

Package leaflet: Information for the patient

Omeprazole 10 mg oral solution

Omeprazole 20 mg oral solution

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

1. What Omeprazole oral solution is and what it is used for

Omeprazole oral solution contains 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 oral solution 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).
- 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 oral solution 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 ≥ 10 kg

'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 oral solution

Do not take Omeprazole oral solution:

- If you are allergic 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 a medicine containing nelfinavir (for HIV infection).

Do not take Omeprazole oral solution if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Omeprazole oral solution.

Warnings and precautions

Talk to your doctor or pharmacist before taking Omeprazole oral solution.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP) have been reported in association with omeprazole treatment. Stop taking Omeprazole oral solution and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Omeprazole oral solution may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Omeprazole oral solution 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).
- 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 oral solution that reduces stomach acid.
- You are due to have a specific blood test (Chromogranin A).

If you take Omeprazole oral solution 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 oral solution, 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 oral solution. Remember to also mention any

other ill-effects like pain in your joints.

When taking omeprazole, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

This medicine may affect the way that your body absorbs vitamin B12, particularly if you need to take it for a long time. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of vitamin B12:

- Extreme tiredness or lack of energy
- Pins and needles
- Sore or red tongue, mouth ulcers
- Muscle weakness
- Disturbed vision
- Problems with memory, confusion, depression

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 < 10 kg.

Other medicines and Omeprazole oral solution

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 Omeprazole oral solution can affect the way some medicines work and some medicines can have an effect on Omeprazole oral solution.

Do not take Omeprazole oral solution 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 oral solution
- 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 oral solution
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infection)
- Tacrolimus (in cases of organ transplantation)
- 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))
- Erlotinib (used to treat 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 oral solution treatment.

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

Omeprazole oral solution with food and drink

See section 3.

Pregnancy, breast-feeding and fertility

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.

Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used. Your doctor will decide whether you can take Omeprazole oral solution if you are breast-feeding.

Driving and using machines

Omeprazole oral solution 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 oral solution contains sodium.

Both Omeprazole oral solution 10 mg and 20 mg contain 9.14 mg sodium (main component of cooking/table salt) in each ml or 137 mg sodium per 15 ml dose.

This 15 ml dose is equivalent to 6.85% of the recommended maximum daily dietary intake of sodium for an adult.

Omeprazole oral solution contains propylene glycol

Omeprazole 10 mg oral solution contains 8.9 mg propylene glycol in 15 ml, which is equivalent to 0.593 mg/ml.

Omeprazole 20 mg oral solution contains 6.7 mg propylene glycol in 15 ml, which is equivalent to 0.447 mg/ml.

3. How to take Omeprazole oral solution

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 much solution to take and how long to take it for. This will depend on your condition and how old you are.

The recommended dose is given below:

Use in 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.
- If your gullet has not been damaged, the usual 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 ulcers do 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 the 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 oral solution 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 and adolescents

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 10 kg may take Omeprazole oral solution. 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 oral solution. 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

- Take this medicine by mouth
- It is recommended that you take this medicine in the morning.
- This medicine should be taken on an empty stomach, at least 1 hour before a meal. 10 mg and

20 mg strengths are equivalent with to buffering capacity (same amount of buffer on a ml basis). To achieve a 40 mg dose Omeprazole 20 mg oral solution should be used.

- This medicine can also be administered via nasogastric (NG) or percutaneous endoscopic gastronomy (PEG) tubes.
- Instructions for use via NG or PEG tube:
 - 1) Ensure that the enteral feeding tube is free from obstruction before administration.
 - 2) Flush the enteral tube with 5 ml of water
 - 3) Administer the required dose of Omeprazole oral solution with a suitable measuring device.
 - 4) Flush the enteral tube with at least 20 ml of water

This product can be used with Polyurethane nasogastric (NG) and percutaneous endoscopic gastrostomy (PEG) tubes of size 6 Fr to 15 Fr. For the smallest diameter tubes (6 Fr) a smaller flush volume of 3ml may be used in very young children where fluid intake restriction may be of relevance.

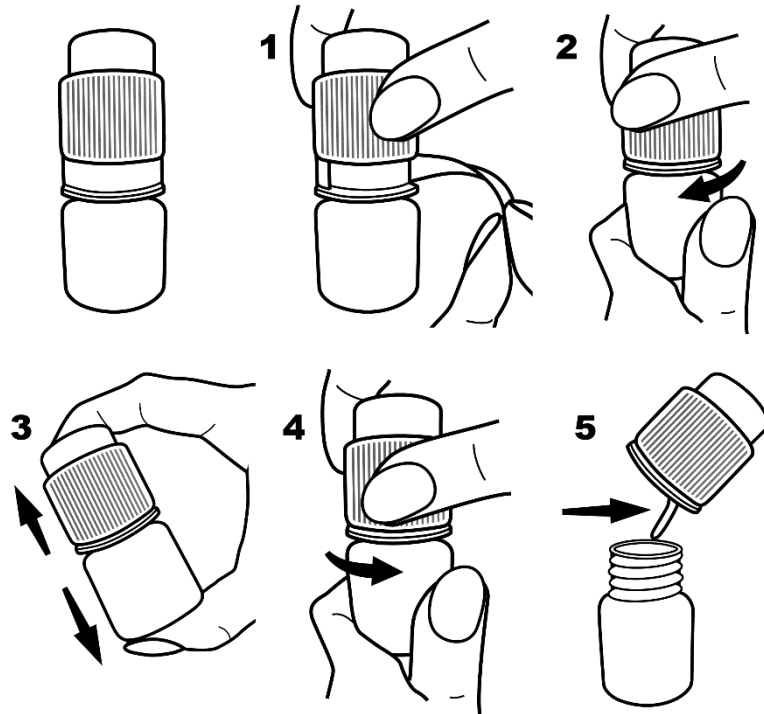
For children that are unable to drink directly from the bottle, an option for administration of the product is using a plastic needleless medication syringe, spoon or a cup appropriate to transfer the amount of the bottle content (as per the recommended dosing). Ask your doctor or pharmacist to show you how much medicine to give using the tool you plan to use at home.

Preparing and taking the solution

The container is two compartment system containing solution both in the cap and in the bottle. The two solutions first need to be combined and are then to be taken by the patient.

Instructions for mixing of the two solutions

1. Remove the safety ring
2. Press down and twist the cap clockwise until the end of the screw neck
3. Shake well for at least 15 seconds to mix the solutions and leave to settle for 60 seconds
4. Remove plastic cap by turning counterclockwise
5. Assure that the bottom surface of the cap has been pierced and has opened
6. Take/give the solution directly from the bottle



Omeprazole 10 mg oral solution

The final solution ready to use will be off white to pale yellow viscous solution, with menthol odour.

Omeprazole 20 mg oral solution

The final solution ready to use will be off white to pale yellow viscous solution, with menthol and lemon odour.

If you take more Omeprazole oral solution than you should

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

If you forget to take Omeprazole oral solution

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 oral solution

Do not stop taking Omeprazole oral solution without first talking to your doctor or pharmacist.

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 (may affect up to 1 in 1,000 people) or very rare (may affect up to 1 in 10,000 people) but serious side effects, stop taking Omeprazole oral solution and contact a doctor immediately:

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

- in swallowing (severe allergic reaction). (rare)
- 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’. (very rare)
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome). (rare)
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis). (rare)
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems. (rare)

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).
- 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.
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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.
- 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.
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- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (interstitial nephritis).

- Increased sweating.

Very rare side effects (may affect up to 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.
- Erythema multiforme.
- Muscle weakness.
- Enlarged breasts in men.

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

- Inflammation in the gut (leading to diarrhoea).
- If you are on Omeprazole oral solution 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.
- Rash, possibly with pain in the joints.

Omeprazole oral solution 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.

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 Yellow Card Scheme Website: 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 oral solution

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 and the carton after 'EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C)

Store in the original package to protect from light.

Product may be used for a period of 28 days if removed unopened from refrigerator (2°C – 8°C) and kept in room temperature (15°C - 25°C).

The product should be taken within 20 minutes of preparation. During this time, it should be kept out of the sight and reach of children.

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 oral solution contains

The active substance is omeprazole.

One bottle of the constituted Omeprazole 10 mg oral solution (entire bottle content – 15 mL) contains 10 mg of omeprazole.

One bottle of constituted Omeprazole 20 mg oral solution (entire bottle content – 15 mL) contains 20 mg of omeprazole.

The other ingredients are: glycerol (E422), xanthan gum (E415), sodium carboxymethylcellulose (E468), sucralose (E955), emulsion simethicone 30%, sodium hydrogen carbonate, sodium dihydrogen phosphate dehydrate, domiphen bromide, polysorbate 80 (E433), disodium edetate, N-acetyl L cysteine, sodium hydroxide (E524), nitrogen, menthol flavour (consisting of acacia gum (E414), flavouring components), taste masking flavour (consisting of water, propylene glycol (E1520), flavouring components), lemon flavour (for 20mg) (consisting of maize maltodextrin, flavouring components)

What Omeprazole oral solution looks like and contents of the pack

Omeprazole 10 mg oral solution is off white to pale yellow viscous solution, with menthol odour.

Omeprazole 20 mg oral solution is off white to pale yellow viscous solution, with menthol and lemon odour.

The dual-chamber primary packaging for Omeprazole 10 mg, 15 ml is composed of assembled:

- HDPE (high density polyethylene) Cap with tamper evident ring, with PP (polypropylene) plunger and PE (polyethylene) membrane filled with 5 ml of Omeprazole 2 mg/ml solution
- HDPE (high density polyethylene) Bottle with neck filled with 10 ml of diluent for Omeprazole 10 mg oral solution

The dual-chamber primary packaging for Omeprazole 20 mg, 15 ml is composed of assembled:

- HDPE (high density polyethylene) Cap with tamper evident ring, with PP (polypropylene) plunger and PE (polyethylene) membrane filled with 5 ml of Omeprazole 4 mg/ml solution
- HDPE (high density polyethylene) Bottle with neck filled with 10 ml of diluent for Omeprazole 20 mg oral solution

Cardboard box containing 14 number of single-dose, dual-chamber HDPE (high density polyethylene) bottles located on PVC (polyvinyl chloride) saucer and an instruction leaflet inside.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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