

## **Esomeprazole Magnesium gastro-resistant granules for oral suspension, sachet 10mg/20mg/40mg Taj Pharma**

### **Package leaflet: Information for the patient**

(Esomeprazole Magnesium)

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

## **1. What Esomeprazole Magnesium is and what it is used for**

Esomeprazole Magnesium contains a substance called esomeprazole. This belongs to a group of medicines called proton pump inhibitors. These

work by reducing the amount of acid that your stomach produces.

Esomeprazole Magnesium is used to treat the following conditions:

*Children over 1 year of age*

Esomeprazole Magnesium is used to treat a condition called “gastroesophageal reflux disease” (GERD).

- This is where acid from the stomach escapes into the gullet (esophagus) causing pain, inflammation and heartburn. Heartburn is a burning feeling rising from the stomach or lower chest up towards the neck.
- 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 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 Esomeprazole Magnesium**

### **Do not take Esomeprazole Magnesium :**

- If you are allergic to esomeprazole or other similar proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole), or any other ingredients of this medicine (listed in section 6).
- If you are taking a medicine containing nelfinavir (used to treat HIV infection).

Do not take Esomeprazole Magnesium if any of the above apply to you. If you are not sure, talk

to your doctor or pharmacist before taking Esomeprazole Magnesium .

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Esomeprazole Magnesium :

- If you have severe liver problems.
- If you have severe kidney problems.
- If you have ever had a skin reaction after treatment with a medicine similar to Esomeprazole Magnesium that reduces stomach acid.
- If you are due to have a specific blood test (Chromogranin A).

Esomeprazole Magnesium may hide the symptoms of other diseases. **Therefore, if any of the following happen to you while you are taking Esomeprazole Magnesium , you should talk to your doctor immediately:**

- You lose a lot of weight for no reason.
- You get stomach pain or indigestion.
- You begin to vomit repeatedly.
- You have problems swallowing.
- You vomit blood or pass black (blood-stained) motions (faeces).

If you have been prescribed Esomeprazole Magnesium “on demand” you should contact your doctor if the symptoms are persistent or change character. “On demand” treatment has not been investigated in children and is therefore not recommended in this patient group.

Taking a proton pump inhibitor like Esomeprazole Magnesium , 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).

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 Esomeprazole Magnesium . Remember to

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

### **Other medicines and Esomeprazole Magnesium**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines that you buy without a prescription. This is because Esomeprazole Magnesium can affect the way some medicines work and some medicines can have an effect on Esomeprazole Magnesium .

Do not take Esomeprazole Magnesium if you are taking nelfinavir (used to treat HIV infection).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Atazanavir (used to treat HIV infection).
- Clopidogrel (used to prevent blood clots).
- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).
- Erlotinib (used to treat cancer).
- Diazepam (used to treat anxiety or relax muscles).
- Citalopram, imipramine or clomipramine (used to treat depression).
- Phenytoin (used in epilepsy).
- Warfarin or coumarin (medicines called anticoagulants that are used to thin your blood).
- Cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply).
- Cisapride (used for indigestion and heartburn).
- Digoxin (used for heart 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 Esomeprazole Magnesium treatment.
- Tacrolimus (organ transplantation).

- Rifampicin (used for treatment of tuberculosis).
- St. John's wort (*Hypericum perforatum*) (used to treat depression).

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

#### **Esomeprazole Magnesium gastro-resistant granules with food and drink**

Esomeprazole Magnesium gastro-resistant granules can be taken with or without food.

#### **Pregnancy, breast-feeding and fertility**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will decide whether you can take Esomeprazole Magnesium during this time.

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

#### **Driving and using machines**

Esomeprazole Magnesium is not likely to affect you being able to drive or use 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.

#### **Esomeprazole Magnesium contains sucrose and glucose**

Esomeprazole Magnesium contains sucrose and glucose which are both types of sugars. Careful oral hygiene and regular tooth brushing are therefore important. If you have been told by your doctor, that you have an intolerance to some sugars, contact your doctor before taking Esomeprazole Magnesium .

### **3. How to take Esomeprazole Magnesium**

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

Your medicine comes as granules in individual sachets. Each sachet contains 10 mg of esomeprazole. Your doctor will tell you how many sachets to take each day. He or she will also tell you how long you should take them for.

- Empty the contents of the sachet or sachets into a glass containing some water. Do not use fizzy (carbonated) water. The amount of water depends on the number of sachets that your doctor has told you to take at one time.
- Use 15 millilitres (ml) of water (3 teaspoonfuls) for each sachet. This means that you will need 15 ml for one sachet and 30 ml for two sachets.
- Stir the granules in the water.
- Leave the mixture for a few minutes until it has thickened.
- Stir again and drink the mixture. The granules must not be chewed or crushed. Do not leave the mixture to stand for more than 30 minutes before you drink it.
- If anything remains in the glass, add some more water, stir and drink it immediately.

Esomeprazole Magnesium gastro-resistant granules can be taken with or without food.

If you are being fed using a feeding (gastric) tube, your doctor or nurse can give you Esomeprazole Magnesium through your tube. Information for your doctor or nurse is provided at the end of this leaflet.

#### **The recommended doses are given below:**

##### **Use in children aged 1 to 11 years**

- Esomeprazole Magnesium is not recommended for children younger than 1 year.

To treat gastroesophageal reflux disease (GERD)

- The recommended dose is one sachet (10 mg) or two sachets (20 mg) once daily. The dose for children is based on the child's weight and the doctor will decide the correct dose.

**Use in children aged 4 years and older**

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

- The dose for children is based on the child's weight and your doctor will decide the correct dose. The doctor will also prescribe two antibiotics for your child.

**Use in adults and adolescents**

Esomeprazole Magnesium oral suspension may also be used by patients having difficulty swallowing dispersed Esomeprazole Magnesium gastro-resistant tablets. Information on dosing for patients from the age of 12 years is in Esomeprazole Magnesium gastro-resistant tablet product information (ask your doctor or pharmacist if you require further information).

**Elderly**

There is no need to alter the dose if you are elderly.

**People with liver problems**

- For people with severe liver problems, the maximum daily dose of Esomeprazole Magnesium is two sachets (20 mg). For children 1-11 years with severe liver problems, a maximum dose of 10 mg should not be exceeded.

**People with kidney problems**

- There are no special dosage restrictions for people with kidney problems. However, if you have severe kidney problems your doctor may decide to carry out regular tests.

**If you take more Esomeprazole Magnesium than you should**

If you have taken more Esomeprazole Magnesium than prescribed by your doctor, seek medical advice.

**If you forget to take Esomeprazole Magnesium**

If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then. Do not take a double dose to make up for the forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Allergic reactions**

A severe allergic reaction (anaphylaxis) is a rare side effect, affecting less than 1 in 1,000 people taking Esomeprazole Magnesium. You may notice sudden wheezing, swelling of your face or body, rash, fainting or difficulties in swallowing. **If this happens to you, stop taking Esomeprazole Magnesium and contact a doctor immediately.**

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)

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as “pins and needles”, feeling sleepy.
- Spinning feeling (vertigo).
- Dry mouth.
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Fracture of the hip, wrist or spine (if Esomeprazole Magnesium is used in high doses and over long duration).

**Rare** (may affect up to 1 in 1,000 people)

- Blood problems such as a reduced number of white cells or platelets.
- Low levels of sodium in the blood.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- An inflammation of the inside of the mouth.
- An infection called “thrush” which can affect the gut and is caused by a fungus.
- Hepatitis with or without jaundice
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Generally feeling unwell and lacking energy.
- Increased sweating.

**Very rare** (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.
- Severe kidney problems.
- Enlarged breasts in men.

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

- If you are on Esomeprazole Magnesium 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 or 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.
- Inflammation in the gut (leading to diarrhoea).
- Rash, possibly with pain in the joints.

Esomeprazole Magnesium 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.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

## 5. How to store Esomeprazole Magnesium

This medicinal product does not require any special storage conditions.

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and sachet after EXP. The expiry date refers to the last day of that month.
- The reconstituted suspension should be used within 30 minutes.

Do not throw away any medicines 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 Esomeprazole Magnesium gastro-resistant granules for oral suspension contains

The active substance is esomeprazole.

- a) Each packet contains:  
Esomeprazole (as magnesium trihydrate) 10mg  
Excipients q.s.
- b) Each packet contains:  
Esomeprazole (as magnesium trihydrate) 20mg  
Excipients q.s.
- c) Each packet contains:  
Esomeprazole (as magnesium trihydrate) 40mg  
Excipients q.s.

The other ingredients are:

*Esomeprazole granules:*

Glycerol monostearate, Hydroxypropyl cellulose, Hypromellose, Magnesium stearate, Methacrylic acid – ethyl acrylate copolymer (1:1) 30% dispersion, Polysorbate, Sugar spheres (sucrose and maize starch), Talc, Triethyl citrate

*Excipient granules:*

Citric acid anhydrous (for pH adjustment), Crospovidone, Glucose, Hydroxypropyl cellulose, Yellow iron oxide, Xanthan gum.

### What Esomeprazole Magnesium looks like and contents of the pack

Each sachet of Esomeprazole Magnesium contains fine granules.

Each carton contains 28 or 30 sachets. Not all pack sizes may be marketed.

### 7. MANUFACTURED IN INDIA BY: TAJ PHARMACEUTICALS LTD.

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