

## Package Leaflet: Information for the user

### **Esomeprazole 20 mg gastro-resistant tablets** **Esomeprazole 40mg gastro-resistant tablets** esomeprazole

**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 Esomeprazole gastro-resistant tablets are and what they are used for
2. What you need to know before you take Esomeprazole gastro-resistant tablets
3. How to take Esomeprazole gastro-resistant tablets
4. Possible side effects
5. How to store Esomeprazole gastro-resistant tablets
6. Contents of the pack and other information

#### **1. What Esomeprazole Gastro-resistant Tablets are and what they are used for**

Esomeprazole Tablets 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.

Esomeprazole is used to treat the following conditions

Adults and young people 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 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.

Adults

- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Esomeprazole Tablets can also be used to stop stomach ulcers or ulcers in the upper part of the gut (intestine) 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 Esomeprazole.

#### **2. What you need to know before you take Esomeprazole Gastro-resistant Tablets**

##### **Do not take Esomeprazole Gastro-resistant tablets**

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

Do not take Esomeprazole gastro-resistant Tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Esomeprazole gastro-resistant Tablets.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Esomeprazole gastro-resistant tablets

- if you have severe liver problems.
- if you have severe kidney problems.
- If you have low vitamin B12 level in your body or are at risk of developing it.

Esomeprazole gastro-resistant Tablets may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you start taking Esomeprazole gastro-resistant Tablets 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 Esomeprazole gastro-resistant Tablets “on demand” you should contact your doctor if your symptoms continue or change in character.

Inform your doctor if you are going to have a laboratory examination for cancer (CgA measurement). Your doctor will advise you to stop taking this medicine for at least five days before going for this test.

Taking a proton pump inhibitor like Esomeprazole, 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 Esomeprazole gastro-resistant tablets**

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

Do not take Esomeprazole gastro-resistant tablets if you are taking a medicine containing **nelfinavir** (used to treat HIV).

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

- Atazanavir (used to treat HIV)
- Clopidogrel (used to prevent blood clots)
- Ketoconazole, itraconazole or voriconazole, used to treat infections caused by a fungus)
- Erlotinib (used to treat cancer)
- Citalopram, imipramine or clomipramine (used to treat depression).
- 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 Esomeprazole Tablets.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking Esomeprazole Tablets.
- 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 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 Tablets 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**

Before taking Esomeprazole Tablets, tell your doctor if you are pregnant or trying to get pregnant. As your doctor or pharmacist for advice before taking any medicine. Your doctor will decide whether you can take Esomeprazole Tablets during this time. It is not known if Esomeprazole passes into breast milk. Therefore, you should not take Esomeprazole Tablets if you are breast-feeding.

### **Esomeprazole gastro-resistant tablets with food and drink**

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

### **Driving and using machines**

Esomeprazole tablets is not likely to affect you being able to drive or use any tools or machines.

Esomeprazole gastro-resistant tablets contains sucrose, which is a type of sugar.

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 Esomeprazole Gastro-resistant Tablets**

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

- Esomeprazole gastro-resistant tablets are 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 symptoms change.

### **Methods and routes of administration**

- 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 30 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').

#### **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.

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

##### **Adults and children aged 12 years or above:**

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the usual dose is one Esomeprazole 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 Esomeprazole 20 mg gastro-resistant tablet once a day
- If your gullet has not been damaged, the usual dose is one Esomeprazole 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 Esomeprazole 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:**

- Adults and young people aged 12 or above: the usual dose is one Esomeprazole 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):**

- Adults aged 18 and above: the usual dose is one Esomeprazole 20 mg gastro-resistant tablet once a day for 4 to 8 weeks.

#### **To prevent stomach ulcers or ulcers in the upper part of the gut (intestine) if you are taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):**

- Adults aged 18 and above: the usual dose is one Esomeprazole 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):**

- Adults aged 18 and above: the usual dose is Esomeprazole 40 mg 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 esomeprazole:**

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

#### **If you take more Esomeprazole gastro-resistant tablets than you should**

If you take more Esomeprazole gastro-resistant Tablets than prescribed by your doctor, talk to your doctor or pharmacist straight away.

#### **If you forget to take Esomeprazole gastro-resistant tablets**

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 (two doses at the same time) to make up for a forgotten tablet

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 Esomeprazole Tablets 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.

These effects are rare, affecting less than 1 in 1,000 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)**

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dry mouth.
- 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.
- Fracture of the hip, wrist or spine (if Esomeprazole gastro-resistant Tablets 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. 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.
- 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.
- 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).
- 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 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)

Esomeprazole 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.

Do not be concerned by this list of possible side effects. You may not get any of them.

#### **Reporting of side effects**

##### 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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Esomeprazole Gastro-resistant Tablets**

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 blister and carton after {Exp}. The expiry date refers to the last day of that month.

Store below 30°C.

Store in the original package (blister) 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 Esomeprazole gastro-resistant tablets contain**

The active substance is esomeprazole

20mg: Each tablet contains 20 mg esomeprazole (as esomeprazole magnesium amorphous).

40mg: Each tablet contains 40mg esomeprazole (as Esomeprazole magnesium amorphous)

The other ingredients are:

*Tablet core:* Sugar spheres (sucrose and maize starch), Hydroxypropyl cellulose (E463), Crospovidone (Type B), Povidone (K30), Macrogol-400, Talc (E553b), Hypromellose phthalate (HP-55S), Hypromellose phthalate (HP-50), Diethylphthalate, Macrogol 6000, Crospovidone (Type A) Microcrystalline cellulose (PH 101), Microcrystalline cellulose (PH 112), Sodium stearyl fumarate, Coat: Macrogol-4000, Opadry 03B86651 Brown (HPMC 2910/Hypromellose 6cP (E464), Titanium Dioxide(E171), Macrogol/PEG 400, Talc (E553b), Iron Oxide red (E172)).

#### **What Esomeprazole gastro-resistant tablets look like and contents of the pack**

**Esomeprazole 20 mg gastro-resistant tablets** are light brick red to brown coloured, oval, biconvex, film-coated tablets with 'E5' debossed on one side and plain on other side

**Esomeprazole 40 mg gastro-resistant tablets** are light brick red to brown coloured, oval, biconvex, film-coated tablets with 'E6' debossed on one side and plain on other side

#### **Product is available in following pack size**

20 mg and 40mg: 28 tablets

#### **Product procured from within the EU by the Parallel Product Authorisation Holder:**

WPR Healthcare Limited, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

PPA No.: 20mg 565/53/1

PPA No.: 40mg 565/53/2

#### **Product repackaged and distributed by:**

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

#### **Manufacturer**

**Ranbaxy Ireland Ltd.**, Spafield, Cork Road, Cashel, Co. Tipperary, Ireland

**Basics GmbH**, Hemmelrather Weg 201, D-51377 Leverkusen, Germany

**Terapia SA**, 124 Fabricii Street, 400 632 Cluj Napoca, Romania

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