

**PACKAGE LEAFLET**

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### OMEPRAZOLE 10, 20 & 40 mg GASTRO-RESISTANT CAPSULES

(omeprazole)

**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. 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. See section 4.

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

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

## **1. WHAT OMEPRAZOLE IS AND WHAT IT IS USED FOR**

Omeprazole belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

#### **Omeprazole is used to treat the following conditions:**

##### **In adults:**

- 'Gastro-esophageal 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.
- Ulcers in the upper part of the intestines (duodenal ulcer) or stomach (gastric ulcer).
- To stop ulcers in the upper part of the intestines (duodenal ulcer) or stomach (gastric ulcer) from coming back.
- Ulcers which are also infected with a 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.
- Ulcers caused by medicines called NSAIDs (non-steroidal anti inflammatory drugs). Omeprazole can also be used to stop ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

**In children:****Children over 1 year of age and  $\geq 10$ kg:**

- ‘Gastro-esophageal 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.

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 and adolescents 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 OMEPRAZOLE****Do not take Omeprazole if you:**

- are allergic to omeprazole or any of the other ingredients of this medicine (listed in Section 6).
- are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- are taking a medicine containing nelfinavir (used for HIV infection).

If you are not sure, talk to your doctor or pharmacist before taking Omeprazole.

**Warnings and Precautions**

Omeprazole may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Omeprazole or while you are taking it, talk to your doctor or pharmacist before taking Omeprazole if:

- 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).
- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.
- You have severe liver problems.
- You have ever had a skin reaction after treatment with a medicine similar to omeprazole that reduces stomach acid
- You are due to have a specific blood test (Chromogranin A)

If you take Omeprazole on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Taking a proton pump inhibitor like Omeprazole, 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 omeprazole. Remember to also mention any other ill-effects like pain in your joints.

**Other medicines and Omeprazole**

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

Do not take Omeprazole if you are taking a medicine containing nelfinavir (used to treat HIV infection).

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any of the following medicines:

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus).
- Digoxin (used to treat heart problems).
- 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 Omeprazole.
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking Omeprazole.
- Rifampicin (used to treat tuberculosis).
- Atazanavir (used to treat HIV infections).
- Tacrolimus (in cases of organ transplantation).
- St John's Wort (*Hypericum perforatum*) (used to treat mild depression).
- Cilostazol (used to treat intermittent claudication).
- Saquinavir (to treat HIV infections).
- Clopidogrel (used to prevent blood clots (thrombi)).
- Erlotinib (used to treat different types of cancer).
- 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 Omeprazole treatment.

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

Tell your doctor or the medical staff if you undergo a test for tumours.

### **Omeprazole with food and drink**

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

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

If you are pregnant or breastfeeding, 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 Omeprazole if you are breast-feeding.

### **Driving and using machines**

Omeprazole is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

### **Important information about some of the ingredients of Omeprazole**

Omeprazole 40mg contains Sunset Yellow (E110) and Allura red (E129). May cause allergic reactions.

This medicine contains sucrose. 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 OMEPRAZOLE**

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

Your doctor will tell you how many capsules to take and how long to take them for. This will depend on your condition and how old you are.

#### **Adults:**

##### **To treat symptoms of GERD such as heartburn and acid regurgitation:**

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is 20 mg once a day for 4-8 weeks. Your doctor may tell you to take a dose of 40 mg for a further 8 weeks if your gullet has not yet healed.
- The recommended dose once your gullet has healed is 10 mg once a day.
- If your gullet has not been damaged, the recommended dose is 10 mg once a day.

##### **To treat ulcers in the upper part of the intestine (duodenal ulcer):**

- The recommended dose is 20 mg once a day for 2 weeks. Your doctor may tell you to take the same dose for a further 2 weeks if your ulcer has not yet healed.
- If the ulcer does not fully heal, the dose can be increased to 40 mg once a day for 4 weeks.

##### **To treat ulcers in the stomach (gastric ulcer):**

- The recommended dose is 20 mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your ulcer has not yet healed.
- If the ulcers do not fully heal, the dose can be increased to 40 mg once a day for 8 weeks.

##### **To prevent duodenal and stomach ulcers from coming back:**

- The recommended dose is 10 mg or 20 mg once a day. Your doctor may increase the dose to 40 mg once a day.

##### **To treat duodenal and stomach ulcers caused by NSAIDs (non-steroidal anti inflammatory drugs):**

- The recommended dose is 20 mg once a day for 4 to 8 weeks.

##### **To prevent duodenal and stomach ulcers if you are taking NSAIDs**

- The recommended dose is 20 mg once a day.

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

- The recommended dose is 20 mg Omeprazole twice a day for one week.
- Your doctor will also tell you to take two antibiotics among amoxicillin, clarithromycin and metronidazole.

##### **To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison Syndrome):**

- The recommended dose is 60 mg daily.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for.

#### **Use In children:**

##### **To treat symptoms of GERD such as heartburn and acid regurgitation:**

- Children over 1 year of age and with a body weight of more than 10kg may take Omeprazole. The recommended dose for children is based on the child's weight and the doctor will decide the correct dose.

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

- Children aged over 4 years may take Omeprazole. The recommended dose for children is based on the child's weight and the doctor will decide the correct dose.

- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child.

### **Taking this medicine:**

It is recommended that you take your capsules in the morning.

You can take your capsules with food or on an empty stomach

Swallow your capsules whole with half a glass 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 or your child have trouble swallowing the capsules:**

If you or your child have trouble swallowing the capsules:

- Open the capsules and swallow the contents directly with half a glass of water or put the contents into a glass of still (non-fizzy) water, any acidic fruit juice (e.g. apple, orange or pineapple) or apple sauce.
- Always stir the mixture just before drinking it (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes.
- 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 take more Omeprazole than you should**

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

### **If you forget to take Omeprazole**

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 to make up for a forgotten dose.

## **4. POSSIBLE SIDE EFFECTS**

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

### **If you notice any of the following rare but serious side effects, stop taking Omeprazole and contact your doctor immediately:**

- Sudden wheezing, swelling of the 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’.
- Severe liver problems leading to liver failure and inflammation of the brain. Symptoms include jaundice which can cause yellow skin, dark urine and tiredness.
- Omeprazole may in very rare cases affect the white blood cells leading to immune deficiency (agranulocytosis). If you have an infection with symptoms of 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 a 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 medicine at this time.
- Severe kidney problems (interstitial nephritis).
- Rash, possibly with pain in the joints

**Other side-effects include:**

**Common side effects (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 side effects (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).
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.
- Fracture of the hip, wrist or spine.

**Rare side effects (may affect up to 1 in 1000 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).
- Dry mouth.
- 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 pain (arthralgia) or muscle pains (myalgia).
- Increased sweating.

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

- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Sudden onset of severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme).
- Muscle weakness.
- Enlarged breasts in men.

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

- Inflammation of the gut (leading to diarrhoea).
- If you are on omeprazole 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.

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

### **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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE OMEPRAZOLE**

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 carton or label after “EXP”. The expiry date refers to the last day of that month.

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

HDPE bottle: Do not store above 25°C. Keep the bottle tightly closed in order to protect from moisture.

Do not throw away 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 Omeprazole contains**

The active substance is omeprazole. Each gastro-resistant capsule contains 10 mg, 20 mg or 40 mg of omeprazole.

Components of the Capsule are: Sugar Spheres (sucrose, maize starch), Hypromellose, Sodium hydroxide, Methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30% (methacrylic acid-ethyl acrylate (1:1), sodium lauryl sulphate, polysorbate 80), Talc, Titanium dioxide (E171), Macrogol 6000, Polysorbate 80.

Components of the Capsule shell (see section 2, ‘Important information about some of the ingredients of Omeprazole’):

10 mg - Shell cap - Iron oxide red (E 172), Titanium dioxide (E171), Gelatin, Sodium lauryl sulphate.  
Shell Body - Titanium dioxide (E171), Gelatin, Sodium lauryl sulphate.

20 mg - Shell cap - Titanium dioxide (E171), Iron oxide black, Iron oxide red (E172), Gelatin, Sodium lauryl sulphate.

Shell Body - Titanium dioxide (E171), Gelatin, Sodium lauryl sulphate.

40 mg - Shell cap - Titanium dioxide (E171), Sunset yellow (E110), Brilliant blue (E133), Allura red (E129), Gelatin, Sodium lauryl sulphate.

Shell Body - Titanium dioxide (E171), Sunset yellow (E110), Brilliant blue (E133), Allura red (E129), Gelatin, Sodium lauryl sulphate.

Capsule Printing Ink - Shellac, Ammonia solution concentrated, Iron Oxide black (E172), Potassium Hydroxide.

### **What Omeprazole looks like and contents of the pack**

The 10 mg capsules have a light pink cap and white body, filled with white to off-white pellets, and are marked ‘MYLAN’ over ‘OM10’ on both cap and body.

The 20 mg capsules have a dark pink cap and white body, filled with white to off-white pellets, and are marked ‘MYLAN’ over ‘OM20’ on both cap and body.

The 40 mg capsules have a dark pink cap and body, filled with white to off-white pellets, and are marked ‘MYLAN’ over ‘OM40’ on both cap and body.



The capsules are available in plastic bottles or blister packs which contain:

7, 14, 15, 21, 28, 30, 50, 56, 60, 84, 100, 112, 200, 500 in bottles.

7, 14, 15, 21, 28, 30, 50, 56, 60, 84, 98, 100, 112, 200, 500 in blisters.

2 x 50.

250 (dose dispensing in hospitals – bottle only).

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

**Manufacturers:**

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

or

Generics [UK] Limited, Potters Bar, Herts., EN6 1TL, United Kingdom.

or

Mylan Hungary Kft, H-2900 Komarom, Mylan utca 1, Hungary

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