

Emazole 20 mg Gastro-Resistant Tablets Emazole 40 mg Gastro-Resistant Tablets

Esomeprazole

ROWEX[®]

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

1. What Emazole is and what it is used for

Emazole contains a medicine called esomeprazole. This belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Emazole is used to treat the following conditions:

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 stomach or upper part of the gut (intestine) that 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.
- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Emazole can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).
- Prolonged treatment after prevention of rebleeding of ulcers with intravenous Emazole.

Adolescents aged 12 years and above

- '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 stomach or upper part of the gut (intestine) that 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.

2. What you need to know before you take Emazole

Do not take Emazole

- if you are **allergic** to esomeprazole or any of the other ingredients of this medicine (listed in section 6)
 - if you are **allergic** to similar medicines with active substance names ending in '-prazole' (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole)
 - if you are taking medicines containing the active substance **nelfinavir**, a medicine to treat HIV infection.
- Do not take Emazole if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Emazole.

Warnings and precautions

Talk to your doctor before taking Emazole:

- if you have severe liver problems
- if you have severe kidney problems
- 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 Emazole 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 Emazole. Remember to also mention any other ill-effects like pain in your joints.

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

If you have been prescribed Emazole "on demand" you should contact your doctor if your symptoms continue or change in character.

Taking a proton pump inhibitor like Emazole, 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).

Children

Emazole is not recommended for children under 12 years of age, as insufficient data exists.

Other medicines and Emazole

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is because Emazole can affect the way some medicines work and some medicines can have an effect on Emazole.

Do not take Emazole if you are taking a medicine containing nelfinavir (used to treat HIV).

The following medicines can influence or be influenced by Emazole:

- **atazanavir**, a medicine to treat HIV infection
- **ketoconazole**, **itraconazole**, or **voriconazole**, medicines to treat fungal infections.
If necessary, the doctor will adjust the Emazole dose for patients treated continuously, and patients with severely reduced liver functions.
- **erlotinib** (used to treat cancer)
- medicines that are metabolised by a specific enzyme such as
 - **diazepam**, a sedative to calm and induce sleep
 - **citalopram**, **imipramine**, **clomipramine**, medicines to treat depression
 - **phenytoin**, a medicine to treat epilepsy and certain pain conditions.
 If necessary, your doctor must reduce the dose of these medicines, particularly during occasional use. If you take phenytoin, your doctor will monitor phenytoin levels in your blood, particularly when beginning or ending Emazole treatment.
- **warfarin**, **phenprocoumon**, **acenocoumarol**, medicines used to prevent normal blood clotting. Your doctor will monitor blood clotting values, particularly when beginning or ending Emazole treatment.
- **cilostazol** (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply)
- **cisapride**, a medicine to treat stomach and bowel problems
- **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 Emazole treatment
- **rifampicin**, an antibiotic (used for treatment of tuberculosis)
- **St. John's wort**, an herbal treatment for depression
- **digoxin**, a medicine to treat different heart conditions
- **clopidogrel**, used to prevent atherothrombotic events (e.g. a heart attack or stroke)
- **tacrolimus** used to prevent rejection after organ transplantation.

If your doctor has prescribed the antibiotics **amoxicillin** and **clarithromycin** as well as Emazole to treat ulcers caused by *Helicobacter pylori* infection, it is very

important that you tell your doctor about any other medicines you are taking.

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.

• **Pregnancy**

Your doctor will decide whether you can take Emazole during this time.

• **Breast-feeding**

It is not known if Emazole passes into breast milk. Therefore, you should not take Emazole if you are breast-feeding.

Driving and using machines

Emazole is not likely to affect you being able to drive or use any tools or machines. However, side effects such as dizziness and blurred vision may uncommonly or rarely occur (see section 4). If affected, you should not drive or use machines.

Emazole contains 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 Emazole

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

- Emazole is not recommended for children less than 12 years old.
- If you are taking this medicine for a long time, your doctor will want to monitor you (particularly if you are taking it for more than a year).
- If your doctor has told you to take this medicine as and when you need it, tell your doctor if your signs of illness change.

How much to take

- Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition, how old you are and how well your liver works.
- The usual doses are given below.

Adults

To treat heartburn caused by gastro-oesophageal reflux disease (GORD):

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the usual dose is one Emazole 40 mg gastro-resistant tablet once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your gullet has not yet healed.
- The usual dose once the gullet has healed is one Emazole 20 mg gastro-resistant tablet once a day.
- If your gullet has not been damaged, the usual dose is one Emazole 20 mg gastro-resistant tablet each day. Once the condition has been controlled, your doctor may tell you to take your medicine as and when you need it, up to a maximum of one Emazole 20 mg gastro-resistant tablet each day.
- If you have severe liver problems, your doctor may give you a lower dose.

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

- The usual dose is one Emazole 20 mg gastro-resistant tablet twice a day for one week.
- Your doctor will also tell you to take antibiotics for example amoxicillin and clarithromycin.

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

- The usual dose is one Emazole 20 mg gastro-resistant tablet once a day for 4 to 8 weeks.

To prevent stomach ulcers if you are taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- The usual dose is one Emazole 20 mg gastro-resistant tablet once a day.

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

- The usual dose is one Emazole 40 mg gastro-resistant tablet twice a day.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for. The maximum dose is 80 mg twice a day.

Prolonged treatment after prevention of rebleeding of ulcers with intravenous Emazole:

The usual dose is one Emazole 40 mg tablet once a day for 4 weeks.

Adolescents (12 years or older)

To treat heartburn caused by gastro-oesophageal reflux disease (GORD):

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the usual dose is one Emazole 40 mg gastro-resistant tablet once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your gullet has not yet healed.
- The usual dose once the gullet has healed is one Emazole 20 mg gastro-resistant tablet once a day.
- If your gullet has not been damaged, the usual dose is one Emazole 20 mg gastro-resistant tablet each day. Once the condition has been controlled, your doctor may tell you to take your medicine as and when you need it, up to a maximum of one Emazole 20 mg gastro-resistant tablet each day.
- If you have severe liver problems, your doctor may give you a lower dose.

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

- The usual dose is one Emazole 20 mg gastro-resistant tablet twice a day for one week.
- Your doctor will also tell you to take antibiotics for example amoxicillin and clarithromycin.

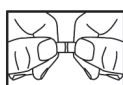
Taking this medicine

- You can take your tablets at any time of the day.
- You can take your tablets with food or on an empty stomach.
- Swallow your tablets whole with a drink 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.

Emazole 40 mg

Tablet dividing instruction

The tablet can be divided into equal doses. Divide the tablet as illustrated in this figure:



What to do if you have trouble swallowing the tablets

- If you have trouble swallowing the tablets:
 - Put them into a glass of still (non-fizzy) water. Do not use any other liquids.
 - Stir until the tablets break up (the mixture will not be clear). Then drink the mixture straight away or within 15 minutes. Always stir the mixture just before drinking it.
 - 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. The solid pieces contain the medicine - do not chew or crush them.
- If you cannot swallow at all, the tablet can be mixed with some water and put into a syringe. It can then be given to you through a tube directly into your stomach ('gastric tube').

If you take more Emazole than you should

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

If you forget to take Emazole

- 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.

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If you stop taking Emazole

Always take the prescribed dose for as long as your doctor prescribed. Interrupting or stopping treatment without your doctor's advice might reduce the success of your therapy.

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.

If you notice any of the following serious side effects, stop taking this medicine 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) (rare: may affect up to 1 in 1,000 people).
- Reddening of the skin with blisters or peeling. There may also be severe blisters, bleeding in the lips, eyes, mouth, nose and genitals or high fever and joint pains. This could be 'Erythema multiforme', 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis' (very rare: may affect up to 1 in 10,000 people).
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems (very rare: may affect up to 1 in 10,000 people).
- This medicine 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 medication at this time (very rare: may affect up to 1 in 10,000 people).
- Severe liver problems leading to liver failure and a disease of the brain, which may cause you to become confused or behave strangely, and/or feel drowsy (encephalopathy) (very rare: may affect up to 1 in 10,000 people).

Other side effects include:

Common, 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, may affect up to 1 in 100 people

- swollen hands, ankles or feet
- sleeplessness
- dizziness
- needles and pins sensation
- sleepiness
- dry mouth
- changes in blood tests that check how the liver is working
- itching
- skin rash
- lumpy rash (hives)
- fracture of the hip, wrist or spine (if this medicine is used in high doses and over long duration)
- spinning feeling (vertigo).

Rare, 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)
- low levels of sodium in the blood (this may cause weakness, being sick (vomiting) and cramps) feeling agitated, confused or depressed
- taste changes
- blurred vision
- suddenly feeling wheezy or short of breath (constriction of the airways)
- inflammation of the mouth lining
- an infection called "thrush" which can affect the gut and is caused by a fungus
- hair loss
- skin rash on exposure to sunshine
- joint or muscle pain
- generally feeling unwell
- increased sweating.

Very rare, may affect up to 1 in 10,000 people

- equal lack of white and red blood cells and blood platelets
- aggression
- seeing, feeling or hearing things that are not there (hallucinations)
- muscle weakness
- severe kidney problems
- breast enlargement in men.

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

- If you are taking this medicine 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, 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.
- Inflammation in the gut (microscopic colitis) leading to diarrhoea
- Rash, possibly with pain in the joints.

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 Emazole

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 carton and the blister or bottle after EXP. The expiry date refers to the last day of that month.

Aluminium/aluminium blisters and aclar/aluminium blisters:

Do not store above 25°C.

For HDPE bottles:

Storage conditions before opening of the HDPE bottle: Do not store above 30°C.

Storage conditions after first opening of the HDPE bottle: Do not store above 30°C.

Shelf life after first opening of the bottle: 6 months.

Keep the container tightly closed 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 Emazole contains

Emazole 20 mg gastro-resistant tablet:

- The active substance is esomeprazole. Each gastro-resistant tablet contains 20 mg esomeprazole (as magnesium dihydrate).
- The other ingredients are:

Tablet core: sucrose, maize starch, liquid glucose, hydroxypropylcellulose, povidone, talc, titanium dioxide (E171), methacrylic acid-ethyl acrylate copolymer (1:1), glycerol monostearate, propylene glycol, stearic acid, polysorbate 80, simethicone, microcrystalline cellulose, macrogol 6000, crospovidone, silica colloidal anhydrous, magnesium stearate.

Tablet coating: hypromellose, macrogol 6000, titanium dioxide (E171), talc, red and yellow iron oxide (E172).

Emazole 40 mg gastro-resistant tablet:

- The active substance is esomeprazole. Each gastro-resistant tablet contains 40 mg esomeprazole (as magnesium dihydrate).
- The other ingredients are:

Tablet core: sucrose, maize starch, liquid glucose, hydroxypropylcellulose, povidone, talc, titanium dioxide (E171), methacrylic acid-ethyl acrylate copolymer (1:1), glycerol monostearate, propylene glycol, stearic

acid, polysorbate 80, simethicone, microcrystalline cellulose, macrogol 6000, crospovidone, silica colloidal anhydrous, magnesium stearate.

Tablet coating: hypromellose, macrogol 6000, titanium dioxide (E171), talc, red iron oxide (E172).

What Emazole looks like and contents of the pack

Emazole 20 mg are light pink oval film-coated tablets. Emazole 40 mg are pink oval film-coated tablet with a score-line on both sides. The tablet can be divided into equal doses.

Emazole are available in blister packs with 7, 14, 15, 28, 30, 56, 60, 90, 98, 100 and 100x1 gastro-resistant tablets and in HDPE bottles with 7, 14, 15, 28, 30, 56, 60, 90, 98, 100 and 250 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, Dieselstr. 5, 70839 Gerlingen, Germany.

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

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

S.C. Sandoz S.R.L., 4 and 7A Livezeni Street, 540472, Targu Mures, Mures County, Romania.

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

Denmark: Esomeprazol Hexal

Austria: Esomeprazol Hexal 20 mg – magensaftresistente Tabletten

Ireland: Emazole 20 mg Gastro-Resistant Tablets

Denmark: Esomeprazol Hexal

Austria: Esomeprazol Hexal 40 mg – magensaftresistente Tabletten

Ireland: Emazole 40 mg Gastro-Resistant Tablets

This leaflet was last revised in 02/2017.

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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.