

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Esomeprazol Mylan 20 mg Gastro-resistant tablets**

### **Esomeprazol Mylan 40 mg 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet.

#### **What is in this leaflet:**

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

## **1. WHAT ESOMEPRAZOL MYLAN IS AND WHAT IT IS USED FOR**

Esomeprazol Mylan 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.

Esomeprazol Mylan 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 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.

Adults

- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Esomeprazol Mylan 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 Esomeprazol Mylan.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ESOMEPRAZOL MYLAN**

#### **Do not take Esomeprazol Mylan:**

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

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Esomeprazol Mylan:

- if you have severe liver problems.
- if you have severe kidney problems.

- If you have reduced body stores or risk factors for reduced vitamin B12 absorption and receive Esomeprazol Mylan long-term treatment. As with all acid reducing agents, Esomeprazol Mylan may lead to a reduced absorption of vitamin B12
- If you have ever had a skin reaction after treatment with a medicine similar to esomeprazole that reduces the 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 esomeprazole. Remember to also mention any other ill-effects like pain in your joints.

Esomeprazol Mylan may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you start taking Esomeprazol Mylan or while you are taking them, 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 Esomeprazol Mylan “on demand” you should contact your doctor if your symptoms continue or change in character.

### **Other medicines and Esomeprazol Mylan**

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 Esomeprazol Mylan can affect the way some medicines work and some medicines can have an effect on Esomeprazol Mylan.

Do not take Esomeprazol Mylan 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).
- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).
- 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 Esomeprazol Mylan.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking Esomeprazol Mylan.
- 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).
- Clopidogrel (used to prevent blood clots (thrombi)).
- 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 Mylan treatment.
- 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 Esomeprazol Mylan to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

### **Esomeprazol Mylan with food and drink**

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

**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. Your doctor will decide whether you can take Esomeprazol Mylan during this time.

It is not known if Esomeprazol Mylan passes into breast milk. Therefore, you should not take Esomeprazol Mylan if you are breastfeeding.

**Driving and using machines**

Esomeprazol Mylan is not likely to affect you being able to drive or use any tools or machines.

**Esomeprazol Mylan contains Sucrose**

If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

**3. HOW TO TAKE ESOMEPRAZOL MYLAN**

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

- Esomeprazol Mylan 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.

**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 liquid.
  - 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 recommended doses are given below.

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

Adults and children aged 12 or above:

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one Esomeprazol Mylan 40mg 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 recommended dose once the gullet has healed is one Esomeprazol Mylan 20mg gastro-resistant tablet once a day.
- If your gullet has not been damaged, the recommended dose is one Esomeprazol Mylan 20mg 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 Esomeprazol Mylan 20mg 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 recommended dose is one Esomeprazol Mylan 20mg gastro-resistant tablet twice a day for one week.
- Your doctor will also tell you to take antibiotics called amoxicillin and clarithromycin.

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

- Adults aged 18 and above: the recommended dose is one Esomeprazol Mylan 20mg 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):**

- Adults aged 18 and above: the recommended dose is one Esomeprazol Mylan 20mg 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 recommended dose is one Esomeprazol Mylan 40mg 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 80mg twice a day.

**To be used as prolonged treatment after prevention of rebleeding of ulcers with intravenous Esomeprazol Mylan**

- Adults aged 18 and above: the recommended dose is one Esomeprazol Mylan 40mg gastro-resistant tablet once daily for 4 weeks.

**If you take more Esomeprazol Mylan than you should**

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

**If you forget to take Esomeprazol Mylan**

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 dose.

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

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Esomeprazol Mylan can cause side effects, although not everybody gets them.

**If you notice any of the following serious side effects, stop taking Esomeprazol Mylan and contact a doctor immediately:**

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow (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.

- Rash, possibly with pain in the joints.

The frequency of this effect cannot be estimated from the available data.

Taking a proton pump inhibitor like Esomeprazol Mylan, 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 side effects include:

**Common (affects less than 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 (affects less than 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 Mylan is used in high doses and over long duration).

**Rare (affects less than 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 sunlight.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Generally feeling unwell and lacking energy.
- Increased sweating.

**Very rare (affects less than 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 available data)**

- Inflammation in the gut (leading to diarrhoea)
- If you are on Esomeprazole Mylan 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, 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.

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

## **5. HOW TO STORE ESOMEPRAZOL MYLAN**

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

This medicinal product does not require any special storage conditions.

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 to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Esomeprazol Mylan contains**

The active substance is esomeprazole. Each gastro-resistant tablet contains either 20mg or 40mg of esomeprazole (as esomeprazole magnesium).

The other ingredients are:

- Core: Sugar spheres (sucrose and maize starch), Crospovidone (Type B) (E1202), Hydroxypropylcellulose (E463), Sodium lauryl sulphate
- Sub Coating 1: Mannitol (E421)
- Sub Coating 2: Povidone (E1201), Talc (E553b), Macrogol 6000
- Enteric Coating: Methacrylic acid-ethyl acrylate co polymer (1:1) Dispersion 30%, Triethyl citrate (E1505), Glycerol monostearate (E471), Polysorbate 80 (E433), Talc (E553b), Titanium dioxide (E171)
- Lubrication: Talc (E553b)
- Blending and Compression: Cellulose microcrystalline (E460), Mannitol (E421), Crospovidone (Type A) (E1202), Macrogol 6000, Sodium stearyl fumarate.
- Opadry Clear Coating consisting of Hypromellose (E464), Macrogol 400, Macrogol 8000.
- For 20mg only: Opadry Pink Coating consisting of: Hypromellose (E464), Titanium dioxide (E171), Macrogol 400, Sodium lauryl sulphate, Iron oxide red (E172), Iron oxide yellow (E172), Iron oxide black (E172).
- For 40mg only: Opadry Brown Coating consisting of: Hypromellose (E464), Titanium dioxide (E171), Macrogol 400, Sodium lauryl sulphate, Iron oxide red (E172), Iron oxide yellow (E172).

### **What Esomeprazol Mylan looks like and contents of the pack**

Esomeprazol Mylan 20mg gastro-resistant tablets are light pink, film-coated, oblong, biconvex tablets debossed with “M” on one side of the tablet and “EM3” on the other side.

Esomeprazol Mylan 40mg gastro-resistant tablets are pink, film-coated, oblong, biconvex tablets debossed with “M” on one side of the tablet and “EM4” on the other side.

Esomeprazol Mylan is available in blisters of 7, 14, 15, 28, 30, 50, 56, 60, 90, 98, 100 or 200 gastro-resistant tablets.

Esomeprazol Mylan is available in perforated unit-dose blisters of (14 x 1), (28 x 1), (56 x 1) or (100 x 1) gastro-resistant tablets.

Esomeprazol Mylan is available in high-density polyethylene bottles containing 14, 28, 56, 98, 100, 200 or 500 gastro-resistant tablets.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder:**

McDermott Laboratories Ltd. T/A Gerard Laboratories  
35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

### **Manufacturers:**

McDermott Laboratories Ltd. T/A Gerard Laboratories  
35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Generics [UK] Ltd.

Station Close, Potters Bar, Hertfordshire EN6 1TL, United Kingdom.

Mylan Hungary Kft.

H-2900 Komarom, Mylan utca 1, Hungary

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

|                 |   |
|-----------------|---|
| Austria         | Esomeprazol Arcana 20mg & 40mg magensaftresistente Tabletten      |
| Belgium         | Esomeprazole Mylan 20mg & 40mg maagsapresistente tabletten        |
| Czech Republic  | Esomeprazol Mylan 20mg & 40mg entersolventní tablety              |
| France          | Esomeprazole Mylan 20mg & 40mg Comprimé gastro-résistant          |
| Germany         | Esomeprazol Mylan 20mg & 40mg magensaftresistente Tabletten       |
| Hungary         | Esomeprazole Mylan 20 mg & 40 mg gyomornedv-ellenálló tabletta    |
| Ireland         | Esomeprazole Mylan 20mg & 40mg Gastro-resistant Tablets           |
| Portugal        | Esomeprazol Mylan 20mg & 40mg Gastro-resistant tablets            |
| Slovenia        | Esomeprazol Mylan 20 mg & 40 mg Gastrozistentna tableta           |
| Spain           | Esomeprazol Mylan 20 mg & 40 mg comprimidos gastroresistentes EFG |
| The Netherlands | Esomeprazol Mylan 20mg & 40mg maagsapresistente tablet            |
| United Kingdom  | Esomeprazole 20mg / 40mg Gastro-resistant Tablets                 |

**This leaflet was last revised in March 2013.**