

Romep MUT 10 mg Gastro-resistant tablets

Romep MUT 20 mg Gastro-resistant tablets

Romep MUT 40 mg Gastro-resistant tablets

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

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1 What Romep MUT is and what it is used for

Romep MUT gastro-resistant tablets contain 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 MUT 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 MUT 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-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 MUT

Do not take Romep MUT

- 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).

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

Warnings and precautions

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

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

Do not take Romep MUT 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 MUT.
- 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 MUT.
- 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 Romep MUT treatment.

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Romep MUT 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 MUT with food and drink

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

Pregnancy and breast-feeding

Before taking Romep MUT, tell your doctor if you are pregnant or trying to get pregnant. Your doctor will decide whether you can take Romep MUT during this time.

Your doctor will decide whether you can take Romep MUT if you are breastfeeding.

Driving and using machines

Romep MUT 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 MUT 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 medicinal product.

3 How to take Romep MUT

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 tablets 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 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 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 to 8 weeks.

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

- The usual dose is 20 mg once a day.

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

- The usual dose is 20 mg Romep MUT 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 MUT. 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 MUT. 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 Romep MUT than you should

If you take more Romep MUT than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take Romep MUT

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.

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 MUT 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.
- Inflammation in the gut (leading to diarrhoea).

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.
- Dyspepsia (indigestion).

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

- If you are on Romep MUT 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 MUT 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.

Tel: +353 1 6764971, Fax: +353 1 6762517,

Website: www.imb.ie,

e-mail: imbpharmacovigilance@imb.ie

5 How to store Romep MUT

Keep out of the reach and sight of children.

Do not use Romep MUT 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.

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 MUT 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 Romep MUT 10 mg and Romep MUT 40 mg: Iron oxide, yellow (E 172)

What Romep MUT look like and contents of the pack

Romep MUT 10 mg Gastro-resistant tablets
Light pink oval film-coated tablet (11.2x5.8 mm).

Romep MUT 20 mg Gastro-resistant tablets
Pink, oval film-coated tablet with a breaking notch on both sides. The tablet can be divided into equal halves (14.2x7.2 mm).

Romep MUT 40 mg Gastro-resistant tablets
Reddish oval film-coated tablet with a score line on both sides. The tablet can be divided into equal halves (18.2x9.0 mm).

Pack sizes:

Romep MUT 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.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

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

Manufacturers

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

Salutas Pharma GmbH, Dieselstrasse 5, 70839 Gerlingen, Germany.

Lek Pharmaceuticals d.d, Verovškova 57, 1526 Ljubljana, Slovenia.

Lek Pharmaceuticals d.d., Trimlini 2 D, 9220 Lendava, Slovenia.

Lek SA., ul. Domaniewska 50, 02-672

Warszawa, Poland.

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

NL	Omeprazol (als magnesium) Sandoz MUT 10mg, maagsapresistente tabletten Omeprazol (als magnesium) Sandoz MUT 20mg, maagsapresistente tabletten Omeprazol (als magnesium) Sandoz MUT 40mg, maagsapresistente tabletten
DE	OMEPR [®] MUT [®] 10mg magensaftresistente Tabletten OMEPR [®] MUT [®] 20mg magensaftresistente Tabletten OMEPR [®] MUT [®] 40mg magensaftresistente Tabletten
IE	Romep MUT 10mg Gastro-resistant tablets Romep MUT 20mg Gastro-resistant tablets Romep MUT 40mg Gastro-resistant tablets
LU	OMEPR [®] MUT [®] 10mg magensaftresistente Tabletten OMEPR [®] MUT [®] 20mg magensaftresistente Tabletten OMEPR [®] MUT [®] 40mg magensaftresistente Tabletten

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I.M. L/348a+b+c 11-13

Article no

Artwork Checklist

Artwork Checklist	Job Description	Version Number	Size	Inks	ACCF					
	Romep MUT PIL	2	130x630	Colour						black
	Market	Proof Date	Cutter Ref.	Front						
	IM	10/12/2013	N/A	Back						