

**Package leaflet:
Information for the user
Ibuprofen Lysine 684 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 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).

What is in this leaflet

1. What Ibuprofen Lysine is and what it is used for
2. What you need to know before you take Ibuprofen Lysine
3. How to take Ibuprofen Lysine
4. Possible side effects
5. How to store Ibuprofen Lysine
6. Contents of the pack and other information

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

The active ingredient is ibuprofen. It belongs to a group of medicines known as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

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

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).

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

Do not take Ibuprofen Lysine if you:

- are allergic to ibuprofen, aspirin or other painkillers, or any of the other ingredients of this medicine (listed in section 6);
- have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, aspirin or similar medicines;
- have (or have had two or more episodes of) a stomach ulcer, gastrointestinal perforation or bleeding;
- have had stomach or intestinal bleeding or perforation when previously taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs);
- are taking other NSAID painkillers or more than 75 mg aspirin a day;
- have severe heart, kidney or liver problems;
- have bleeding of the brain (cerebrovascular bleeding) or other active bleeding;
- suffer from unclarified blood-formation disturbances;
- are severely dehydrated (caused by vomiting, diarrhoea or insufficient fluid intake);
- weigh less than 40 kg;
- are under 12 years of age;
- are in the last 3 months of pregnancy (see "Pregnancy and breast-feeding").

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.

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).

Talk to your doctor or pharmacist before taking Ibuprofen Lysine if you:

- have or have had asthma;
- have kidney, heart, liver or bowel problems;
- have high cholesterol or previously have had a heart attack or stroke;
- have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease);
- have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain skin changes and other organ disorders);
- are a smoker;
- 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 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);
- are elderly, as you may be more likely to suffer from side effects.

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 or if you have had previous stroke;
- 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.

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 general, the frequent use of painkillers can lead to lasting severe kidney problems. 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. Speak to your doctor if you feel unwell.

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

Children

Do not give this medicine to children under 12 years.

Other medicines and Ibuprofen Lysine

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

To reduce the risk of side effects, do not take this medicine with other NSAID medicines (such as aspirin, ibuprofen).

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)
- to stimulate your heart (such as digoxin) or treat high blood pressure (ACE-inhibitors, beta-blockers, angiotensin-II receptor antagonists)
- to help you passing water (diuretics)
- for the temporary suppression of your immune system (such as methotrexate, ciclosporine, tacrolimus)
- for mania or depression (such as lithium or SSRIs)
- for pregnancy termination (such as mifepristone)
- for HIV 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)

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.

Pregnancy

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.

Breast-feeding

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.

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

As side effects such as tiredness and dizziness may occur on use of Ibuprofen Lysine at higher dosage, the ability to react and take part actively in road traffic and to operate machines may be impaired in isolated cases. This applies to a greater extent in combination with alcohol. If you experience any 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

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. Take the lowest dose for the shortest time necessary to relieve your symptoms.

Adults and adolescents (12 years and above and with body weight 40 kg and above)

Take 1 tablet whole, with water, up to three times a day as required. If you have a sensitive stomach, take the tablets with food.

Leave at least six hours between doses. Do not take more than 3 tablets in 24 hours.

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.

Use in children

Do not give this medicine to children under 12 years of age.

If you take more Ibuprofen Lysine than you should

If you accidentally take too many tablets, contact your doctor or hospital immediately, even if you feel well.

The symptoms of an overdose include: nausea, stomach pain, vomiting, diarrhoea, stomach bleeding, ringing in the ears, headache, drowsiness, excitation, disorientation loss of consciousness, convulsions, kidney and liver damage.

If you forget to take Ibuprofen Lysine

Simply refer to the directions above on how to take the medicine and do not take more than is advised.

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 ibuprofen lysine can cause side effects, although not everybody gets them. 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.

- 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.

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, stomach pain, nausea, vomiting, 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)

- allergic reactions with skin rashes, itching and breathing problems
- headache, dizziness, sleeplessness, agitation, irritability and tiredness
- sight problems
- gastrointestinal ulcers, potentially with bleeding and perforation
- inflammation of the mouth and lips (ulcerative stomatitis)
- worsening of colitis and Crohn's disease
- gastritis
- 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

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 life-threatening 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 (lupus, mixed connective-tissue disease) appear to be predisposed.
- psychotic reactions, depression
- heart palpitations, heart failure, heart attack
- high blood pressure
- inflammation of the blood vessels (vasculitis)
- inflammation of the gullet (oesophagus), inflammation of the pancreas, 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 dysfunction or damage, particularly in long-term use, liver failure, acute inflammation of the liver (hepatitis)
- severe skin reactions with bullous eruptions 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)
- lessening of urine excretion and increased build-up of tissue fluid (oedema), particularly in patients with high blood pressure or impaired kidney function;
- kidney damage (nephrotic syndrome, interstitial nephritis that may be accompanied by acute renal insufficiency)

Not known

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.

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 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

Keep this medicine out of the sight and reach of children.

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 store above 25°C.

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 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 glycollate type A, colloidal silicon dioxide, magnesium stearate, purified water, isopropyl alcohol, Opadry II White 85F18422 (contains polyvinyl alcohol-partially hydrolyzed, titanium dioxide, poly ethylene glycol and talc) and Opacode Black S-1-17823 (shellac, iron oxide black, N-butyl alcohol, propylene glycol and ammonium hydroxide).

What Ibuprofen Lysine looks like and contents of the pack

White to Off-white, film-coated, capsule-shaped tablet, imprinted with "S5" in black on one face.

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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