

Omeprazole 10 mg and 20 mg Gastro-resistant capsules

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.

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1 What Omeprazole capsules are and what they are used for

Omeprazole capsules 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.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer), prevention of reoccurrence of ulcers.
- Bacteria 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 10kg

- '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 capsules

Do not take Omeprazole capsules and **tell** your doctor 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

Talk to your doctor or pharmacist before taking Omeprazole capsules. 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 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** Capsules that reduces stomach acid.
- 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 Capsules. Remember to also mention any other ill-effects like pain in your joints
- you take **atazanavir**
- your body does not absorb **vitamin B12 (cobalamin)** very well
- you are due to have a specific blood test (Chromogranin A)

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). Your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Children

Some children with chronic illnesses may require long-term treatment although it is not recommended. Do not give this medicine to children under 1 year of age or weigh less than 10kg.

Other medicines and Omeprazole capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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, 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 infection)
- Tacrolimus (in cases of organ transplantation)
- Methotrexate (used to treat arthritis, Crohn's or psoriasis)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- Cilostazol (used to treat intermittent claudication)
- Saquinavir (used to treat HIV infection)
- Clopidogrel (used to prevent blood clots (thrombi))
- Ertinib (used in some cancers)
- Clarithromycin (to treat infections)

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. Your doctor will decide whether you can take Omeprazole during this time. Your doctor will decide whether you can take Omeprazole if you are breastfeeding.

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 capsules contain sucrose

Omeprazole capsules contain 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 capsules

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

Doses:

• Adult

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

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

- The recommended dose is 20mg 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 40mg once a day for 4 weeks.

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

- The recommended dose is 20mg 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 40mg once a day for 8 weeks.

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

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

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

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

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

- The recommended dose is 20mg once a day.

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

- The recommended dose is 20mg 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 60mg 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 GORD 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 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 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.

Patients with kidney or liver problems

- Dose adjustment is not required in patients with kidney problems
- Patients with liver problems may require a smaller dose of 10-20mg a day.

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

- 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.
- Alternatively you or your child can suck the capsule and swallow the pellets with half a glass of water. The pellets must not be chewed.

If you take more Omeprazole capsules than you should

If you (or someone else) swallow a lot of capsules at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Take this leaflet and any remaining capsules that you have to show the doctor.

Symptoms of an overdose may include feeling or being sick, dizziness, stomach pain, diarrhoea, headache, depression and confusion.

If you forget to take Omeprazole capsules

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Omeprazole capsules

Do not stop treatment early otherwise your symptoms may reappear. **Talk to your doctor** before you stop taking the capsules and follow his advice.

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 Omeprazole and contact a doctor immediately:

Rare side effects (may affect up to 1 in 1,000 people)

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).

Very rare side effects (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. This could be 'erythema multiforme', 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'.
- Yellow skin, dark urine and tiredness which can be symptoms of liver failure.
- Shortness of breath, tiredness, dizziness, bleeding or bruising may be caused by a reduction in red, white blood cells and platelets (pancytopenia). A blood test may be required.
- Omeprazole 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 medicine at this time.

Side effects may occur with certain frequencies, which are defined as follows:

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Common side effects (may affect up to 1 in 10 people)

- Headache.
- Diarrhoea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).
- Benign polyps in the stomach.

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.
- Increased risk of fracture of the hip, wrist or spine.

Rare side effects (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.
- Blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Dry mouth.
- An inflammation of the inside of the mouth.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (interstitial nephritis).
- Increased sweating.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- An infection called "thrush" which can affect the gut and is caused by a fungus.

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

- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Muscle weakness.
- Enlarged breasts in men.

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

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

- 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.
- Inflamed colon causing watery diarrhoea (microscopic colitis).
- Rash, possible with pain in the joints.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5 How to store Omeprazole capsules

Store below 25°C. Store in the original package to protect from moisture. Keep this medicine out of the sight and reach of children.

Do not use Omeprazole capsules after the expiry date stated on the carton. The expiry date refers to the last day of that month.

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 capsules contain

- The active substance (the ingredient that makes the capsule work) is Omeprazole. Each capsule contains either 10mg or 20mg of omeprazole.
- The other ingredients are sugar spheres (consisting of corn starch and sucrose), sodium lauryl sulfate, disodium phosphate, mannitol, hypromellose, polyethylene glycol 6000, talc, polysorbate 80, titanium dioxide, Eudragit L30-D55 (poly(methacrylic acid, ethyl acrylate)). Capsules consist of gelatin and contain the colours quinoline yellow (E104) and titanium dioxide (E171).

What Omeprazole capsules look like and contents of the pack

10mg capsules are hard gelatine capsules of size 3, Opaque yellow cap and body, containing white to off-white spherical pellets.

20mg capsules are hard gelatin capsules of size 2, Opaque yellow cap and body, containing white to off-white spherical pellets.

Pack sizes are 7, 10, 14, 15, 20, 21, 28, 30, 50, 56, 60, 84, 90, 98, 100 capsules (blister packs); 30, 90 (tablet containers).

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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If you would like a leaflet with larger text, please contact 01271 385257.