

Information for the user



Ibuprofen Long Lasting 200 mg Capsules

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to treat minor conditions. However, you still need to take it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice

What this medicine is for

This medicine contains Ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory medicines, which act to relieve pain and reduce swelling.

The Ibuprofen in the capsule is released slowly over 12 hours. It can be used to relieve headaches, rheumatic and muscular pain, backache, migraine, period pain, dental pain and neuralgia. It can also be used to reduce fever and relieve the symptoms of colds and flu.

Before you take this medicine

This medicine can be taken by adults and children aged 12 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

X Do not take:

- **If you have a stomach ulcer, perforation or bleeding of the stomach**, or have had one in the past (you may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in your stools or passed black tarry stools)
- **If you have had perforation or a bleeding stomach** after taking a non-steroidal anti-inflammatory medicine
- **If you are allergic** to ibuprofen or any other ingredients in the product, aspirin or other non-steroidal anti-inflammatory medicines (you have ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
- **If you are taking aspirin with a daily dose above 75 mg**, or other non-steroidal anti-inflammatory medicines
- **If you have severe heart, kidney or liver failure**
- **If you are pregnant**

Other important information

Risk of heart attack or stroke:

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 stated dose or duration of treatment.

Skin reactions:

Serious skin reactions have been reported in association with this medicine treatment. You should stop taking this medicine 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.

! Talk to your pharmacist or doctor:

- If you have asthma, a history of asthma or other allergic disease, stomach or bowel

problems

- If you have other kidney or liver problems (see “Do not take”)
- If you are elderly – you may get more side effects (see back of leaflet)
- If you are taking any other painkillers or receiving regular treatment from your doctor
- 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") - see '**Risk of heart attack or stroke**' under **Other Important Information**
- If you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker
- **Children and adolescents:** There is a risk of renal impairment in dehydrated adolescents
- If you have an infection – please see heading “Infections” below.

Infections

This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine 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 important information

Breastfeeding: You can use this medicine.

Women of childbearing age: If you take this medicine, it may reduce your ability to become pregnant. This effect will be reversed when you stop the medicine.

If you take other medicines

Before you take these capsules, make sure that you tell your doctor or pharmacist about ANY other medicines you might be using at the same time. Ibuprofen may affect or be affected by some other medicines. For example:

- Aspirin 75 mg (to prevent heart attacks and strokes) – the protection may be reduced when you take ibuprofen
- Other pain killers
- Medicines to thin your blood (e.g. warfarin, ticlopidine)
- Mifepristone (for termination of pregnancy) – do not take ibuprofen if you have taken mifepristone in the last 12 days
- Water tablets (diuretics)
- Medicines to treat high blood pressure (e.g. ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan), medicines for heart problems
- Corticosteroids, lithium, methotrexate, zidovudine
- Quinolone antibiotics (for infections)
- Medicines for depression
- Ciclosporin or tacrolimus (given after transplant surgery, or for psoriasis or rheumatism)

Some other medicines may also affect or be affected by the treatment of ibuprofen. You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen with any other medicines, including herbal and homeopathic remedies.

✓ How to take this medicine

Check the foil is not broken before use. If it is, do not take that capsule.

| Age | How many to take | How often to take them |
|--|------------------|--|
| Adults and children of 12 years and over | Two capsules | Morning and evening, if you need to. Don't take more than 4 capsules in 24 hours. |
| Take the lowest effective dose for the shortest duration necessary to relieve symptoms | | |

Swallow each capsule whole with water.

Do not give to children under 12 years.

Do not take more than the amount recommended above.

If your symptoms worsen at any time, talk to your pharmacist or doctor.

In adults: If your symptoms do not go away within 10 days, talk to your pharmacist or doctor.

In children and adolescents (aged 12-18 years): If this medicinal product is required for more than 3 days, talk to your doctor.

! If you take more capsules than you should:

If you have taken more 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 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.

Possible side effects

Most people will not have problems, but some may get some.

If you are elderly you may be more likely to have some of these side effects.

! If you get any of these serious side effects, stop taking the capsules. See a doctor at once:

- You are sick and it contains blood or dark particles that look like coffee grounds
- Pass blood in your stools or pass black tarry stools
- Stomach problems including pain, indigestion or heartburn
- Allergic reactions such as skin rash (which can sometimes be severe and include peeling and blistering of the skin), swelling of the face, neck or throat, worsening of asthma, difficulty in breathing
- 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 this medicine if you develop these symptoms and seek medical attention immediately. See also section 2.
- Skin becomes sensitive to light – frequency unknown

If you get any of the following side effects see your pharmacist or doctor:

- Kidney problems, which may lead to kidney failure
- Feeling sick or being sick
- Headache, hearing problems
- Fluid retention, which may cause swelling of the limbs
- Rarely, liver problems, diarrhoea, wind, constipation, worsening of colitis or Crohn's disease, meningitis (e.g. stiff neck, fever and disorientation)
- Very rarely, tiredness or severe exhaustion, changes in the blood which may cause unusual bruising and an increase in the number of infections that you get (e.g. sore throats, mouth ulcers, flu-like symptoms)
- A small increased risk of heart attack or stroke if you take large amounts for a long time

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

How to store this medicine

Store below 25°C.

Store in the original package.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the end flap of the carton.

What is in this medicine

Each modified release hard capsule contains Ibuprofen 200 mg, which is the active ingredient.

As well as the active ingredient, the capsules also contain microcrystalline cellulose, Eudragit NE 30D, hypromellose, talc, colloidal silicon dioxide. The capsule shell contains gelatin, titanium dioxide (E171), patent blue V (E131), erythrosine (E127).

The pack contains 8 or 16 pale blue and clear coloured capsules, containing white beads.

Who makes this medicine

Manufactured for The Boots Company PLC Nottingham NG2 3AA by Galpharm International Ltd Elmhirst Park Middle Field Road Barnsley South Yorkshire S75 4LS, UK. Marketing Authorisation held by Galpharm Healthcare Ltd Wrafton Braunton Devon EX33 2DL, UK

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If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA

Other formats

To request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only)

Please be ready to give the following information:

Product name: Boots Ibuprofen Long Lasting 200 mg Capsules

Reference number: 16028/0120

This is a service provided by the Royal National Institute for Blind People.