

Package leaflet: Information for the patient

Omeprazole 10 mg Gastro-resistant Tablets

Omeprazole 20 mg Gastro-resistant Tablets

Omeprazole 40 mg Gastro-resistant Tablets

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 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 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 gastro-resistant tablets contain the active substance omeprazole. It 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-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. Omeprazole is also used in the long term management of this condition.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer). Omeprazole can be used to treat this condition or prevent its reoccurrence.
- Ulcers which 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.
- 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 weighing 10 kg or more

- '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.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Omeprazole if:

- You have reduced body stores or risk factors for reduced vitamin B₁₂ and are to receive omeprazole long term. Omeprazole may reduce the absorption of vitamin B₁₂.
- 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 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.

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 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 (be sick) food regularly or if you notice your vomit contains blood (this may look like coffee granules).
- You pass black stools (blood-stained faeces).
- You have severe liver problems.

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).

During treatment

Talk to your doctor or pharmacist if you experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.

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.

Certain diagnostic tests

Omeprazole may alter the results of some tests related to cancer. Tell your doctor, nurse or hospital staff that you are taking this medicine. Your doctor may advise you to stop taking this medicine for at least five days if you are undergoing certain tests.

Other medicines and Omeprazole

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

- Ketoconazole, posaconazole, itraconazole 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 and saquinavir (used to treat HIV infections)
- Tacrolimus (in cases of organ transplantation)
- Clarithromycin (an antibiotics) unless you are being treated with this medicine for *H. Pylori*
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- Cilostazol (used to treat intermittent claudication)
- Clopidogrel (used to prevent blood clots (thrombi))
- Erlotinib (used to treat cancer).
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer and inflammatory conditions) – 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.

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.

Pregnancy

Omeprazole can be used during pregnancy.

Breast-feeding

Your doctor will decide whether you can take omeprazole during this time.

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.

Omeprazole gastro-resistant tablets contain

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

3. How to take Omeprazole

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

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

The recommended dose is

Adults:

To treat symptoms of GORD 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 the gullet has healed is 10 mg once a day but can be increased to 20 mg to 40 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 ulcer does not fully heal, the dose can be increased to 40 mg once a day for 8 weeks.

To **prevent the duodenal 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 **prevent the stomach ulcers** from coming back:

- The recommended dose is 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 magnesium twice a day for one week or 40 mg Omeprazole once a day for one week.
- Your doctor will also tell you to take two antibiotics among amoxicillin, clarithromycin and metronidazole or tinidazole.

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. If your doctor recommends that you need to take more than 80 mg per day, you should split the dose and take twice a day.

If you have severe liver problems, your doctor may recommend a lower dose from listed above.

Use in children

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

- Children over 1 year of age and with a body weight of 10 kg or more may take Omeprazole. The 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 to treat ulcers specifically caused by *Helicobacter pylori*. The 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 tablets in the morning.
- You can take your tablets with food or on an empty stomach.
- Swallow your tablets whole with half a glass 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 or your child has trouble swallowing the tablets

- If you or your child have trouble swallowing the tablets:
 - Break the tablet and disperse it in a spoonful of water (non-fizzy), any acidic fruit juice (e.g. apple, orange or pineapple) or apple sauce.
 - Always stir the mixture just before drinking (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. **Do not use** milk or fizzy water. The solid pieces contain the medicine - do not chew or crush them.

The tablet can be divided into equal doses.

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. You may suffer from symptoms such as feeling or being sick (nausea or vomiting), feeling dizzy, stomach pain, diarrhoea, headache, lack of interest, feeling depressed and confusion.

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

If you stop taking Omeprazole

Do not stop treatment early because your symptoms have got better. Your condition may not have been fully healed and may reoccur if you do not finish your course of treatment.

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 rare but serious side effects, stop taking this medicine and contact a doctor or go to the nearest hospital casualty department immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing and breathing (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 inflammation or failure and inflammation of the brain. Symptoms can include jaundice which can cause yellow skin, dark urine, and tiredness.
- A reduction in your red or white blood cells or platelets which may lead to more frequent infections (such as sore throat and mouth ulcers), fever, weakness, easy bruising or bleeding, pain in the neck, throat or mouth.
- Severe kidney problems (interstitial nephritis). You may pass little or no urine, have cloudy urine or blood in the urine or have severe pain in the lower back.
- Inflammation of the bowel with signs such as abdominal pain, bloating, inability to control bowel movement and nausea (feeling sick).
- An infection called “thrush” which can affect the gut and is caused by a fungus.
- Rash, possibly with pain in the joints.

Other possible side effects:

Common: may affect up to 1 in 10 people

- Headache.
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence), benign polyps in the stomach.
- 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).
- 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 in the hip, wrist or spine

Rare: may affect up to 1 in 1,000 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).
- Dry mouth.
- An inflammation of the inside of the mouth, sore mouth or ulcers.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Increased sweating.

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

- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Sudden onset of a 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: frequency cannot be estimated from the available data

- Low levels of magnesium in the blood (hypomagnesaemia).

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 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.

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: www.hpra.ie; e-mail: medsafety@hpra.ie. 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 label or carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package 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 Omeprazole contains

The active substance is omeprazole. Each gastro-resistant tablet contains omeprazole magnesium corresponding to 10 mg, 20 mg or 40 mg omeprazole.

The other ingredients are sugar spheres; crospovidone; hydroxypropylcellulose; Polysorbate 80; mannitol; povidone; talc; macrogol; methacrylic acid – ethyl acrylate copolymer (1:1); triethyl citrate; glycerol monostearate; titanium dioxide (E171); sodium hydroxide; silicified microcrystalline cellulose; silica, colloidal anhydrous; hydrogenated vegetable oil; magnesium stearate; sodium stearyl fumarate; hypromellose; iron oxide yellow (E172).

What Omeprazole looks like and contents of the pack

The 10 mg gastro-resistant tablet is yellow, film-coated, oblong, biconvex tablet (approximately 6.8 mm x 13.2 mm) marked with 'M' on one side of the tablet and 'OM1' on the other side.

The 20 mg gastro-resistant tablet is yellow, film-coated, oblong, biconvex tablet (approximately 9.5 mm x 16.5 mm) marked with 'M' on one side of the tablet and 'OM2' on the other side.

The 40 mg gastro-resistant tablet is yellow, film-coated, oblong, biconvex tablet (approximately 11.0 mm x 20.7 mm) marked with 'M' on one side of the tablet and 'OM' on the left side of the score and '4' on the right of the score on the other side.

Omeprazole gastro-resistant tablets are available in plastic bottles which contain 7, 14, 30, 100, 250 and 500 tablets, and blister packs which contain 7 (*only for 40mg strength*), 14 (*only for 40mg strength*), 15, 28, 30, 50 (single-unit dose) tablets.

Bottle packs of 250 and 500 tablets contain a desiccant. Do not eat the desiccant.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturers

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

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

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

Ireland	Omeprazole 10 mg Gastro-resistant Tablets Omeprazole 20 mg Gastro-resistant Tablets Omeprazole 40 mg Gastro-resistant Tablets
The Netherlands	Omeprazol Mylan 10 mg, maagsapresistente tabletten Omeprazol Mylan 20 mg, maagsapresistente tabletten Omeprazol Mylan 40 mg, maagsapresistente tabletten
United Kingdom	Omeprazole 10 mg Gastro-resistant Tablets Omeprazole 20 mg Gastro-resistant Tablets Omeprazole 40 mg Gastro-resistant Tablets

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