

- fever
- excessive sweating
- swelling in face and throat as a result of allergy
- loss of appetite
- impotence
- swelling around your face, especially around mouth (tongue and/or throat and/or difficulty in swallowing) or rashes with breathing difficulty (angioedema)
- Very rare side effects (may be observed in more than one in 10000 patients):**
- agranulocytosis (reduction in the number of white blood cells)
- pancytopenia (reduction in the number of all blood cells)
- colitis (bowel inflammation)
- inflammation in mouth
- Stevens Johnson Syndrome (inflammation characterized with blood blisters, swelling and redness on skin and around the eye)
- toxic epidermal necrolysis (a serious disease characterized with bullous lesions on skin)
- anaphylactic shock (a sudden hypersensitivity reaction)
- increase in levels of lipid substances known as cholesterol and triglyceride
- hyponatremia (low sodium concentration in the blood)
- Frequency not known (frequency cannot be estimated from the available data):**
- hypomagnesemia (low magnesium levels in the blood)

Reporting of side effects

Talk with your doctor, pharmacist or nurse if you experience any side effect that is included or not included in this patient information leaflet. Also, report the side effects you have encountered, to Turkish Pharmacovigilance Center (TUFAM) via clicking “Drug Side Effect Report” icon on www.titck.gov.tr or via calling the side effect report line on 0800 314 00 08. By reporting experienced side effects, you will be contributing in obtaining more information regarding the safety of your drug.

If you encounter any side effect that is not included in this patient information leaflet, inform your doctor or pharmacist.

5. How to store LANZOL

Keep out of the sight and reach of children and in its original package.

Store at room temperature below 25°C by protecting from light and moisture.

Use in line with the expiry date

Do not use LANZOL after the expiry date indicated on the package.

Do not throw away drugs that have expired or are not being used! Give them to the collection system determined by the Ministry of Environment and Urbanism.

This patient information leaflet was approved on 30.05.2015.

PATIENT INFORMATION LEAFLET

LANZOL 30 mg enteric coated micropellet capsule

It is taken orally.

Active substance: Lansoprazole 30 mg

Excipients: Contains mannitol (E421), sucrose, sodium lauryl sulfate, disodium hydrogen phosphate, calcium carbonate, sodium carboxy methyl cellulose, hydroxy propyl methyl cellulose (E464), hydroxy propyl methyl cellulose phthalate, cetyl alcohol, titanium dioxide (E171), sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), yellow iron oxide (E172), gelatin (E441) (bovine gelatin).

Read this LEAFLET carefully before you start to use the medicine. It contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please consult your doctor or pharmacist.*
- *This medicine is prescribed for you personally. Do not give it to others.*
- *During the use of this medicine, when you visit a doctor or a hospital, tell your doctor that you are using this medicine.*
- *Follow the directives in this leaflet strictly. Do not use higher or lower dose of the medicine than the one recommended to you.*

In this patient information leaflet:

1. **What LANZOL is and what it is used for**
2. **What you need to know before you take LANZOL**
3. **How to take LANZOL**
4. **Possible side effects**
5. **How to store LANZOL**

Topics are included.

1. What LANZOL is and what it is used for

- The active substance in LANZOL is lansoprazole. One enteric coated micropellet capsule contains 30 mg active substance. Lansoprazole is included in a drug group called proton pump inhibitor. Proton pump inhibitors reduce the amount of acid secreted by the stomach.
- LANZOL consist of micropellets in opaque yellow-white capsules. LANZOL is presented for use in packages containing 14 or 28 capsules. The capsule contains gelatin that is obtained from bovine.
- LANZOL inhibits acid secretion of the gastric cells of stomach. It is used for;
- Treatment and prevention of duodenal and stomach ulcers,
- Treatment of inflammation in oesophagus (reflux oesophagitis),
- Treatment of duodenal and stomach ulcers derived from *Helicobacter pylori* infection,
- Treatment and prevention of ulcers caused by medicines called Non-Steroidal Anti-Inflammatory Drugs (such as aspirin, ibuprofen, ketoprofen and piroxicam),
- Treatment of gastroesophageal reflux disease (stomach acid comes up from the stomach into the esophagus and causes inflammation)
- Prevention of acid hypersecretion in stomach (pathological hypersecretion conditions including Zollinger-Ellison Syndrome).

2. What you need to know before you take LANZOL

DO NOT TAKE LANZOL in following situations

If you are;

- allergic (hypersensitive) to lansoprazole or any of the other ingredients in the capsule,
- taking anti-viral medicine called atazanavir (used in the treatment of HIV).

TAKE LANZOL WITH SPECIAL CARE in following situations

If you;

- have serious liver disease (the doctor may have to adjust the dosage),
- are pregnant or planning to become pregnant,
- are breast-feeding or planning to breast-feed,
- have low levels of magnesium in your blood,
- experience diarrhea during the treatment.

Before starting stomach ulcer treatment with LANZOL, possibility of malign stomach cancer should be evaluated.

Taking a proton pump inhibitor like lansoprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Serum chromogranin A (CgA) levels, which proposed as markers for diagnosis of endocrine (hormonal) tumors in blood, increase due to drug-induced decreases in gastric acidity. The increased CgA level may cause false positive results in diagnostic investigations for neuroendocrine tumors (cancers between nervous system and endocrine system). To eliminate such situation, lansoprazole treatment should temporarily be stopped and the test should be repeated in the same laboratory.

LANZOL might be expected to increase gastric counts of bacteria which are normally present in the gastrointestinal tract and may lead to a increased risk of gastrointestinal infections.

If these cautions are valid for you, even for a period in the past, please consult your doctor.

Taking LANZOL with food and drinks

LANZOL should be taken on empty stomach.

Pregnancy

Please consult your doctor or pharmacist before using the medicine.

It is not recommended to use LANZOL during pregnancy. If you realize that you are pregnant during the treatment, please consult your doctor or pharmacist immediately.

Breast-feeding

Please consult your doctor or pharmacist before using the medicine.

It is not recommended to use LANZOL during breast-feeding period.

Driving and using machines

Side effects such as dizziness, tiredness, feeling of sickness, headache and visual disturbances may occur in patients taking LANZOL. In this case, driving and using machines should be avoided.

Important information about some of the excipients of LANZOL

LANZOL contains sucrose. If you have been told by your doctor previously that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

LANZOL might have a slight laxative (stool softener) effect due to the excipients mannitol.

LANZOL contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate. Therefore, it can cause allergic reactions (probably delayed).

Taking with other medicines

The medicines which could be affected due to LANZOL administration are listed below. Tell your doctor if you are taking any of the following medicines:

- Atazanavir (used to treat HIV)
- Theophylline (used to treat lung disorders such as asthma)
- Ketoconazole, itraconazole, rifampicin (used to treat infections)
- Digoxin (used to treat heart diseases)
- Tacrolimus (used to prevent transplant rejection)
- Fluvoxamine (used to treat depression and other psychiatric diseases)
- St John’s wort (Hypericum perforatum) (used to treat mild depression)
- Antacids (used to treat heartburn or indigestion)
- Sucralfate (used to treat ulcers)

If you are using a prescribed or non-prescribed medicine currently, or have used recently, please inform your doctor or pharmacist about these.

3. How to take LANZOL

Instructions for proper use and dose/dosing intervals:

- If you are taking LANZOL once a day, have it at the same time before breakfast.
- If you are taking LANZOL twice a day, you should have the first dose before the breakfast and the second dose in the evening.

Treatment of stomach ulcer:

Once a day 30 mg enteric coated micropellet capsule for 4 weeks.

Treatment of duodenal ulcer:

Once a day 30 mg enteric coated micropellet capsule for 2 weeks.

Treatment of reflux oesophagitis:

Once a day 30 mg enteric coated micropellet capsule for 4 weeks.

Prevention of reflux oesophagitis:

Once a day 15 mg enteric coated micropellet capsule.

Treatment of Non-Steroidal Anti-Inflammatory Drugs (NSAID) related duodenal and benign stomach ulcer in patients requiring continued NSAID treatment:

Once a day 30 mg enteric coated micropellet capsule for 4 weeks.

Prevention of NSAID related duodenal and stomach ulcer in patients under risk (aged > 65 years old or with a history of stomach or duodenal ulcer) requiring continued NSAID treatment:

Once a day 15 mg enteric coated micropellet capsule.

Treatment of gastroesophageal reflux disease:

Once a day 15 mg or 30 mg enteric coated micropellet capsule for 4 weeks.

Zollinger-Ellison syndrome:

The recommended initial dose is 60 mg once a day. This dose should be individually adjusted up to 180 mg/day.

Treatment of ulcers caused by Helicobacter pylori:

The recommended lansoprazole dose is two 30 mg/day enteric coated micropellet capsules in combination with following antibiotics for 7 days:

- 250-500 mg clarithromycin twice a day + 1000 mg amoxicillin twice a day
- 250 mg clarithromycin twice a day + 400-500 mg metronidazole twice a day

Administration route and method:

Swallow the enteric coated micropellet capsule as a whole with a glass of water. Do not crush or chew the capsules.

Patients, who have trouble with swallowing the capsules, can use the capsules as followings according to studies and clinical administrations:

- Capsules are opened. Micropellets can either be mixed with plenty of water, apple/tomato juice or be spread over a soft food (eg. yogurt, apple pulp) and then, taken.
- Capsules are opened. Micropellets can be mixed with 40 ml of apple juice for application with nasogastric tube (when oral administration cannot be applied in individuals, especially who have difficulty in swallowing, feeding tube inserted from

nose through the stomach).

Medicine should be administered immediately after the mixture is prepared.

Micropellets should not be chewed or crushed. It is not recommended to use in other foods and liquids since it has not been studied clinically.

Various age groups:

Pediatric use:

It is not recommended to use in children.

Geriatric use:

If you are aged 65 years old or above, your doctor will continue the treatment by monitoring your values closely.

Special administration conditions:

Renal failure:

No dose adjustment is required in patients with renal failure.

Hepatic failure:

Patients with moderate or severe hepatic failure should be under close monitoring and daily dose should be reduced in half.

If you have the impression that the effect of LANZOL is either very potent or very weak, please talk to your doctor or pharmacist.

If you take more LANZOL than you should:

Your doctor will monitor you and apply treatment methods intended for your complaints.

If you used more LANZOL than you should, please talk to a doctor or pharmacist.

If you forget to take LANZOL:

If you are using the medicine regularly and forget to take a dose, take the missed dose as soon as you remember. If it is nearly time for your next dose, skip the missed dose. Take the remaining doses as normal.

Do not take double doses to make up the missed dose.

Possible effects after the discontinuation of LANZOL treatment:

No undesirable events are expected after the discontinuation of LANZOL. However, it is recommended that you should continue your treatment along the period recommended by your doctor to recover fully.

4. Possible side effects

As with all medicines, there may be side effects in the individuals who are sensitive to any of the ingredients of LANZOL.

The following side effects may occur as a result of using LANZOL.

Common side effects (may be observed less than one in 10 patients, but more than one in 100 patients):

- headache
- dizziness
- nausea
- diarrhea
- abdominal pain
- constipation
- vomiting
- gas
- dry mouth or throat
- increase in liver enzyme levels
- urticaria
- itching
- redness
- fatigue

Uncommon side effects (may be observed less than one in 100 patients, but more than one in 1000 patients):

- thrombocytopenia (decrease in thrombocyte count)
- an increase in blood cells called eosinophils (eosinophilia)
- a slight decrease in the number of white blood cells (leukopenia)
- depression
- joint pain
- muscle pain
- fracture of the hip, wrist or spine
- oedema

Rare side effects (may be observed in less than one in 1000 patients, but more than one in 10000 patients):

- anemia
- insomnia
- hallucinations
- confusions
- restlessness
- vertigo (dizziness due to balance disorder)
- paralyzing
- somnolence
- tremor
- visual impairment
- inflammation of tongue
- oesophageal candidiasis (a type of fungal infection)
- pancreatitis
- taste disorders
- hepatitis
- jaundice
- subcutaneous hemorrhages with dot patterns
- a condition characterized with hemorrhage in skin
- hair loss
- erythema multiforme (a hypersensitivity condition causing redness in hand, face and foot such as lace which is generally spontaneously healed)
- hypersensitivity to light or illumination
- nephritis accompanied with loss of appetite, excessive thirst, vomiting
- gynecomastia