

Space for Pharma code

Package leaflet: Information for the user

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 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

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 or 2 tablets 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 6 tablets in 24 hours.

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

130 x 650 mm

Front Page

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