

## Package leaflet: Information for the patient

### Esomeprazole Mylan 20 mg Gastro-resistant Hard Capsules Esomeprazole Mylan 40 mg Gastro-resistant Hard Capsules esomeprazole

#### Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### In this leaflet:

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

#### 1. What Esomeprazole Mylan is and what it is used for

Esomeprazole 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.

Esomeprazole 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). Esomeprazole 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 esomeprazole.

#### 2. What you need to know before you take Esomeprazole Mylan

##### **Do not take Esomeprazole 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 the group of medicines called 'benzimidazoles', which includes other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole) as well as other different types of medicine.
- If you are taking a medicine containing nelfinavir (used to treat HIV infection).

Do not take Esomeprazole Mylan if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Esomeprazole Mylan.

## Warnings and Precautions

Talk to your doctor or pharmacist before taking Esomeprazole Mylan:

- 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 that reduces 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.

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).

Esomeprazole Mylan may also reduce the absorption of vitamin B12, especially on long-term therapy.

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

## Other medicines and Esomeprazole

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

Do not take Esomeprazole 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).
- 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 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 Esomeprazole 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).
- Tacrolimus (used to reduce the immune response, helping to prevent rejection of organ transplant or to treat skin reactions such as eczema)
- 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 Esomeprazole 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.

### **Pregnancy and breast-feeding**

If you are pregnant, think you might 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 Mylan during this time.

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

### **Driving and using machines**

Esomeprazole Mylan can cause side effects such as dizziness and blurred vision. If you are affected by these you should not drive, use tools or operate machinery.

### **Esomeprazole Mylan contains sucrose**

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

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

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

- Esomeprazole Mylan is 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 capsules at any time of the day.
- You can take your capsules with food or on an empty stomach.
- Swallow your capsules whole with a drink of water. Do not chew or crush the capsules. This is because the capsules 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 capsules**

If you have trouble swallowing the capsules:

- Open the capsule and empty the pellets into half a glass of still (non-fizzy) water. Do not use any other liquid.
- 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 capsule 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 capsules 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. If you have severe liver problems, your doctor may give you a lower dose.

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 Esomeprazole Mylan 40 mg Capsule 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 Esomeprazole Mylan 20 mg Capsule once a day.
- If your gullet has not been damaged, the recommended dose is one Esomeprazole Mylan 20 mg Capsule 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 Mylan 20 mg Capsule each day.

**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 Esomeprazole Mylan 20 mg Capsule 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 Esomeprazole Mylan 20 mg Capsule once a day for 4 to 8 weeks.

**To prevent stomach ulcers if you are taking NSAIDs:**

- Adults aged 18 and above: the recommended dose is one Esomeprazole Mylan 20 mg Capsule 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 Esomeprazole Mylan 40 mg Capsule 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.

**To be used as prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole:**

- Adults aged 18 and above: the recommended dose is one Esomeprazole Mylan 40 mg Capsule once daily for 4 weeks.

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

If you take more Esomeprazole Mylan than your doctor has told you to, talk to your doctor or pharmacist straight away.

**If you forget to take Esomeprazole 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.

**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 Mylan and contact a doctor immediately:**

**Uncommon** (may affect up to 1 in 100 people):

- Fracture of the hip, wrist or spine (if Esomeprazole Mylan is used in high doses and over long duration)

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

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulty swallowing or breathing (severe allergic reaction).
- Yellow skin, dark urine, pale stools with fever, feeling or being sick and tiredness, which can be signs of liver problems.
- Low numbers of white blood cells, which may lead to a severely reduced general condition or fever with signs of a local infection such as pain in the neck, throat or mouth or difficulty urinating.

**Very rare** (may affect up to 1 in 10,000 people):

- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals, with joint pain and high fever. This could be 'erythema multiforme', 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'.
- Changes to the number of certain cells in your blood causing tiredness, weakness or pale skin (low red blood cells), bruising or bleeding more frequently or for longer than normal (low platelets).
- Passing less urine than usual or being unable to pass urine, blood or mucous in the urine, pain in the lower back possibly with rash, fever, feeling or being sick. These may be signs of kidney problems.
- For patients who have liver problems, these may get worse and lead to swelling of the brain, which can cause changes in concentration, personality or behaviour, problems concentrating or thinking or feeling sleepy or drowsy.

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

- Inflammation in the gut causing pain and diarrhea, possibly containing blood.
- Rash, possibly with pain in the joints.

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.

**Rare (may affect up to 1 in 1000 people)**

- 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.
- 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)**

- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Muscle weakness.
- Enlarged breasts in men.

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

- 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.

**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.

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; website: <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 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.

Blister: Do not store above 25° C. Store in the original package in order to protect from moisture.

Bottle: Do not store above 25° C. Keep the bottle tightly closed in order to protect from moisture. Use within 3 months after first opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Esomeprazole Mylan contains**

The active substance is esomeprazole. Esomeprazole Mylan Gastro-resistant Hard Capsules come in two strengths containing 20 mg or 40 mg of esomeprazole (as esomeprazole magnesium).

The other ingredients of the capsule content are:

- Core: sugar spheres (sucrose and maize starch), crospovidone, hydroxypropyl cellulose, sodium hydroxide
- Sub-coating: mannitol, sucrose
- Enteric coating: methacrylic acid - ethyl acrylate polymer (1:1) dispersion 30%, triethyl citrate, glycerol monostearate, polysorbate 80
- Lubricant: talc

The other ingredients of the capsule shell are iron oxide red E172, iron oxide yellow E172 (40mg only), titanium dioxide E171, gelatin, water, sodium laurilsulfate.

The other ingredients of the printing ink are shellac, propylene glycol, concentrated ammonia solution, iron oxide black E172 and potassium hydroxide.

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

Esomeprazole Mylan 20 mg Capsules are hard gelatin capsules with pink cap and pink body, imprinted with 'Mylan' over 'EM 20' in black ink on cap and body filled with white to cream coloured pellets.

Esomeprazole Mylan 40 mg Capsules are hard gelatin capsules with brown cap and brown body, imprinted with 'Mylan' over 'EM 40' in black ink on cap and body filled with white to cream coloured pellets.

Your capsules come in blister packs containing 7, 14, 15, 28, 30, 50, 56, 60, 90, 98 or 100 capsules and in bottles containing 7, 14, 28, 30, 56, 98 or 100 capsules.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

### **Manufacturers**

McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Mylan Hungary Kft., H-2900 Komárom, Mylan utca 1, Hungary

Generics [UK] Ltd, Station Close, Potters Bar, AN6 1TL, United Kingdom

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

Austria	Esomeprazol Arcana 20 mg & 40 mg
Belgium	Esomeprazole Mylan 20 mg & 40 mg
Bulgaria	Esopragen 20 mg & 40 mg
Denmark	Esomeprazol Mylan 20 mg & 40 mg
France	Esomeprazole Mylan Pharma 20 mg & 40 mg
Germany	Esomeprazol Mylan 20 mg & 40 mg
Greece	Esomeprazole/Mylan GR, CAPS 20 mg & 40 mg
Hungary	Esomeprazol Mylan 20 mg & 40 mg
Ireland	Esomeprazole Mylan 20 mg & 40 mg
Luxembourg	Esomeprazole Mylan 20 mg & 40 mg
Norway	Esomeprazol Mylan 20 mg & 40 mg
Portugal	Esomeprazol Mylan 20 mg & 40 mg
Romania	Esomeprazol Mylan 20 mg & 40 mg
Spain	Esomeprazol Mylan 20 mg & 40 mg
Sweden	Esomeprazol Mylan 20 mg & 40 mg
The Netherlands	Esomeprazol Mylan 20 mg & 40 mg
United Kingdom	Esomeprazole 20 mg & 40 mg

**This leaflet was last approved in**