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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
- 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

information

- 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

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 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

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:

at higher than recommended doses you

are at risk of serious harms. These

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
- 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 had previous stroke;

- have heart problems or if you
- 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").

ibuprofen).

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 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, betablockers, angiotensin-II receptor antagonists) to help you passing water (diuretics)
- for the temporary suppression of your immune system (such as methotrexate, ciclosporine,
- for mania or depression (such as lithium or SSRIs) for pregnancy termination (such as mifepristone)
- for HIV treatment (such as zidovudine)

tacrolimus)

- 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

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

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 belongs to a group of

decomposition products pass into breast

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

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. It

symptoms.

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

Do not take for more than 5 days (3

doctor tells you to.

days in case of migraine) unless your

130 x 650 mm

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depending upon the folding dimension or as per machine requirements.

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 have taken more tablets than you should, or if children have taken 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, vomiting (may

be blood streaked), gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, headache, confusion and shaky eye movement. Also agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), 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. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

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 if you notice any of the following: Liver, kidney problems or difficulty

- 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 lightheadedness.

seek immediate medical help if you signs of intestinal bleeding such

STOP TAKING the medicine and

- 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
- 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
- various skin rashes Rare (may affect up to 1 in 1,000

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gastritis

people)

ringing in the ears (tinnitus) kidney tissue damage (papillary

- 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 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.

provide more information on the safety of this medicine. 5. How to store Ibuprofen Lysine

By reporting side effects you can help

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.

information What Ibuprofen Lysine contains

6. Contents of the pack and other

The active substance is ibuprofen (as ibuprofen lysine). Each

film-coated tablet contains the active ingredient ibuprofen 200 mg (as ibuprofen lysine 342 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 "S4" 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: 8, 12, 16 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 Strides Pharma UK limited Unit 4, The Metro Centre,

Dwight Road, Watford, WD18 9SS, United Kingdom

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