in packs containing 10, 12, 16, 18, 20, 24, 28, 30, 32, 36, 48, 96 capsules. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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### **Manufacturer(s)**

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