

Package leaflet: Information for the user

Emazole Control 20 mg Gastro-Resistant Tablets

Esomeprazole

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

Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet

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

1. What Emazole Control is and what it is used for

Emazole Control 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.

This medicine is used in adults for the short-term treatment of reflux symptoms (for example, heartburn and acid regurgitation).

Reflux is the backflow of acid from the stomach into the gullet ("foodpipe") which may become inflamed and painful. This may cause you symptoms such as a painful sensation in the chest rising up to your throat (heartburn) and a sour taste in the mouth (acid regurgitation).

Emazole Control is not meant to bring immediate relief. You may need to take the tablets for 2-3 days in a row before you feel better. 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 Emazole Control

Do not take Emazole Control

- 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 Control if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Emazole Control.

Warnings and precautions

Talk to your doctor before taking Emazole Control:

- if you have jaundice (yellowing of skin or eyes) or severe liver problems
- if you have severe kidney problems
- if you have had a stomach ulcer or stomach surgery in the past
- if you have been taking treatment continuously for reflux or heartburn for 4 or more weeks
- if you are aged over 55 years and have new or recently changed reflux symptoms or need to take a non-prescription indigestion or heartburn remedy treatment every day
- if you have ever had a skin reaction after treatment with a medicine similar to Emazole Control that reduces stomach acid.

Rash and skin symptoms

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 Control. Remember to also mention any other ill-effects like pain in your joints.

Serious skin rashes have occurred in patients taking esomeprazole (see also section 4). The rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes often come after flu-like symptoms such as fever, headache, body ache. The rash may cover large parts of the body with blistering and peeling of the skin.

If at any time during the treatment (even after several weeks) you develop a rash or any of these skin symptoms, stop taking this medicine and contact your doctor immediately.

Tell your doctor before taking this medicine, if:

- You are due to have an endoscopy or a urea breath test.
- You are due to have a specific blood test (Chromogranin A)

Emazole Control may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you start taking Emazole Control 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 have severe or persistent diarrhoea; esomeprazole has been associated with a small increased risk of infectious diarrhoea
- 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 Control. Remember to also mention any other ill-effects like pain in your joints.

Seek urgent medical attention if you experience chest pain with light-headedness, sweating, dizziness or shoulder pain with shortness of breath. This could be a sign of a serious condition with your heart.

Taking a proton pump inhibitor like Emazole Control, 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 and adolescents:

Emazole Control is not recommended for children under 18 years of age.

Other medicines and Emazole Control

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

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

The following medicines can influence or be influenced by Emazole Control:

- **atazanavir**, a medicine to treat HIV infection
- **ketoconazole, itraconazole, or voriconazole**, medicines to treat fungal infections.
If necessary, the doctor will adjust the Emazole Control 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 conditionsIf 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 Control treatment.
- **warfarin, phenprocoumon, acenocoumarol**, medicines used to prevent normal blood clotting. Your doctor will monitor blood clotting values, particularly when beginning or ending Emazole Control 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 Control 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.

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 Control during this time.
- **Breast-feeding**
It is not known if esomeprazole passes into breast milk. Therefore, you should not take Emazole Control if you are breastfeeding.

Driving and using machines

Emazole Control 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 Control 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 Control

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

- Emazole Control is not recommended for children less than 18 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

- The recommended dose is one tablet a day.
- Do not take more than this recommended dose of one tablet (20 mg) a day, even if you don't feel an improvement immediately.
- You may need to take the tablets for 2 or 3 days in a row before your reflux symptoms (for example, heartburn and acid regurgitation) get better.
- The treatment length is up to 14 days.
- When your reflux symptoms have completely gone, you should stop taking this medicine.
- If your reflux symptoms get worse or do not improve after taking this medicine for 14 days in a row, you should consult a doctor.

If you have persistent or longstanding, frequently recurring symptoms even after treatment with this medicine, you should contact your doctor.

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.

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 Control than you should

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

If you forget to take Emazole Control

- 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 Emazole Control

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).
- Sudden onset of a severe rash or reddening of the skin with blisters or peeling may occur even after several weeks of treatment. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. The skin rashes may develop into serious widespread skin damage (peeling of the epidermis and superficial mucous membranes) with life threatening consequences. This could be 'erythema multiforme', 'Stevens-Johnson syndrome', 'toxic epidermal necrolysis' or 'drug reaction with eosinophilia and systemic symptoms' (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).

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)
- 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, drug reaction with eosinophilia and systemic symptoms)
- 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 HPRC 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 Emazole Control

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 Control contains

Emazole Control 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, simeticone, 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).

What Emazole looks like and contents of the pack

Emazole Control 20 mg are light pink oval film-coated tablets.

Emazole Control are available in blister packs with 7, 14 & 28 gastro-resistant tablets and in HDPE bottles with 7, 14 gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowa Pharmaceuticals Ltd., Newtown, 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.

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FURTHER HELPFUL INFORMATION

What are the symptoms of heartburn?

The normal symptoms of reflux are a painful sensation in the chest rising up to your throat (heartburn) and a sour taste in the mouth (acid regurgitation).

Why do you get these symptoms?

Heartburn can be a result of eating too much, eating high fat food, eating too quickly and drinking lots of alcohol. You may also notice that when you lie down, that your heartburn gets worse. If you are overweight or smoke you increase the probability of suffering from heartburn.

What can I do to help relieve my symptoms?

- Eat healthier food and try to avoid spicy and fatty foods and large meals late before bedtime.
- Avoid fizzy drinks, coffee, chocolate and alcohol.
- Eat slowly and eat smaller portions.
- Try to lose weight.
- Stop smoking.

When should I seek advice or help?

- You should seek urgent medical advice if you experience chest pain with light-headedness, sweating, dizziness or shoulder pain with shortness of breath.
- If you experience any of the symptoms detailed in Section 2 of this leaflet and it advises you to talk to your doctor or pharmacist
- If you are suffering from any of the side effects detailed in Section 4 which require medical attention.