

Rare (affecting 1 in 10,000 to 1 in 1000 people)

- Diarrhoea, flatulence, constipation and vomiting.

Very Rare (affecting less than 1 in 10,000 people)

- Stomach ulcer or perforation, worsening of bowel problems (ulcerative colitis or Crohn's disease)
 - Kidney problems that might be indicated by passing less or more urine than normal, cloudy urine, blood in the urine, pain in the back and/or swelling (particularly of the legs) – very rarely kidney failure.
- Ibuprofen Lysine Tablets, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness
- Liver problems that might be indicated by yellowing of the skin and eyes (jaundice) and/or pale coloured stools and dark urine
 - Blood disorders which can cause: unexplained or unusual bruising or bleeding, sore throat or mouth ulcers, fever (high temperature), extreme paleness or weakness and exhaustion.

Unknown

- High blood pressure, heart failure, swelling due to fluid build-up (oedema) or stroke
- Skin becomes sensitive to light.

Medicines such as Ibuprofen Lysine Tablets may be associated with a small increased risk of heart attack (myocardial infarction). If you experience any of these symptoms, or have any other unusual symptoms or concerns with your medicine, 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 in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5 STORING THE MEDICINE

Do not store above 25°C. Do not use after the expiry date shown on the pack. Store in the original container.

Keep out of the sight and reach of children.

6 FURTHER INFORMATION

What is in this medicine:

The active ingredient is: Ibuprofen 200 mg (as ibuprofen lysine) per coated tablet.

The other ingredients are:

Crospovidone, copovidone, microcrystalline cellulose, magnesium stearate, Opadry II White (contains polyvinyl alcohol, titanium dioxide E171, macrogol and talc).

What this medicine looks like and contents of the pack

Each tablet is a film-coated white tablet, embossed with 'IBL' on one side. This product is available in a pack size of 8, 12 or 16 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Wrafton Laboratories Limited, Braunton, Devon, EX33 2DL, United Kingdom.

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Galpharm Rapid Ibuprofen Lysine 342 mg Tablets

Ibuprofen Lysine

PATIENT INFORMATION LEAFLET

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or pharmacist if your symptoms worsen or do not improve.

IN THIS LEAFLET:

- 1. What this medicine is for**
- 2. Before you take the medicine**
- 3. How to take the medicine**
- 4. Possible side effects**
- 5. Storing the medicine**
- 6. Further information**

1 WHAT THIS MEDICINE IS FOR

This medicine contains ibuprofen lysine which is the lysine salt of ibuprofen. Ibuprofen is one of a group of non-steroidal anti-inflammatory drugs (known as NSAIDs) which work to reduce pain, fever and swelling.

This medicine is used to relieve:

- rheumatic and muscular pain, backache
- neuralgia (nerve pain)
- headache, migraine
- dental pain, period pain
- fever (high temperature)
- the symptoms of colds and flu.

2 BEFORE YOU TAKE THE MEDICINE

Do not take this medicine if you:

- have (or have had 2 or more episodes of) a stomach ulcer, perforation or bleeding of the stomach
- are allergic to ibuprofen, to any of the ingredients (listed in section 6), or to aspirin or other painkillers (an allergic reaction may be recognised as shortness of breath, runny nose, skin rash or itching)
- have severe kidney, heart or liver failure
- are taking aspirin with a daily dose above 75 mg
- are in the last 3 months of pregnancy.

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 generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using this medicine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Talk to your doctor or pharmacist before taking ibuprofen tablets if you:

- are elderly because you may be at more risk of having serious side effects, particularly stomach problems
- have or have suffered from asthma, diabetes, high cholesterol or have allergies
- have liver or kidney problems
- have stomach or bowel disorders including Crohn's disease or a condition known as ulcerative colitis
- have Systemic Lupus Erythematosus (SLE) – an illness which affects your immune system. It causes joint pains, skin changes and problems with other parts of your body
- have, have previously had, or are at risk of heart problems, high blood pressure or stroke
- 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.

If you are taking other medicines

You must not take these tablets if you are taking certain other medicines - see section 2 'Do not take this medicine if you'.



Ibuprofen Lysine Tablets may affect or be affected by some other medicines. For example:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/ acetylsalicylic acid, warfarin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan).

Some other medicines may also affect or be affected by the treatment of Ibuprofen Lysine Tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen Lysine with other medicines, especially:

- two or more NSAID painkillers, including cyclooxygenase-2 selective inhibitors
- antidepressants called selective-serotonin reuptake inhibitors (SSRIs) e.g. fluoxetine
- corticosteroids (for skin problems and allergies e.g. cortisol)
- methotrexate (a medicine for cancer)
- cardiac glycosides (medicines used to treat heart failure e.g. digoxin)
- ciclosporin and tacrolimus (immunosuppressant medicines often used following organ transplants)
- mifepristone (a medicine used to terminate pregnancy – NSAIDs should not be used for 12 days after mifepristone)
- lithium (for depression or mental problems)
- zidovudine (a medicine to treat viruses)
- quinolone antibiotics (medicines used to treat bacterial infections e.g. ciprofloxacin).

Other Warnings

- 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 this medicine and contact immediately your doctor or medical emergencies if you notice any of these signs.
- 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. You should discuss your treatment with your doctor or pharmacist before taking Ibuprofen Lysine Tablets 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.

- If you are taking Ibuprofen Lysine Tablets for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).
- Ibuprofen Lysine Tablets belong to a group of medicines which may affect fertility in women. Fertility goes back to normal when you stop taking the medicine. It is unlikely that if you only take these tablets occasionally it will affect your chances of becoming pregnant. If you have problems becoming pregnant talk to your doctor before taking this medicine.
- There is a risk of renal impairment in dehydrated adolescents.

Pregnancy and Breastfeeding

Do not take Ibuprofen Lysine Tablets 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 baby. 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 Lysine Tablets 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, Ibuprofen Lysine Tablets 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. Talk to your doctor before taking Ibuprofen Lysine Tablets if you are breastfeeding.

3 HOW TO TAKE THE MEDICINE

Age	Dose and how often to take
Adults, the elderly and adolescents between 12 and 18 years	Initial dose 1 or 2 tablets to be taken with water, preferably with or after food, then if necessary 1 or 2 tablets every 4 hours. Do not take more often than every 4 hours. Do not take more than 6 tablets in any 24 hour period.
Do not give to children under 12 years.	
<ul style="list-style-type: none">• This medicine is intended for short term use only• Take the lowest effective dose for the shortest duration necessary to relieve symptoms.	
In Adults: Do not take these tablets for longer than 10 days unless your doctor tells you to. Talk to a doctor or pharmacist if you do not get better or get worse, or if new symptoms occur.	
In Adolescents between 12 and 18 years: If in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen, a doctor should be consulted.	

If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

If you take more Ibuprofen Lysine 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.

4 POSSIBLE SIDE EFFECTS

Most people take these tablets without any problems, but they can have side effects, like all medicines. To reduce the chance of side effects, especially if you are elderly, use the lowest effective dose for the shortest possible time.

If you get any of the following at any time during your treatment STOP TAKING, and get medical help straight away:

- **Signs of intestinal bleeding** such as vomiting blood or dark particles (that look like coffee grounds), black tarry stools or motions, or blood passed in your stools or motions
- **Signs of serious allergic reaction** such as:
 - asthma, worsening of asthma, unexplained wheezing or shortness of breath
 - swelling of the face, lips, tongue and throat (causing difficulty in swallowing or breathing)
 - rapid heart rate, low blood pressure and collapse
 - also, there may be severe skin reactions with rashes, blistering and peeling skin
 - aseptic meningitis (which can have symptoms such as severe headache, stiff neck, disorientation, fever and eye sensitivity to light in those with existing auto-immune disorders such as lupus)
 - chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
 - 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]
 - widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome)
 - a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

Tell your doctor or pharmacist if any of the following side effects persist, get worse, or if you notice any other side effects not listed:

Uncommon (affecting 1 in 1000 to 1 in 100 people)

- Stomach discomfort or pain, nausea (feeling sick), indigestion or heartburn
- Headache
- Skin reactions, such as hives, rash and itching.