

PACKAGE LEAFLET: INFORMATION FOR THE USER

Romep 10 mg Gastro-Resistant Capsules
 Romep 20 mg Gastro-Resistant Capsules
 Romep 40 mg Gastro-Resistant Capsules

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

1 What Romep is and what it is used for

Romep 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.

Romep is used to treat the following conditions:

In adults:

- ‘Gastro-esophageal reflux disease’ (GERD). 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). Romep 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-Ellisson syndrome).

In children:

Children over 1 year of age and ≥ 10 kg

- ‘Gastro-esophageal reflux disease’ (GERD). 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 and adolescents over 4 years of age

- 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 Romep

Do not take Romep

- 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 (used to treat HIV infection).

If you are not sure, talk to your doctor or pharmacist before taking Romep.

Warnings and precautions

Romep may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Romep 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.

If you take Romep 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.

Taking a proton pump inhibitor like Romep, 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).

Other medicines and Romep

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Romep can affect the way some medicines work and some medicines can have an effect on Romep.

Do not take Romep 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 Romep
- 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 Romep
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infection)
- 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 Romep treatment

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

Romep with food and drink

You can take your capsules with food or on an empty stomach.

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 for advice before taking this medicine. Your doctor will decide whether you can take Romep during this time.

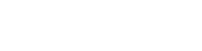
Your doctor will decide whether you can take Romep if you are breast-feeding.

Driving and using machines

Romep 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.

Romep contains lactose

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



3 How to take Romep

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

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

The usual doses are given below.

Adults

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

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the usual 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 usual 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 usual 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 ulcer does 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 usual dose is 20 mg once daily 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 ulcer does 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 usual 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 usual dose is 20 mg once a day for 4-8 weeks.

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

- The usual dose is 20 mg once daily.

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

- The usual dose is 20 mg Romep 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 usual 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.

Children:

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

- Children over 1 year of age and with a body weight of more than 10 kg may take Romep. 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 Romep. 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 capsules in the morning.
- You can take your capsules with food or on an empty stomach.
- Swallow your capsules whole with half a glass of water. Do not chew or crush the capsules. This is because the capsules contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the coated pellets.

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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 Romep 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).

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 Romep 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.

Romep 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Romep

Keep out of reach and sight of children.

Do not use Romep after the expiry date which is stated on carton, label, blister.

The expiry date refers to the last day of the month.

10 mg and 20 mg:

In-use shelf life in HDPE bottles

3 months

Do not store above 25°C.

Store in the original package in order to protect from light and moisture.

Keep the tablet container tightly closed

Bottle: Keep the bottle tightly closed.

40 mg:

Do not store above 30°C.

Store in the original package in order to protect from moisture.

Bottle: Keep the bottle tightly closed.

Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Romep Gastro-Resistant Capsules contain:

The active substance is omeprazole.

Each gastro-resistant capsule, hard contains 10 mg, 20 mg or 40 mg of omeprazole.

10 mg and 20 mg:

The other ingredients are:

Granules:

low-substituted hydroxypropyl cellulose, microcrystalline cellulose, lactose anhydrous, Povidone, Polysorbate 80, talc, magnesium oxide, methacrylic acid copolymer dispersion type C, triethyl citrate, magnesium stearate.

Capsule shell:

Cap and body Romep 10 mg:

gelatine, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172).

Cap and body Romep 20 mg:

gelatine, titanium dioxide (E171).

Printing ink: shellac, propylene glycol, ammonium hydroxide, black iron oxide (E172) or shellac, black iron oxide (E172), propylene glycol, strong ammonia solution, potassium hydroxide.

40 mg:

The other ingredients are:

Capsule content: low-substituted hydroxypropyl cellulose, microcrystalline cellulose, lactose anhydrous, croscarmellose sodium, Povidone (K 25), Polysorbate 80, hypromellose phthalate, dibutyl sebacate, talc.

Capsule shell

Cap and body Romep 40 mg: carrageenan, potassium chloride, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172),

hypromellose.

Printing ink: shellac, propylene glycol, ammonium hydroxide, potassium hydroxide, black iron oxide (E172).

What Romep Gastro-Resistant Capsules look like and contents of the pack

Romep 10 mg Gastro-Resistant Capsules:

Light brown cap, light brown body, each imprinted with “OME 10” containing white to beige coated pellets (granules).

Romep 20 mg Gastro-Resistant Capsules:

White cap, white body, each imprinted with “OME 20” containing white to beige coated pellets (granules).

Romep 40 mg Gastro-Resistant Capsules:

White cap, light brown body, each imprinted with “OME 40” containing dull yellowish brown granules.

Pack sizes:

Romep 10 mg Gastro-Resistant Capsules:

Blister: 7, 14 and 28 gastro-resistant capsules, hard.

White plastic tablet container with tamper-evident screw cap with (integrated) dessicant: 14 and 28 gastro-resistant capsules, hard

Romep 20 mg & 40 mg Gastro-Resistant Capsules:

Blister: 7, 14 and 28 gastro-resistant capsules, hard

White plastic tablet container with tamper-evident screw cap with (integrated) dessicant: 7, 14 and 28 gastro-resistant capsules, hard.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing authorisation holder:

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers:

Lek Pharmaceuticals d.d., Verovškova 57, 1526

Ljubljana, Slovenia.

LEK S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Salutas Pharma GmbH, Dieselstrasse 5, 70839

Gerlingen, Germany.

S.C. Sandoz S.R.L., Str. Livezeni nr. 7A, RO-540472

Targu-Mures, Romania.

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

United Kingdom: Omeprazole 10 mg Gastro-resistant Capsules

Omeprazole 20 mg Gastro-resistant

Capsules

Omeprazole 40 mg Gastro-resistant

Capsules

Spain Omeprazol Bexalabs 10 mg cápsulas

duras EFG

Omeprazol Bexalabs 20 mg cápsulas

duras EFG

Omeprazol Bexalabs 40 mg cápsulas

duras EFG

Ireland Romep 10 mg Gastro-Resistant

Capsules

Romep 20 mg Gastro-Resistant

Capsules

Romep 40 mg Gastro-Resistant

Capsules

Italy OMEPRAZOLO HEXAL A/S 10 mg

capsule rigide gastroresistenti

OMEPRAZOLO HEXAL A/S 20 mg

capsule rigide gastroresistenti

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