Information for the user

Ibuprofen Lysine 342 mg Tablets

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 Lysine which belongs to a group of medicines called non-steroidal anti-inflammatory medicines, which act to relieve pain and reduce swelling.
It can be used to relieve rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, period pain, fever and the symptoms of colds and flu.

Before you take this medicine
This medicine can be taken by adults and adolescents (aged 12-18 years old). 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 stomach, or have had one or more twice in the past
• If you have had perforation or a bleeding stomach after taking a non-steroidal anti-inflammatory medicine (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 are allergic to ibuprofen or any other ingredients of 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, and in the last 3 months of pregnancy

Skin reactions
Serious skin reactions have been reported in association with Ibuprofen Lysine 342mg Tablets 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.

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.

! Talk to your pharmacist or doctor:
• If you have asthma, a history of asthma or other allergic disease, bowel problems, Crohn's disease, ulcerative colitis
• If you have other kidney, heart or liver problems (see "Do not take")
• If you have a connective tissue disorder such as SLE (Systemic Lupus Erythematosus)
• 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
• If you are pregnant, and in the first 6 months of pregnancy
• Children and adolescents: There is a risk of renal impairment in dehydrated adolescents

Other information

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

If you take other medicines
Before you take these tablets, 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:
• Other painkillers
• Aspirin 75 mg (to prevent heart attacks and strokes) – the protection may be reduced when you take ibuprofen
• 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
• Medicines for depression
• 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 (for pain and swelling)
• Lithium (for bipolar disorder)
• Methotrexate (for cancer, psoriasis, or rheumatism)
• Zidovudine (for HIV infection)
• Quinolone antibiotics (for infections)
• 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 tablet.

<table>
<thead>
<tr>
<th>Age</th>
<th>How many to take</th>
<th>How often to take</th>
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<tbody>
<tr>
<td>Adults, the elderly and adolescents between 12 and 18 years</td>
<td>One or two</td>
<td>Every 4 hours, if you need to. Don’t take more than 6 tablets in 24 hours.</td>
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Take the lowest amount for the shortest possible time to relieve your symptoms

Swallow each tablet 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 doctor.

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

**Adolescents:** (aged 12-18 years old): If this medicinal product is required for more than 3 days, talk to your doctor.

**! If you take more tablets than you should:** If you have taken more 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.

**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 tablets. 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
- 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, fast heart rate, low blood pressure, collapse
- Meningitis (e.g. stiff neck, fever, disorientation)
- **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 Lysine 342mg Tablets if you develop these symptoms and seek medical attention immediately. See also section 2.

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

- Uncommon side effects: (may affect up to 1 in 100 people)
  - Stomach discomfort or pain, feeling sick, indigestion or heartburn
  - Headache
  - Skin rash, hives, itching

- Rare side effects: (may affect up to 1 in 1,000 people)
  - Diarrhoea, wind, constipation, being sick

- Very rare side effects: (may affect less than 1 in 10,000 people)
  - Stomach ulcer or perforation, worsening of bowel problems such as ulcerative colitis or Crohn’s disease
  - Kidney problems, which may lead to kidney failure (you may pass more or less urine than
normal, have blood in your urine or cloudy urine, or feel breathless, very tired, or weak, have no appetite, or have swollen ankles)

- Yellowing of the skin or eyes, pale stools or upper abdominal pain (these may be signs of liver problems)
- Tiredness or severe exhaustion, changes in the blood which may cause unusual bruising or unexplained bleeding and an increase in the number of infections that you get (e.g. sore throats, mouth ulcers, flu-like symptoms including fever)

Side effects with an unknown frequency:

- Fluid retention, which may cause swelling of the limbs
- High blood pressure, heart failure, stroke

There may be a small increased risk of heart attack or stroke if you take large amounts of this medicine for a long time. If you get any symptoms, stop taking the tablets and see your doctor.

**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 on this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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**

Do not store above 25°C.

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 film-coated tablet contains Ibuprofen 200 mg (as Ibuprofen Lysine 342 mg), which is the active ingredient.

As well as the active ingredient, the tablets also contain crospovidone, copovidone, microcrystalline cellulose, magnesium stearate.

The tablet coating contains Opadry II White (containing polyvinyl alcohol, titanium dioxide (E171), macrogol, talc).

The pack contains 8 or 16 white capsule-shaped film-coated tablets.

The tablet is marked with the letters ‘IBL’ on one side.

**Who makes this medicine**

Manufactured for The Boots Company PLC Nottingham NG2 3AA by the Marketing Authorisation holder Wrafton Laboratories Limited Braunton Devon EX33 2DL

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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 Lysine 342 mg Tablets

Reference number: 12063/0071
This is a service provided by the Royal National Institute of Blind People.

Artwork reference number: AB272QAJ3