

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 or 2 tablets up to three times a day as required.

Leave at least six hours between two doses. Do not take more than 6 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 overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, 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 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 tablets, 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 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 (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 200 mg (as ibuprofen lysine 342 mg).
- The other ingredients are: microcrystalline cellulose, povidone, sodium starch glycollate, 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 tablet, debossed with S4 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: 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

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United Kingdom

This leaflet was last revised in: 09/2024.



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MFG. LOCATION: PONDY

Non Printing Colours

ARTWORK DETAIL LABEL

Product	Ibuprofen Lysine Tablets 342mg			
Buyer/Country	SPUK	Component	Pack Insert	
Dimension	140 x 600 mm	Pack	—	
New Item Code	1051236	Old Item Code	1049884	
Colour Shades	BLACK	No. of Colours	1	

Change Control No.	PC-PYF/2024/266 - Record Number: 432935	Artwork Version	10.0
Design/Style	Front & Back Printing. To be supplied in the folded size of 140 x 35 mm. Product name and Pharma code shall be appeared at front side after final folding.		
Substrate	40 GSM Bible Paper		
Special Instructions	Printing clarity to be clear & sharp.		
Autocartanator Requirements	NA		

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**