

Package leaflet: Information for the user

**Ibuprofen Lysine 684 mg
film-coated tablets**
Ibuprofen Lysine
Fast Acting

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 doctor or 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 5 days (3 days in case of migraine).
- You must talk to a doctor after 3 days if your adolescent does not feel better or if your adolescent feels worse.

What is in this leaflet

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1. What Ibuprofen Lysine Tablets are and what it is used for

The active ingredient in this medicine is ibuprofen as ibuprofen with lysine. It belongs to a group, of medicines known as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) which relieve pain, reduce swelling and lower temperature when you have a fever.

Ibuprofen Lysine is used for the short-term symptomatic relief of headache and migraine in adults and adolescents aged 12 years and above and with body weight 40 kg and above.

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);
- have previously had allergic reactions (such as hives, runny nose, swelling or bronchial asthma) after taking acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs);
- have (or have ever had two or more episodes of) a stomach ulcer, stomach or intestinal perforation or bleeding;
- have ever had stomach or intestinal bleeding or perforation when previously taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs);
- have severe heart, kidney or liver failure;
- have bleeding of the brain (cerebrovascular bleeding) or other active bleeding;
- have bleeding predisposition (unusual tendency to bleed);
- suffer from unclarified blood-formation disturbances;
- are severely dehydrated (caused by vomiting, diarrhoea or insufficient fluid intake);
- are in the last 3 months of pregnancy (see "Pregnancy and breastfeeding").

Warnings and precautions

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 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 lysine 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.

Talk to your doctor or pharmacist before taking Ibuprofen Lysine and if you have an infection - please see heading "Infections" below:

- have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes and other organ disorders) and mixed connective tissue disease; (rare autoimmune disorder affecting connective tissue);
- have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease);
- have kidney, heart, liver or bowel problems;
- have or have ever had asthma;
- are in the first 6 months of pregnancy;
- have chicken pox (varicella);
- have a hereditary blood formation disorder (acute intermittent porphyria);
- have just undergone a major surgery;
- have ever had allergic reactions to other medicines;
- suffer from hay fever, nasal polyps or chronic breathing problems, as there is an increased risk of experiencing allergic reactions;
- have problems with blood coagulation (thickening);
- 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).
- you have an infection - please see heading "Infections" below.

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.

Avoid the use of Ibuprofen Lysine with other NSAIDs, including cyclooxygenase-2 selective inhibitors at the same time.

There is a risk of gastro-intestinal bleeding, ulceration or perforation, which can be fatal, with or without warning symptoms, they may also occur in patients with earlier warning symptoms. If you experience stomach or intestinal bleeding or ulceration, stop taking this medicine immediately. If you suffer from any gastrointestinal diseases, especially if you are over 65 years old, you must report any unusual gastrointestinal symptoms (especially bleeding) to your doctor, particularly at the beginning of treatment.

Skin reactions

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

Anti-inflammatory/pain-killer medicines such as Ibuprofen Lysine may be associated with a **small increased risk of heart attack or stroke**. Any risk is more likely with high doses or prolonged treatment. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking Ibuprofen Lysine if you:

- have heart problems including heart failure, angina pectoris (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 if you have had previous stroke (including 'mini-stroke' or transient ischaemic attack "TIA");
- might be at risk of the heart problems (for example, if you have high blood pressure, diabetes or high cholesterol, have a family history of heart disease or stroke, or if you are a smoker).

For prolonged use of Ibuprofen Lysine, regular checking of your liver values, kidney function and blood count is required.

Long term use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, talk to your doctor and stop taking this medicine.

In general, the frequent use of painkillers can lead to lasting severe kidney damage with the risk of kidney failure (analgesic nephropathy). This risk may be increased under physical strain associated with dehydration. Do not take this medicine if you feel dehydrated.

NSAIDs such as Ibuprofen Lysine may mask the symptoms of infection and fever.

Tell your doctor, even if the above warnings refer to conditions occurring in the past.

Stop taking the medicine and contact your doctor immediately at the first appearance of an allergic reaction (see section "Possible side effects").

Children and adolescents

Ibuprofen Lysine is not intended for adolescents weighing less than 40 kg or children under 12 years of age.

There is a risk of renal impairment in dehydrated adolescents.

Elderly patients

The elderly have an increased risk of side effects than the younger patients.

Other medicines and Ibuprofen Lysine Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

To reduce the risk of side effects, do not take this medicine with other NSAID medicines (such as acetylsalicylic acid, ibuprofen), including selective cyclooxygenase-2 inhibitors (nonsteroidal anti-inflammatory drug (NSAID) that directly targets the enzyme responsible for inflammation and pain, e.g. celecoxib).

Ibuprofen Lysine may affect or be affected by some other medicines.

Avoid taking this medicine with anti-inflammatory medicines (corticosteroids), herbal extracts (Ginkgo biloba) or medicines that are prescribed:

- to treat infections (quinolone antibiotics)
- to thin your blood or prevent clotting (such as warfarin, acetylsalicylic acid, ticlopidine)
- to stimulate your heart (such as digoxin) or treat high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan)
- to help you passing water (diuretics)
- for the temporary suppression of your immune system (such as methotrexate, ciclosporin, tacrolimus)
- for mania or depression (such as lithium or SSRIs)
- for pregnancy termination (such as mifepristone)
- for HIV infection treatment (such as zidovudine)
- to treat seizures (such as phenytoin)
- to treat chronic gout and gouty arthritis (such as probenecid and sulfinpyrazone)
- to treat fungal infections (voriconazole or fluconazole)
- to treat diabetes (sulfonylureas)

Ibuprofen Lysine Tablets with alcohol

Alcohol may enhance side effects of Ibuprofen Lysine, especially those affecting the central nervous system and the gastrointestinal tract. Do not drink alcohol while using Ibuprofen Lysine.

Pregnancy, breast-feeding and fertility

Do not take this medicine 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.

Pregnancy

Do not take this medicine in the last 3 months of pregnancy as it may severely affect your pregnancy and your baby's heart and kidneys, and/or may cause complications during delivery.

If you are in the first 6 months of pregnancy, you can use this medicine only after a consultation with your doctor and if it is clearly necessary.

Breast-feeding

Only small amounts of ibuprofen and its decomposition products pass into breast milk. There are no known side effects in breast-fed infants, therefore this medicine may be taken during breast-feeding if it is used at the recommended dose and for the shortest possible time.

Fertility

Ibuprofen Lysine belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine.

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines when is taken according to the recommended instructions. However, at higher dosage it can cause tiredness and dizziness and the ability to react and take part actively in road traffic and to operate machines may be affected. The risk is higher when taking this medicine in combination with alcohol. If you experience these side effects, do not drive or use machines.

Information on sodium content

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 use 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 from 40 kg body weight (12 years and above)

Take 1 tablet up to three times a day as required.

Leave at least six hours between two doses.

Do not take more than 3 tablets in any 24 hours

Adults

Do not take for more than 5 days (3 days in case of migraine) unless your doctor tells you to.

If symptoms persist or worsen, or if any new symptoms occur, consult your doctor or pharmacist.

Adolescents

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

Patients with kidney or liver impairment

Ask your doctor before taking Ibuprofen Lysine to determine the dose and duration of treatment.

Elderly patients

The elderly patients are at greater risk of developing side effects. Side effects can be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms.

Method of administration:

This medicine is for oral use.

Do not chew the tablets. Take the tablets with a glass of water.

If you have a sensitive stomach, take the 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 an overdose 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.

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, ibuprofen lysine tablets can cause side effects, although not everybody gets them. Tell your doctor or pharmacist if you notice any of the following:

- Liver, kidney problems or difficulty urinating
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

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.

Some side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. If any of the side effects get serious or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

STOP TAKING the medicine and seek immediate medical help if you develop:

- **signs of intestinal bleeding** such as: bright red or black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- **signs of serious allergic reaction** such as:
 - difficulties in breathing or unexplained wheezing,
 - dizziness or faster heartbeat,
 - severe skin reactions (rashes, itchiness, peeling, flaking or blistering),
 - swelling of your face, tongue or throat
- **signs of aseptic meningitis** such as: headache, stiff neck, feeling sick, being sick, fever or disorientation. Patients with autoimmune disorders (lupus, mixed connective tissue disease) may be more likely to be affected.
- 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 if you have any of the following side effects or they become worse:

- blood disorder resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms, severe exhaustion;
- indigestion, stomach or abdominal pain, constipation, diarrhoea, flatulence, feeling sick, or if you experience chest pain or fast irregular heartbeat;
- liver and kidney problems associated with swelling in your arms and legs.

Medicines such as Ibuprofen Lysine may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke (see section 2 "Warnings and precautions").

With Ibuprofen Lysine the following side effects may be experienced:

- **Common** (may affect up to 1 in 10 people)
 - stomach complaints such as acid burn 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)
 - allergic reactions with skin rashes, itching and breathing problems such as asthma attacks (possibly with drop in blood pressure), aggravated asthma, bronchospasm, dyspnoea (difficulty of breathing).
 - headache, dizziness, sleeplessness, agitation, irritability and tiredness
 - sight problems
 - stomach and intestinal ulcers, potentially with bleeding and perforation, inflammation of oral mucosa accompanied by ulcers ulcerative

stomatitis), abdominal pain, inflammation of stomach gastritis), nausea and dyspepsia

- various skin rashes

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

- ringing in the ears (tinnitus)
- kidney tissue damage (papillary necrosis)
- high concentration of uric acid in the blood shown in blood test
- diarrhoea, flatulence, constipation and vomiting

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

- worsening of infection-related inflammations (e.g. necrotising fasciitis). If signs of an infection occur or get worse during use of Ibuprofen Lysine, contact your doctor immediately.
- changes in blood count (anaemia, leukopenia, thrombocytopenia, pancytopenia, agranulocytosis). The first signs may be fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding. In these cases, stop taking this medicine and do not take other similar medicines (pain killers or medicines that reduce fever). Consult a doctor immediately.
- severe general allergic reactions. They may present as face swelling (oedema), swelling of the tongue, swelling of the throat (internal larynx with constriction of the airways), respiratory distress, fast heartbeat, drop in blood pressure up to lifethreatening shock. If any of these symptoms occurs, which can happen even upon first use, contact your doctor immediately.
- aseptic meningitis with stiff neck, headache, nausea, vomiting, fever and consciousness clouding. Patients with autoimmune disorders (SLE mixed connective-tissue disease) appear to be predisposed.
- psychotic reactions, depression
- heart palpitations, heart attack
- inflammation of the gullet (oesophagus), inflammation of the pancreas, peptic ulcers, perforation or bleeding, tarry stools, haematemesis (vomiting blood), lesions (diaphragm-like strictures) in the bowel. Stop taking the medicine and talk to your doctor if you experience severe pain in the upper abdomen or black, tarry stools or vomiting blood.
- liver problems or damage, particularly in long-term use, liver failure, acute inflammation of the liver (hepatitis)
- severe skin reactions with bullous eruptions (fluid-filled blisters) including Stevens-Johnson syndrome and toxic epidermal necrolysis
- severe hair loss (alopecia)
- in exceptional cases, severe infections of the skin and soft tissue complications have occurred during chicken pox (varicella)
- decrease output of urine excretion and increased build-up of tissue fluid (oedema), particularly in patients with high blood pressure or kidney problems;
- kidney damage (nephrotic syndrome, interstitial nephritis that may be accompanied by acute kidney failure)
- decreased haemoglobin level (anaemia or low red blood count)

Not known

- heart failure and oedema (build-up of tissue fluid)
- high blood pressure, inflammation of the blood vessels
- responsiveness of the airways, including asthma, bronchospasm, dyspnoea (difficulty of breathing)
- severe ulcerative colitis (long-lasting inflammation and sores in the digestive tract) and Crohn's disease (inflammatory bowel disease)
- 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)
- Kidney insufficiency (poor function of the kidneys)
- 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 if you develop these symptoms and seek medical attention immediately. See also section 2.
- skin becomes sensitive to light.

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 national reporting system 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. Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the label, carton and blister after EXP.

The expiry date refers to the last day of that month.

Bottle pack:

10 tablets: Discard any remaining tablets 4 days after first opening of the bottle.

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 (as ibuprofen lysine). Each film-coated tablet contains the active ingredient ibuprofen 400 mg (as ibuprofen lysine 684 mg).
- The other ingredients are: microcrystalline cellulose, povidone, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate, the coating (contains polyvinyl alcohol-partially hydrolyzed, titanium dioxide, macrogol and talc)

What Ibuprofen Lysine Tablets looks like and contents of the pack

White to off-white film coated capsule shaped tablets, debossed with S5 on one side and plain on other side.

A blister pack consisting of opaque, white polyvinyl chloride (PVC)/ polyvinylidene chloride (PvDc) laminate heat sealed to aluminium foil.

Pack size: 20 tablets

Or

A bottle pack consisting of high density polyethylene bottle with child resistant closure with wad having induction sealing liner. Outer shell embossed with Push down-CR logo.

Pack size: 10 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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