

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 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.

What is in this leaflet

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

1. What this medicine 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 this medicine

Do not take this medicine:

- 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 lips, face tongue or throat when previously taking ibuprofen, aspirin or similar medicines
- have had gastrointestinal bleeding or perforation when previously taking NSAIDs (Non-steroidal anti-inflammatory drugs)
- are taking other NSAID painkillers or more than 75mg aspirin a day
- have severe liver or kidney problems
- have heart problems, 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 before taking this medicine if you:

- have or have had 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 history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- have a head injury, unexplained bleeding or raised intracranial pressure
- have 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
- are in the first 6 months of pregnancy
- have previously experienced stomach bleeding or perforation after taking ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs)
- 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

Take special care with Ibuprofen soft capsules

Skin reactions

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

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.

Taking other medicines

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:

- anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- aspirin or other NSAIDs (e.g. COX-2 inhibitors).

- corticosteroids (such as prednisolone) since this may increase the risk of gastrointestinal ulceration or bleeding
- drugs for heart failure such as digoxin
- selective serotonin-reuptake inhibitors (a medicine for depression) since these may increase the risk of gastrointestinal side effects
- lithium (a medicine for depression) since there is evidence for a potential increase in plasma levels of lithium
- methotrexate (a medicine for cancer or rheumatism) since there is evidence for a potential increase in plasma levels of methotrexate
- aminoglycosides (a type of antibiotic)
- ciclosporin or tacrolimus (a medicine to suppress the immune reaction) since there is limited evidence of an increased risk for kidney toxicity
- Zidovudine: there is evidence of an increased risk of haemathroses and haematoma in HIV (+) haemophiles receiving concurrent treatment with Zidovudine and ibuprofen
- Quinolone antibiotics since patients taking NSAIDs and quinolone antibiotics may have an increased risk of developing convulsions
- to stimulate your heart (e.g, glycosides)
- to reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-11 receptor antagonists such as losartan)
- Mifepristone (used in pregnancy terminations)
- water tablets (diuretics) since NSAIDs may diminish the effects of these
- for the temporary suppression of your immune system (e.g, methotrexate, ciclosporine, tacrolimus)
- for mania or depression (e.g., Lithium or SSRIs)
- for pregnancy termination (e.g., mifepristone)
- for HIV treatment (e.g., zidovudine)
- probenecid (to treat gout)
- oral hypoglycaemic agents (oral medicines to treat diabetes)

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 and breast-feeding

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

Ibuprofen 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 contain 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 this medicine

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 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 this medicine than you should

You may feel drowsy or nauseous. You should seek immediate medical advice in the event of an overdose, even if you feel well.

If you forget to take this medicine

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 or throat
- severe sore throat with a high fever and, 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
- stomach problems such as unexplained stomach pain, indigestion, feeling sick and/or vomiting, diarrhoea or constipation, flatulence
- stomach ulcers
- liver or kidney problems
- a severe headache, stiff neck, nausea, vomiting, fever or confusion.
- asthma, aggravation of asthma or wheezing
- blood disorders, swelling, high blood pressure, heart failure, blurred vision
- bruising easily, or bleeding (thrombocytopenia)
- severe skin infections and soft tissue complications during chicken pox (varicella) infection.
- **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).
- **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 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.

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

- fever, flu-like symptoms, sore throat, mouth ulcers, headache, a stiff neck. vomiting, unexplained bleeding and bruising, severe exhaustion.
- indigestion, stomach or abdominal pain, constipation, diarrhoea, 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

Medicines such as ibuprofen may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke.

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

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this medicine

- 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 this medicine contains

- Each capsule contains 200 mg of active substance ibuprofen.
- The ingredients of capsule shell are gelatin, polysorb 85/70/00, purified water. The capsule fill contains macrogol 600, polysorbate 80, potassium hydroxide and purified water. The printing ink Opacode monogramming ink S-1-18086 White contains shellac, titanium dioxide, isopropyl alcohol, n-butyl alcohol, and propylene glycol.

What this medicine 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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