

Package Leaflet: Information for the patient

Omeprazol (als magnesium) Sandoz MUT 10 mg, maagsapresistente tabletten
Omeprazol (als magnesium) Sandoz MUT 20 mg, maagsapresistente tabletten
Omeprazol (als magnesium) Sandoz MUT 40 mg, maagsapresistente tabletten

Omeprazole

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

1. What [nationally completed name] is and what it is used for

[Nationally completed name] gastro-resistant tablets contains the active substance omeprazole. It belongs to a group of medicines called ‘proton pump inhibitors’. They work by reducing the amount of acid that your stomach produces.

[Nationally completed name] is used to treat the following conditions:

In adults:

- ‘Gastro-oesophageal reflux disease’ (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).

- Ulcers which are infected with bacteria called '*Helicobacter pylori*'. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). [Nationally completed name] can also be used to stop ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

In children:

Children over 1 year of age and ≥ 10 kg

- 'Gastro-oesophageal reflux disease' (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
In children, the symptoms of the condition can include the return of stomach contents into the mouth (regurgitation), being sick (vomiting) and poor weight gain.

Children over 4 years of age and adolescents

- Ulcers which are infected with bacteria called '*Helicobacter pylori*'. If your child has this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

2. What you need to know before you take [nationally completed name]

Do not take [Nationally completed name]

- if you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- if you are taking a medicine containing nelfinavir (for HIV infection).

Do not take [Nationally completed name] if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking [Nationally completed name].

Warnings and precautions

Talk to your doctor or pharmacist before taking [Nationally completed name].

[Nationally completed name] may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking [Nationally completed name] or while you are taking it, talk to your doctor straight away:

- You lose a lot of weight for no reason and have problems swallowing.
- You get stomach pain or indigestion.
- You begin to vomit food or blood.
- You pass black stools (blood-stained faeces).

- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.
- You have severe liver problems.
- You are due to have a specific blood test (Chromogranin A).
- You have ever had a skin reaction after treatment with a medicine similar to [nationally completed name] that reduces stomach acid.

If you take [Nationally completed name] 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.

When taking omeprazole, 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.

Taking a proton pump inhibitor like [nationally completed name], 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).

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 [nationally completed name]. Remember to also mention any other ill-effects like pain in your joints.

Children

Some children with chronic illnesses may require long-term treatment although it is not recommended. Do not give this medicine to children under 1 year of age or < 10 kg.

Other medicines and [nationally completed name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription. This is because [Nationally completed name] can affect the way some medicines work and some medicines can have an effect on [Nationally completed name].

Do not take [Nationally completed name] if you are taking a medicine containing **nelfinavir** (used to treat HIV infection).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus)
- Digoxin (used to treat heart problems)
- Diazepam (used to treat anxiety, relax muscles or in epilepsy)
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking [Nationally completed name]

- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking [Nationally completed name]
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infections)
- Tacrolimus (in cases of organ transplantation)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- Cilostazol (used to treat intermittent claudication)
- Saquinavir (used to treat HIV infection)
- Clopidogrel (used to prevent blood clots (thrombi))
- Erlotinib (used to treat cancer)
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your [nationally completed name] treatment.

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as [Nationally completed name] to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

[Nationally completed name] with food and drink

See section 3.

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.

Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used. Your doctor will decide whether you can take [Nationally completed name] if you are breast-feeding.

Driving and using machines

[Nationally completed name] is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

[Nationally completed name] gastro-resistant tablets contain glucose and sucrose

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

3. How to take [nationally completed name]

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

Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition and how old you are.

The recommended dose is given below:

Adults

To treat symptoms of GORD such as **heartburn and acid regurgitation**:

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is 20 mg once a day for 4 - 8 weeks. Your doctor may tell you to take a dose of 40 mg for a further 8 weeks if your gullet has not yet healed.
- The recommended dose once the gullet has healed is 10 mg once a day.
- If your gullet has not been damaged, the usual dose is 10 mg once a day.

To treat **ulcers in the upper part of the intestine** (duodenal ulcer):

- The recommended dose is 20 mg once a day for 2 weeks. Your doctor may tell you to take the same dose for a further 2 weeks if your ulcer has not yet healed.
- If the ulcers do not fully heal, the dose can be increased to 40 mg once a day for 4 weeks.

To treat **ulcers in the stomach** (gastric ulcer):

- The recommended dose is 20 mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your ulcer has not yet healed.
- If the ulcers do not fully heal, the dose can be increased to 40 mg once a day for 8 weeks.

To **prevent the duodenal and stomach ulcers** from coming back:

- The recommended dose is 10 mg or 20 mg once a day. Your doctor may increase the dose to 40 mg once a day.

To treat duodenal and stomach **ulcers caused by NSAIDs** (Non-Steroidal Anti-Inflammatory Drugs):

- The recommended dose is 20 mg once a day for 4 to 8 weeks.

To **prevent duodenal and stomach ulcers** if you are taking **NSAIDs**:

- The recommended dose is 20 mg once a day.

To treat **ulcers caused by *Helicobacter pylori*** infection and to stop them coming back:

- The recommended dose is 20 mg [Nationally completed name] twice a day for one week.
- Your doctor will also tell you to take two antibiotics among amoxicillin, clarithromycin and metronidazole.

To treat too much acid in the stomach caused by a **growth in the pancreas (Zollinger-Ellison syndrome)**:

- The recommended dose is 60 mg daily.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for.

Use in children and adolescents

To treat symptoms of GORD such as **heartburn and acid regurgitation**:

- Children over 1 year of age and with a body weight of more than 10 kg may take [Nationally completed name]. The dose for children is based on the child's weight and the doctor will decide the correct dose.

To treat **ulcers caused by *Helicobacter pylori* infection** and to stop them coming back:

- Children aged over 4 years may take [Nationally completed name]. The dose for children is based on the child's weight and the doctor will decide the correct dose.
- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child.

Taking this medicine

- It is recommended that you take your tablets in the morning.
- You can take your tablets with food or on an empty stomach.
- Swallow your tablets whole with half a glass of water. Do not chew or crush the tablets. This is because the tablets contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

What to do if you or your child have trouble swallowing the tablets

If you or your child have trouble swallowing the tablets:

- Break the tablet and disperse it in a spoonful of water (non-fizzy), any acidic fruit juice (e.g. apple, orange or pineapple) or apple sauce.
- Always stir the mixture just before drinking (the mixture will not be clear). Then drink the mixture straight away or within 15 minutes.
- To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. **Do not use** milk or fizzy water. The solid pieces contain the medicine - do not chew or crush them.

If you take more [Nationally completed name] than you should

If you take more [Nationally completed name] than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take [Nationally completed name]

If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking [Nationally completed name]

Do not stop taking [Nationally completed name] without first talking to your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

[20 mg, 40 mg gastro-resistant tablets only]

The 20 mg and 40 mg tablet can be divided into equal doses.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following rare but serious side effects, stop taking [Nationally completed name] and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be ‘Stevens-Johnson syndrome’ or ‘toxic epidermal necrolysis’.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

Other side effects include:

Common side effects (may affect up to 1 in 10 people)

- Headache.
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).
- Benign polyps in the stomach.

Uncommon side effects (may affect up to 1 in 100 people)

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as “pins and needles”, feeling sleepy.
- Spinning feeling (vertigo).
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.
- Fracture in the hip, wrist or spine.

Rare side effects (may affect up to 1 in 1,000 people)

- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.

- Suddenly feeling wheezy or short of breath (bronchospasm).
- Dry mouth.
- An inflammation of the inside of the mouth.
- An infection called “thrush” which can affect the gut and is caused by a fungus.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (interstitial nephritis).
- Increased sweating.

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

- Changes in blood count including agranulocytosis (lack of white blood cells).
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Muscle weakness.
- Enlarged breasts in men.

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

- Inflammation in the gut (leading to diarrhoea).
- If you are on [nationally completed name] 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 or 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.
- Rash, possibly with pain in the joints.

[Nationally completed name] may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medicine at this time.

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 listed in [Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

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 outer and inner pack after EXP. The expiry date refers to the last day of that month.

For HDPE containers, before first opening:

Do not store above 25 °C

For HDPE containers, after first opening:

Shelf life after first opening: 6 months

Do not store above 25 °C

Keep the container tightly closed, in order to protect from moisture.

For Aluminium/aluminium blister:

Do not store above 25 °C

For Aclar/aluminium blister:

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 to protect the environment.

6. Contents of the pack and other information

What [Nationally completed name] contains

The active substance is omeprazole (as omeprazole magnesium).

Each gastro-resistant tablet contains 10 mg omeprazole.

Each gastro-resistant tablet contains 20 mg omeprazole.

Each gastro-resistant tablet contains 40 mg omeprazole.

The other ingredients are:

Tablet core:

Sucrose, maize starch, liquid glucose, copovidone, povidone, talc, titanium dioxide (E 171), methacrylic acid-ethyl acrylate copolymer (1:1), glycerol monostearate, propylene glycol, stearic acid, polysorbate 80, simeticone, cellulose, microcrystalline, macrogol 6000, crospovidone, silica colloidal anhydrous, magnesium stearate

Tablet coating:

Hypromellose, macrogol 6000, titanium dioxide (E 171), talc, iron oxide, red (E 172)
Only for Omeprazole 10 mg and Omeprazole 40 mg: Iron oxide, yellow (E 172)

What [Nationally completed name] look like and contents of the pack

[Nationally completed name, 10 mg, gastro-resistant tablets]
Light pink oval film-coated tablet (11.2x5.8 mm).

[Nationally completed name, 20 mg, gastro-resistant tablets]
Pink, oval film-coated tablet with a breaking notch on both sides. The tablet can be divided into equal doses (14.2x7.2 mm).

[Nationally completed name, 40 mg, gastro-resistant tablets]
Reddish oval film-coated tablet with a score line on both sides. The tablet can be divided into equal doses (18.2x9.0 mm).

Pack sizes:

[Nationally completed name] is available in blister packs with 5, 7, 10, 14, 15, 20, 28, 30, 49, 50, 56, 60, 90, 98, 100 gastro-resistant tablets and in containers with 7, 14, 15, 28, 30, 56, 98, 100 gastro-resistant tablets

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland

Fabrikanten

Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

Lek Pharmaceuticals d.d.
Trimlini 2D
9220 Lendava
Slovenië

LEK S.A.
ul. Domaniewska 50 C
02-672 Warschau
Polen

Salutas Pharma GmbH
Otto-von-Guericke Allee 1

39179 Barleben
Duitsland

In het register ingeschreven onder:

Omeprazol (als magnesium) Sandoz MUT is in het register ingeschreven onder:
RVG 105000 Omeprazol (als magnesium) Sandoz MUT 10 mg
RVG 105001 Omeprazol (als magnesium) Sandoz MUT 20 mg
RVG 105002 Omeprazol (als magnesium) Sandoz MUT 40 mg

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland:

Omeprazol (als magnesium) Sandoz MUT 10 mg, maagsapresistente tabletten
Omeprazol (als magnesium) Sandoz MUT 20 mg, maagsapresistente tabletten
Omeprazol (als magnesium) Sandoz MUT 40 mg, maagsapresistente tabletten

Duitsland:

OMEPR[®] MUT[®] 10 mg magensaftresistente Tabletten
OMEPR[®] MUT[®] 20 mg magensaftresistente Tabletten
OMEPR[®] MUT[®] 40 mg magensaftresistente Tabletten

Ierland:

Romep

Luxemburg:

OMEPR[®] MUT[®] 10 mg magensaftresistente Tabletten
OMEPR[®] MUT[®] 20 mg magensaftresistente Tabletten
OMEPR[®] MUT[®] 40 mg magensaftresistente Tabletten

Deze bijsluiter is voor het laatst goedgekeurd in maart 2023.

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The following information is intended for healthcare professionals only:

Stomach tube administration for doctors:

If the patient is unable to swallow, the tablets can be dissolved in still water and administered via a stomach tube. It is important to ensure that the suitability of the selected syringe and tube is carefully verified.

Administration via a stomach tube

1. Put the tablet into an appropriate syringe and fill the syringe with approximately 25 ml water and approximately 5 ml air.

For some tubes, dispersion in 50 ml water is needed to prevent the pellets from clogging the tube.

2. Immediately shake the syringe for approximately 2 minutes to disperse the tablet.
3. Hold the syringe with the tip up and check that the tip has not clogged.
4. Attach the syringe to the tube whilst maintaining the above position.
5. Shake the syringe and position it with the tip pointing down. Immediately inject 5-10 ml into the tube. Invert the syringe after injection and shake it. Keep the syringe tip pointed upward as this will avoid clogging.
6. Turn the syringe with the tip down and immediately inject another 5-10 ml into the tube. Repeat this procedure until the syringe is empty.
7. Fill the syringe with 25 ml water and 5 ml air and repeat step 5 if necessary to wash down any sediment left in the syringe. Some tubes will require 50 ml water.