

Package leaflet: Information for the user

Zomel 15 mg gastro-resistant capsules, hard

Zomel 30 mg gastro-resistant capsules, hard

lansoprazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

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

1. What Zomel is and what it is used for

The active ingredient in Zomel is lansoprazole, which is a proton pump inhibitor. Proton pump inhibitors reduce the amount of acid that your stomach makes.

Your doctor may prescribe Zomel for the following indications in adults:

- Treatment of duodenal and stomach ulcer
- Treatment of inflammation in your oesophagus (reflux oesophagitis)
- Prevention of reflux oesophagitis
- Treatment of heartburn and acid regurgitation
- Treatment of infections caused by the bacteria *Helicobacter pylori* when given in combination with antibiotic therapy
- Treatment or prevention of duodenal or stomach ulcer in patients requiring continued NSAID (nonsteroidal anti-inflammatory drugs) treatment (NSAID treatment is used against pain or inflammation)
- Treatment of Zollinger-Ellison syndrome

Your doctor may have prescribed Zomel for another indication or with a dose different from that which is written in this information leaflet. Please follow your doctor's instructions for taking your medicine.

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

2. What you need to know before you take Zomel

DO NOT take Zomel

- if you are allergic to lansoprazole or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Please tell your doctor if you have serious liver disease. The doctor may have to adjust your dosage.

Your doctor may perform or have performed an additional investigation called an endoscopy in order to diagnose your condition and/or exclude malignant disease.

If diarrhoea occurs during the treatment with Zomel contact your doctor immediately, as Zomel has

been associated with a small increase in infectious diarrhoea.

If your doctor has given you Zomel in addition to other medicines intended for the treatment of *Helicobacter pylori* infection (antibiotics) or together with anti-inflammatory medicines to treat your pain or rheumatic disease: please also read the package leaflets of these medicines carefully.

Taking a proton pump inhibitor like Zomel, 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 (reduced bone density) or if your doctor has told you that you are at risk of getting osteoporosis (for example, if you are taking steroids).

If you take Zomel on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Talk to your doctor before taking Zomel:

- If you have low vitamin B₁₂ levels or have risk factors for low vitamin B₁₂ levels and receive long-term treatment with lansoprazole. As with all acid reducing agents, lansoprazole may lead to a reduced absorption of vitamin B₁₂.
- If you are due to have a specific blood test (Chromogranin A)
- If you have ever had a skin reaction after treatment with a medicine similar to lansoprazole that reduces stomach acid.
- If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Zomel. Remember to also mention any other ill-effects like pain in your joints.
- Serious skin reactions [Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS)] have been reported in association with lansoprazole treatment. Stop using Zomel and seek medical attention immediately if you notice any of the symptoms described in section 4.
- When taking lansoprazole, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

Other medicines and Zomel

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

In particular tell your doctor or pharmacist if you are taking medicines containing any of the following active substances as Zomel may affect the way these medicines work:

- HIV protease inhibitors such as atazanavir and nelfinavir (used to treat HIV)
- methotrexate (used to treat autoimmune disease and cancer)
- ketoconazole, itraconazole, rifampicin (used to treat infections)
- digoxin (used to treat heart problems)
- warfarin ((used to treat blood clots)
- theophylline (used to treat asthma)
- tacrolimus (used to prevent transplant rejection)
- fluvoxamine (used to treat depression and other psychiatric diseases)
- antacids (used to treat heartburn or acid regurgitation)
- sucralfate (used for healing ulcers)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)

Zomel with food and drink

For the best results from your medicines you should take Zomel at least 30 minutes before food with a glass of water.

Pregnancy and breast-feeding

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.

Driving and using machines

Side effects such as dizziness, vertigo, tiredness and visual disturbances sometimes occur in patients taking Zomel. If you experience side effects like these you should take caution as your ability to react may be decreased.

You alone are responsible to decide if you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration. Because of their effects or undesirable effects, one of the factors that can reduce your ability to do these things safely is your use of medicines.

Descriptions of these effects can be found in other sections.

Read all the information in this leaflet for guidance.

Discuss with your doctor, nurse or pharmacist if you are unsure about anything.

Zomel contains sucrose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per hard capsule, that is to say essentially 'sodium-free'.

3. How to take Zomel

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the capsule whole with a glass of water. If you find the capsules difficult to swallow your doctor may advise on alternative ways to take your medicine. Do not crush or chew these capsules or the content of an emptied capsule because this will stop them from working properly.

If you are taking Zomel once a day, try to take it at the same time each day. You may get best results if you take Zomel first thing in the morning.

If you are taking Zomel twice a day, you should have the first dose in the morning and the second dose in the evening.

The dose of Zomel depends on your condition. The recommended doses of Zomel for adults are given below. Your doctor will sometimes prescribe you a different dose and will tell you how long your treatment will last.

Treatment of heartburn and acid regurgitation

One 15 mg or 30 mg capsule for 4 weeks. If symptoms persist you should report to your doctor. If your symptoms are not relieved within 4 weeks, please contact your doctor.

Treatment of duodenal ulcer

One 30 mg capsule every day for 2 weeks

Treatment of stomach ulcer

One 30 mg capsule every day for 4 weeks

Treatment of inflammation in your oesophagus (reflux oesophagitis)

One 30 mg capsule every day for 4 weeks

Long-term prevention of reflux oesophagitis

One 15 mg capsule every day, your doctor may adjust your dose to one 30 mg capsule every day

Treatment of infection of *Helicobacter pylori*

The recommended dose is one 30 mg capsule in combination with two different antibiotics in the morning and one 30 mg capsule in combination with two different antibiotics in the evening. Treatment will usually be every day for 7 days.

The recommended combinations of antibiotics are:

- 30 mg Zomel together with 250 – 500 mg clarithromycin and 1 000 mg amoxicillin
- 30 mg Zomel together with 250 mg clarithromycin and 400 – 500 mg metronidazole

If you are being treated for infection because you have an ulcer, it is unlikely that your ulcer will return if the infection is successfully treated. To give your medicine the best chance of working, take it at the right time and **do not miss a dose**.

Treatment of duodenal or stomach ulcer in patients requiring continued NSAID treatment

One 30 mg capsule every day for 4 weeks

Prevention of duodenal or stomach ulcer in patients requiring continued NSAID treatment

One 15 mg capsule every day, your doctor may adjust your dose to one 30 mg capsule every day.

Zollinger-Ellison syndrome

The recommended dose is two 30 mg capsules every day to start with, then depending on how you respond to Zomel the dose that your doctor decides is best for you.

Use in children

Zomel should not be given to children.

If you take more Zomel than you should

If you take more Zomel than you have been told to, seek medical advice quickly <or quickly consult the Toxicological Information Service>.

[To be completed nationally - Statement and phone number to be inserted based on national requirement for information on a toxicological service.]

If you forget to take Zomel

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. If this happens skip the missed dose and take the remaining capsules as normal. Do not take a double dose to make up for a forgotten capsule.

If you stop taking Zomel

Do not stop treatment early because your symptoms have got better. Your condition may not have been fully healed and may reoccur if you do not finish your course of treatment.

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 medicine can cause side effects, although not everybody gets them.

Stop using Zomel and seek medical attention immediately if you notice any of the following symptoms

- 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 (Stevens-Johnson syndrome, toxic epidermal necrolysis)
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)

Common (may affect up to 1 in 10 people)

- headache, dizziness
- diarrhoea, constipation, stomach pains, feeling or being sick, wind, dry or sore mouth or throat

- skin rash, itching
- changes in liver function test values
- tiredness
- benign polyps in the stomach

Uncommon (may affect up to 1 in 100 people)

- depression
- joint or muscle pain
- fluid retention or swelling
- changes in blood cell counts

Rare (may affect up to 1 in 1 000 people)

- fever
- restlessness, drowsiness, confusion, hallucinations, insomnia, visual disturbances, vertigo
- a change in the way things taste, loss of appetite, inflammation of your tongue (glossitis)
- skin reactions such as burning or pricking feeling under the skin, bruising, reddening and excessive sweating
- sensitivity to light
- hair loss
- feelings of ants creeping over the skin (paraesthesia), trembling
- anaemia (paleness)
- kidney problems
- pancreatitis
- inflammation of the liver (may be seen as yellow skin or eyes)
- breast swelling in males, impotence
- candidiasis (fungal infection, may affect skin or the mucosa)
- angioedema; You should see your doctor immediately if you experience symptoms of angioedema, such as swollen face, tongue or pharynx, difficulty to swallow, hives and difficulties to breath.

Very rare (may affect up to 1 in 10 000 people)

- severe hypersensitivity reactions including shock. Symptoms of a hypersensitivity reaction may include fever, rash, swelling and sometimes a fall in blood pressure.
- inflammation of your mouth (stomatitis)
- bowel inflammation (colitis)
- changes in test values such as sodium, cholesterol and triglyceride levels
- very severe skin reactions with reddening, blistering, severe inflammation and skin loss
- very rarely Zomel may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis).

Not known (frequency cannot be estimated from the available data)

- if you are on Zomel for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- low levels of sodium in the blood. Common symptoms include nausea and vomiting, headache, drowsiness and fatigue, confusion, muscle weakness or spasms, irritability, seizures, coma.
- rash, possibly with pain in the joints (subacute cutaneous lupus erythematosus)
- visual hallucinations

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:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zomel

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 blister and carton. The expiry date refers to the last day of that month.

Do not store above 30 °C. Store in the original package in order to protect from moisture.

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 Zomel contains

- The active substance is lansoprazole
- The other ingredients are maize starch, sucrose, sodium lauryl sulphate, meglumine, mannitol, hypromellose, macrogol 6000, talc, polysorbate 80, titanium dioxide (E171), purified water and methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 %.

The capsule shell contains gelatin, purified water and the following colours:

15 mg capsule: titanium dioxide (E171) and quinoline yellow (E104)

30 mg capsule: titanium dioxide (E171)

What Zomel looks like and contents of the pack

Zomel 15 mg Gastro-resistant capsules:

Opaque, yellow, hard gelatin capsule containing pellets with enteric coating. Each capsule contains 15 mg lansoprazole.

Zomel 15 mg gastro-resistant capsules are available in packs with 14, 28, 56 and 98 capsules.

Zomel 30 mg Gastro-resistant capsules:

Opaque, white, hard gelatin capsule containing pellets with enteric coating. Each capsule contains 30 mg lansoprazole.

Zomel 30 mg gastro-resistant capsules are available in packs with 7, 14, 28, 56, 60 and 98 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland.

The manufacturer is:

Laboratorios Liconsa, S.A., Avda. Miralcampo, No. 7 Polígono Industrial Miralcampo, 19200 Azuqueca de Henares, Spain.

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark:	Lansoprazol "Stada"
Estonia:	Lanzostad 15 mg Lanzostad 30 mg
Ireland:	Zomel 15 mg gastro-resistant capsules, hard Zomel 30 mg gastro-resistant capsules, hard
Italy:	Lansoprazolo EG

Latvia: Lanzostad
Lithuania: Lanzostad 15 mg skrandyje neiros kietos kapsulės
Lanzostad 30 mg skrandyje neiros kietos kapsulės

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