

IBUPROFEN LYSINE

342 mg film-coated tablets

Ibuprofen lysine

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 after 3 days (for adolescents).
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days in fever and after 4 days in the treatment of pain (for adults).

What is in this leaflet

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1. What Ibuprofen Lysine tablets is and what it is used for

This medicine contains ibuprofen lysine which is the lysine salt of ibuprofen. Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) which relieve pain and lower temperature when you have a fever.

Ibuprofen Lysine tablets is used for the symptomatic treatment of:

- mild to moderate pain, such as headache, period pain and dental pain
- fever and pain associated with common cold.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days (for adolescents).

You must talk to a doctor if you do not feel better or if you feel worse after 3 days in fever and after 4 days in the treatment of pain (for adults).

2. What you need to know before you take Ibuprofen Lysine tablets

Do not take Ibuprofen Lysine tablets:

- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6);
- if you have ever suffered from shortness of breath, asthma, a runny nose, swelling or hives after using acetylsalicylic acid or other similar painkillers (NSAIDs);
- if you have (or have had two or more episodes of) a stomach or duodenal ulcer or bleeding of the stomach;
- if you have ever had gastrointestinal bleeding or perforation related to previous use of NSAIDs ;
- if you have severe liver, kidney or heart failure;
- if you suffer from blood clotting disorders;
- if you have any active bleeding (including bleeding in the brain);
- if you suffer from a currently undiagnosed problem with your body's ability to form blood;
- if you are severely dehydrated (caused by vomiting, diarrhoea or insufficient fluid intake);
- if you are in the last 3 months of pregnancy;
- if you are adolescent weighing under 40 kg or you are younger than 12 years.

Ibuprofen Lysine 342 mg film-coated tablets contains soya lecithin:

If you are allergic to peanut or soya, do not use this medicinal product.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ibuprofen Lysine tablets:

- if you have or have had asthma or allergic disease as shortness of breath may occur;
- if you suffer from hayfever, nasal polyps or chronic obstructive respiratory disorders as an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (so-called analgesic asthma), Quincke's oedema or urticaria;
- if you have kidney or liver problems;
- if you have or have ever had high blood pressure or heart failure;
- if you have or have ever had stomach or bowel disorders (including ulcerative colitis or Crohn's disease);
- if you have certain hereditary blood formation disorder (e.g. acute intermittent porphyria);
- if you have systemic lupus erythematosus (SLE) or mixed connective tissue disease - illnesses that affect the immune system causing joint pain, skin changes and disorders of other organs;
- if you have chicken pox (varicella) - it is advisable to avoid the use of Ibuprofen Lysine tablets;
- if you have an infection - please see heading "Infections" below;
- if you have recently had major surgery;
- if you are taking other NSAIDs. The use with concomitant NSAIDs, including cyclo-oxygenase-2 specific inhibitors, increases the risk of adverse reactions (see section "Other medicines and Ibuprofen Lysine tablets" below) and should be avoided.

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 (3 days in adolescents or in adults 3 days in the treatment of fever and 4 days in the treatment of pain).

You should discuss your treatment with your doctor or pharmacist before taking <Product name> 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 of 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.

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

Serious 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 Lysine and seek medical attention immediately, if you notice any of the symptoms related to these serious skin reactions described in section 4.

Undesirable effects may be minimised by using the minimum effective dose for the shortest period of time. The elderly are at increased risk of side effects.

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If you are taking Ibuprofen Lysine 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).

The habitual use of several sorts of painkillers may cause permanent damage to the kidneys and a risk of kidney failure. This risk may be increased under physical strain associated with loss of salt and dehydration. Therefore, the habitual use of painkillers should be avoided.

Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.

In prolonged administration of Ibuprofen Lysine tablets regular checking of your liver values, the kidney function, as well as of the blood count, is required.

NSAIDs may mask symptoms of infection and fever.

Infections

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

Children and adolescents

There is a risk of renal impairment in dehydrated adolescents. Do not give this medicine to adolescents weighing under 40 kg or children under 12 years of age.

Other medicines and Ibuprofen Lysine tablets

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

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

- acetylsalicylic acid, or other NSAIDs - since they may increase the risk of gastrointestinal ulcers or bleeding;
- digoxin (for heart insufficiency) - since the effect of digoxin may be enhanced;
- glucocorticoids (medicinal products containing cortisone or cortisone-like substances) - since this may increase the risk of gastrointestinal ulcers or bleeding;
- anti-platelet agents - since this may increase the risk of gastrointestinal bleeding;
- acetylsalicylic acid (low dose) - since the blood-thinning effect may be impaired;
- medicines that are anti-coagulants, (i.e thin blood/ prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine) - since ibuprofen may enhance the effects of these medicines;
- phenytoin (for epilepsy) - since the effect of phenytoin may be enhanced;
- selective serotonin reuptake inhibitors (medicines used for depression) - since this may increase the risk of gastrointestinal bleeding;
- lithium (a medicine for manic depressive illness and depression) - since the effect of lithium may be enhanced;
- probenecid and sulfinpyrazones (medicines for gout) - since the excretion of ibuprofen may be delayed;
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan) and water tablets (diuretics) - since ibuprofen may diminish the effects of these medicines and there could be a possible increased risk for the kidney;
- potassium sparing diuretics - since this may lead to high potassium levels in the blood;
- methotrexate (a medicine for cancer or rheumatism) -since the effect of methotrexate may be enhanced;
- tacrolimus and cyclosporine (immunosuppressive medicines) - since kidney damage may occur;
- mifepristone (for pregnancy termination) - since the effect of mifepristone may be reduced;
- zidovudine (a medicine for treating HIV/AIDS) - since the use of ibuprofen may result in an increased risk of bleeding into a joint or a bleeding that leads to swelling in HIV (+) haemophiliacs;
- sulfonyleureas (antidiabetic medicines) - interactions may be possible;
- quinolone antibiotics - since the risk for convulsions may be increased;
- medicines that inhibit CYP2C9 enzyme such as the antifungals voriconazole or fluconazole - since exposure to ibuprofen may be increased;
- a herbal remedy called ginkgo biloba - there is a chance that you may bleed more easily if you are taking ibuprofen and ginkgo biloba at the same time.

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 tablets with other medicines.

Ibuprofen Lysine tablets with food, drink and alcohol

It is recommended that patients with sensitive stomachs take Ibuprofen Lysine tablets with food.

Some side effects, such as those affecting the gastrointestinal system can be more likely when alcohol is taken at the same time as Ibuprofen Lysine tablets.

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 Lysine 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 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 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.

Only small amounts of ibuprofen and its decomposition products pass into breast milk. This medicine may be taken during breast-feeding if it is used at the recommended dose and for the shortest possible time.

Ibuprofen Lysine tablets belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that Ibuprofen Lysine tablets, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.

Driving and using machines

For short-term use and at the recommended dosage, this medicine has little or no influence on the ability to drive and use machines. If side-effects such as tiredness, dizziness, drowsiness and visual disturbances occur, do not drive or operate machines. Alcohol consumption increases the risk of these side effects.

Ibuprofen Lysine 342 mg film-coated tablets contains colour Sunset yellow aluminium lake (E110) and colour Ponceau 4R aluminium lake (E124)

This medicine contains colours (E110 and E124), which may cause allergic reactions.

Ibuprofen Lysine 342 mg film-coated tablets contains glucose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Ibuprofen Lysine tablets

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 only.

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 and adolescents weighing from 40 kg (12 years of age and above)

Take 1 or 2 tablets (200 mg or 400 mg ibuprofen) with water, up to three times a day as required. Leave at least 6 hours between doses. Do not take more than 6 tablets in any 24 hour period.

If you are an adult and need to take Ibuprofen Lysine tablets for more than 3 days if you have fever or for more than 4 days for the treatment of pain or if your symptoms worsen consult your doctor.

Use in children and adolescents

Do not give to adolescents weighing under 40 kg or children under 12 years.

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

The film-coated tablets should be swallowed whole with water.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

It is recommended that patients with sensitive stomachs take Ibuprofen Lysine tablets with food.

If you take more Ibuprofen Lysine tablets than you should

If you have taken more Ibuprofen Lysine 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 of overdose can include nausea, stomach pain, headache, diarrhoea, ringing in the ears, vomiting (may be blood streaked), blood in stools, confusion and shaky eye movements. Also, agitation, somnolence, disorientation or coma may occur. At high doses, drowsiness, excitation, chest pain, palpitations, kidney failure, liver damage, blue discolouring of the skin and mucosa (cyanosis), loss of consciousness, convulsions, cramps (mainly in children), increased bleeding tendency, weakness and dizziness, blood in urine, low levels of potassium in your blood, cold body feeling and breathing problems have been reported. Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Worsening of asthma in asthmatics may occur. Furthermore, there may be low blood pressure and reduced breathing.

If you forget to take Ibuprofen Lysine tablets

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. Elderly people using this product are at increased risk of developing problems associated with side effects.

Medicines such as Ibuprofen Lysine tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

If you suffer from any of the following at any time during your treatment stop taking the medicine and seek immediate medical help:

- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds.

Stop taking the medicine and tell your doctor if you experience:

- Indigestion or heartburn
- Abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

Tell your doctor or pharmacist if you notice any of the following:

- Liver, kidney problems or difficulty urinating. Ibuprofen Lysine, 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.

If any of the following occurs, **stop taking this medicine and consult your doctor immediately or go to the emergency department of the nearest hospital:**

- swelling of the face, tongue or throat, difficulty breathing, racing heart, drop in blood pressure leading to shock [signs of serious allergic reaction] (very rare). These can happen even on first use of this medicine.
- asthma attacks (possibly with drop in blood pressure), worsening of asthma, unexplained wheezing or shortness of breath [signs of serious allergic reaction] (uncommon).
- 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] (very rare).
- widespread rash, high body temperature, enlarged lymph nodes and an increase of eosinophils (a type of white blood cells) [DRESS syndrome] (frequency cannot be estimated from the available data).
- 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 known as AGEP] (frequency cannot be estimated from the available data). See also section 2.
- severe upper stomach pain, often with nausea and vomiting, which occurs [inflammation of the pancreas] (very rarely).
- ever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding[problems in the blood cell production] (very rarely).
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome (frequency cannot be estimated from the available data).

Tell your doctor if you experience any of the below side effects:

Common (may affect up to 1 in 10 people):

- gastrointestinal complaints, such as heartburn, abdominal pain, feeling sick, being sick, wind (flatulence), diarrhoea, constipation and slight blood losses in stomach and/or bowel that may cause anaemia in exceptional cases.

Uncommon (may affect up to 1 in 100 people):

- stomach or intestinal ulcers, sometimes with bleeding and perforation;
- inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis), worsening of colitis and Crohn's disease;
- central nervous system disturbances such as headache, dizziness, sleeplessness, agitation, irritability or tiredness;
- visual disturbances;
- allergic reactions, such as skin rashes and itching;
- various skin rashes.

Rare (may affect up to 1 in 1,000 people):

- ringing in the ears;
- kidney damage (papillary necrosis) and elevated uric acid concentrations in the blood.

Very rare (may affect up to 1 in 10,000 people):

- inflammation of the oesophagus, narrowing of intestines;
- severe skin infections and soft tissue complications may occur if you have chicken pox;
- fluid build-up in the body's tissues especially in patients with high blood pressure or kidney problems, swelling and foamy urine (nephrotic syndrome), inflammatory kidney disease (interstitial nephritis) that may lead to acute kidney failure;
- acute kidney failure;
- psychotic reactions, depression;
- worsening of infection-related inflammations (e.g. development of flesh eating bacteria syndrome – necrotizing fasciitis) associated with use of certain painkillers (NSAIDs) has been described. If signs of an infection occur or get worse during use of ibuprofen, you must go to a doctor without delay. It is to be investigated whether there is an indication for an anti-infective/antibiotic therapy;
- high blood pressure, inflammation of blood vessels, palpitations, heart failure, heart attack;
- liver dysfunction, liver damage (especially in long-term use), liver failure, acute inflammation of the liver (hepatitis);
- aseptic meningitis (inflammation of the linings of the brain with symptoms including neck stiffness, headache, feeling sick, being sick, fever or clouding of the mental state). Patients with autoimmune disorders (SLE, mixed connective-tissue disease) may be more likely to be affected;
- hair loss.

Frequency unknown:

- skin becomes sensitive to light;
- decreased appetite;
- pain, burning or itching associated with urination;
- severe urinary system pain.

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 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. How to store Ibuprofen Lysine tablets

Keep this medicine out of the sight and reach of children. Store below 25° C.

Do not use this medicine after the expiry date which is stated on the 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 Lysine tablets contains

The active substance is ibuprofen lysine. Each tablet contains 342 mg ibuprofen lysine equivalent to 200 mg ibuprofen.

The other ingredients are:

Tablet core: silicified microcrystalline cellulose (contains: Cellulose, microcrystalline and Silica, colloidal anhydrous); copovidone; croscarmellose sodium (E468); silica colloidal anhydrous; magnesium stearate (E470b); talc (E553b).
Film coating: hypromellose (E464), titanium dioxide (E171), polydextrose, talc (E553b), maltodextrin, medium chain triglycerides, colour ponceau 4R aluminium lake (E124), colour Sunset yellow aluminium lake (E110), colour Indigo carmine aluminium lake (E132), carmellose sodium (E466), glucose monohydrate, mica-based pearlescent pigment (Mica/Titanium dioxide) (E555/E171), soya lecithin (E322).

What Ibuprofen Lysine tablets looks like and contents of the pack

Ibuprofen Lysine tablets are oblong, biconvex, pastel-pink film-coated tablets with shiny effect and break mark on one side. The dimensions of each tablet are approximately 20.0 mm x 8.0 mm.

The film coated tablets are blister-packed in hard transparent PVC/Al foil or in child-resistant white opaque PVC/ Al foil fortified with polyester layer. Each blister contains 10 tablets.

Lithographed cardboard box with 1 (10 tablets) or 2 (20 tablets) blisters and a leaflet inside.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

UK (NI):	IBUPROFEN LYSINE 342 mg film-coated tablets
Germany:	Ibuprofen INN-FARM 200 mg Filmtabletten
Hungary:	Dolovill Rapid 342 mg filmtabletta
Netherlands:	IBUPROFEN InnFarm 200 mg filmomhulde tabletten
Poland:	IBUPROFEN LYSINE InnFarm
Romania:	PADUDEN Rapid 200 mg comprimate filmate
Slovenia:	Ibuprofen INN-FARM 200 mg filmsko obložene tablete
Slovak Republic:	IBUPROFEN InnFarm 200 mg, filmom obalené tablety

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