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# ESOZ

(Esomeprazole Magnesium Gastro Resistant Tablets 40 mg)

Consumer Medication Information Leaflet (RiMUP)

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This leaflet answers some common questions about **ESOZ**.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking **ESOZ** against the benefits it is expected to have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

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## What ESOZ is used for

**ESOZ** is used to treat the following conditions:

- ‘Gastroesophageal 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. It also helps to stop reflux oesophagitis from coming back or relapsing.
- A rare condition where the stomach produces large amounts of acid, much more than in ulcers or reflux disease (Zollinger-Ellison syndrome).
- Prevention of rebleeding of ulcers following treatment with esomeprazole IV solution by intravenous infusion.

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## How ESOZ works

**ESOZ** contains a medicine called esomeprazole. Esomeprazole is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach to

relieve symptoms and allow healing to take place. This does not stop food being digested in the normal way.

**Ask your doctor if you have any questions about why ESOZ has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This product is available in 40 mg strength.

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## Before you use ESOZ

**When you must not use it**

**If you have an allergy to:**

- Esomeprazole or any ingredient of **ESOZ** listed at the end of this leaflet (see **Product Description**)
- Any medicines derived from benzimidazole (eg. proton-pump inhibitors)

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**If you have been taking medicines used to treat HIV (atazanavir, nelfinavir)**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.** If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine talk to your doctor.**

**Before you start to use it**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A).**

**Tell your doctor if you have or have had any of the following medical conditions:**

- any problems with your liver or kidney(s)
- persistent vomiting or vomiting of blood or dark stool, unintentional weight loss, difficulty in swallowing. Your doctor may perform an additional investigation in order to diagnose your condition and/or exclude cancer
- if you have been told by your doctor that you are at increased risk of fractures due to weakness of bones (osteoporosis)

You may have a risk to develop bacterial infections in the stomach or gut as this medicine suppresses acid in the stomach.

If you are planning to have a diagnostic test for neuroendocrine tumors. Your doctor will recommend you to temporarily stop esomeprazole for at least five days before the test. As use of esomeprazole may change the results.

If you have low body store or are at risk of developing reduced vitamin B<sub>12</sub> absorption, inform your doctor. As use of esomeprazole may decrease the absorption of vitamin B<sub>12</sub>.

If you have been prescribed **ESOZ** “on demand” you should contact your doctor if your symptoms continue or change in character.

If you are taking **ESOZ** or like medicines from a long time (more than 3 months), there may be a decrease of magnesium in your body (symptoms includes fatigue, muscle spasms, severe confusion, convulsions, dizziness and unusual heart beat). In case you are taking medicines for heart diseases (digoxin) or water pills (diuretics) which would further decrease the magnesium levels in your body.

Your doctor may monitor magnesium levels before starting the treatment

with this medicine and during the treatment.

### ***Pregnancy and Lactation***

**Do not take ESOZ if you are pregnant or breast-feeding unless your doctor says so. Ask your doctor about the risks and benefits involved.**

**Tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding currently.**

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

**If you have not told your doctor about any of the above, tell this before you start taking ESOZ**

### ***Taking other medicines***

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and ESOZ may interfere with each other. These include:

- nelfinavir, atazanavir (medicines for HIV treatment)
- ketoconazole, itraconazole and voriconazole (medicines used to treat fungal infections)
- cisapride (used for indigestion and heartburn)
- diazepam (a medicine used to treat anxiety and some other conditions)
- phenytoin (a medicine used to treat epilepsy)
- citalopram, clomipramine or imipramine (medicines used to treat depression)
- clarithromycin, amoxicillin (a medicine used to treat bacterial infections)
- warfarin (a medicine used to prevent blood clots)
- cilostazol (a medicine used in the alleviation of the symptoms of intermittent claudication in individuals with peripheral vascular disease)
- tacrolimus (medicine used in organ transplant rejection)
- digoxin (used for heart disease)

- erlotinib (a medicine used to treat cancer)
- clopidogrel (used to inhibit blood clots)
- methotrexate (a medicine used to treat arthritis and some types of cancer)
- rifampicin (used for treatment of tuberculosis)
- iron containing products (used as health tonic or for treatment & prevention of anemia)
- St. John's wort (*Hypericum perforatum*) [used to treat depression].

These medicines may be affected by ESOZ, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ESOZ.

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### **How to use ESOZ**

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**Follow all directions given to you by your doctor or pharmacist carefully.** They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the pack ask your doctor or pharmacist for help.**

### ***How much to use***

The dose of ESOZ is usually 40 mg a day depending on what condition you are being treated for and how severe it is.

### ***Children***

Esomeprazole should not be used in children younger than 12 years.

### ***Liver problems***

If you have liver problems, your doctor will decide the right dose for you.

### ***How to use it***

Always take ESOZ exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow ESOZ whole with a glass of water. **Do not crush or chew the tablets.**

If the tablets are chewed or crushed they will not work properly.

**If you have difficulty swallowing the tablets:**

1. Place the tablet in half a glass of non-carbonated water. Mineral water or other liquids are not suitable.
2. Gently mix the tablet and water by stirring, taking care not to crush the tablet.
3. Stir until the tablet dissolves into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets.
5. Rinse the glass with half a glass of water and drink.

**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').**

### ***When to use it***

You can take your tablets at any time of the day with food or on an empty stomach.

Try to take your daily dose at about the same time each day. Keeping a regular time for taking ESOZ will help to remind you to take it.

### ***How long to use it***

Keep taking ESOZ for as long as your doctor recommends.

If you are taking this medicine for a long time, your doctor will want to monitor you. Tell your doctor about any new symptoms or any other exceptional circumstances.

### ***If you forget to use it***

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally. Do not take a double dose to make up for the dose you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

### ***If you use too much (overdose)***

**Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ESOZ. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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#### **While you are using ESOZ**

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**Keep all of your doctor's appointments so that your progress can be checked.**

#### *Things you must do*

**Take ESOZ exactly as your doctor has prescribed.**

Continue taking ESOZ every day as directed by your doctor, even if you have no symptoms.

**If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking ESOZ.**

**Tell your doctor if you are pregnant, planning to become pregnant or are breastfeeding.**

If your symptoms return or your condition gets worse while taking ESOZ, tell your doctor immediately.

**If you need to have any medical tests while you are taking ESOZ, tell your doctor.** It may affect the results of some tests.

#### *Things you must not do*

**Do not take ESOZ to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine because you are feeling better, unless advised by your doctor.**

#### *Things to be careful of*

ESOZ is not likely to affect the ability to drive or use any tools or machines. However, esomeprazole may cause dizziness or blurred vision in some

patients. Make sure you know how you react to ESOZ before you drive a car or operate any machinery.

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#### **Side Effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ESOZ.**

This medicine helps most people with reflux disease, peptic ulcers or Zollinger Ellison syndrome but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**When you are taking this medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor. Please tell your doctor promptly if you get any of the symptoms below:**

- Rash (especially in areas exposed to the sun), possibly with pain in the joints. (Subacute Cutaneous Lupus Erythematosus, SCLE)
- Fever, extreme tiredness, pus/blood in urine.
- Involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate
- Fracture in the hip, wrist or spine.
- Watery stool, stomach pain and fever that do not go away
- Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioral changes).

- a) Subacute Cutaneous Lupus Erythematosus (SCLE) Frequency "not known"
- b) Interstitial Nephritis Kidney problems (interstitial nephritis)
- c) Hypomagnesaemia Frequency "not known": Low levels of magnesium can also lead to a

reduction in potassium or calcium levels in the blood.

- d) Fracture Frequency "uncommon": Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- e) Clostridium Difficile Diarrhea Severe diarrhoea which may be caused by an infection (Clostridium difficile) in your intestines.
- f) Fundic Gland Polyps (Benign) Frequency "Common": Benign polyps in the stomach
- g) Vitamin B12 Deficiency Proton pump inhibitors may cause vitamin B12 deficiency.

**Do not be alarmed by the following list of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

#### Serious side effects

**If any of the following happens, stop taking ESOZ and tell your doctor immediately or go to the casualty/emergency department at your nearest hospital immediately.**

- Rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (anaphylaxis, angioedema).
- Irregular red patches on the skin of the hands and arms (erythema multiforme)
- Severe skin disease with painful red areas, large blisters and ends with peeling of layers of skin. It is accompanied by fever and chills, aching muscles and generally feeling unwell (toxic epidermal necrolysis)
- Rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson syndrome)

#### Other side effects

**Tell your doctor if you notice any of the following:**

- headache
- constipation
- wind (flatulence)
- feeling sick (nausea)/vomiting

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

