

Omeprazole 1 mg/ml Powder for Oral Suspension

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

1. What Omeprazole Oral Suspension is and what it is used for

The name of your medicine is **Omeprazole 1 mg/ml Powder for Oral Suspension** (called **Omeprazole Oral Suspension** in this leaflet).

Omeprazole Oral Suspension 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 is commonly used to treat the following conditions:

In children:

Children 1-12 months of age:

- '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.

Your doctor will tell you why you have been given this medicine.

2. What you need to know before you take Omeprazole Oral Suspension

Do not take Omeprazole Oral Suspension

- 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 (eg pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- If you are taking a medicine containing nelfinavir (used for HIV infection)

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Omeprazole.

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 using Omeprazole suspension and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Omeprazole may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Omeprazole Oral Suspension 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 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.

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.

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 month of age.

Other medicines and Omeprazole Oral Suspension

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 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)
- 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 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.

Omeprazole Oral Suspension with food and drink

You should take Omeprazole Oral Suspension without food on an empty stomach. See section 3 for details for infants and taking with milk.

Pregnancy, breastfeeding and fertility

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.

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 if you are breastfeeding. Omeprazole can be used during pregnancy.

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 Oral Suspension contains maltitol, potassium, sodium, sodium methyl parahydroxybenzoate and sodium benzoate.

- **Maltitol.** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- **Sodium.** This medicine contains 172 mg of sodium (main component of cooking/table salt) in each ml or 86 mg of sodium per 5 ml dose. This 5 ml dose is equivalent to 4.3% of the recommended maximum daily dietary intake of sodium for an adult.
- **Potassium.** This medicine contains 1.39 mmol (or 54.3 mg) potassium per ml or 6.95 mmol (or 271.5 mg) potassium per 5 ml dose. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.
- **Sodium methyl parahydroxybenzoate.** May cause allergic reactions (possibly delayed).
- **Sodium benzoate.** This medicine contains 25 mg sodium benzoate in each 5 ml dose. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take Omeprazole Oral Suspension

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 medicine 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 children and adolescents

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

- Children 1-12 months of age may take Omeprazole. The dose for children is based on the child's weight and the doctor will decide the correct dose based on the following:

Age	Body weight	Posology
1-12 months of age	≤ 10 kg	1 mg/kg body weight once daily. Omeprazole 1 mg/ml oral suspension should be used for patients weighing ≥ 2 kg to ≤ 5 kg.*

*Individual dose measurements ≤ 2 ml are not indicated.

*Omeprazole 2 mg/ml oral suspension is available for patients weighing > 5 kg to ≤ 10 kg.

Taking this medicine

- This medicine contains 5 mg (Omeprazole 1 mg/ml Oral Suspension) in each 5 millilitre (5ml) of suspension.
- Take this medicine by mouth.
- It is recommended that you take your dose of medicine in the morning.
- This medicine should be taken on an empty stomach, at least 30 minutes before a meal.
- In order to aid administration of the product to infants, administration with a small quantity of milk (not more than 10-15 ml) is possible. Administer immediately after mixing, check that the mixture is fully administered to the infant, then wait at least 30 minutes before commencing feeding. The oral suspension should not be mixed or administered with any drinks or foods other than milk as that may affect the effectiveness of the medicine.
- Use the dosing device provided to measure the correct dose (see Measuring your dose).
- This medicine can also be administered via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes.
- Instructions for use via NG or PEG tube:
 - Ensure that the enteral feeding tube is free from obstruction before administration.
 - Flush the enteral tube with 5 ml of water
 - Administer the required dose of Omeprazole Oral Suspension with a suitable measuring device.
 - Flush the enteral tube with 5 ml of water

This product can be used with Polyurethane and PVC nasogastric (NG) and percutaneous endoscopic gastrostomy (PEG) tubes of size 6 Fr to 16 Fr. For the smallest diameter tubes (6 Fr) a smaller flush volume of 2 ml may be used in very young children

Preparing and taking the suspension

The container is a two compartment system containing powder both in the cap and in the bottle. The two powders first need to be combined and are then to be reconstituted in water. A red mixing disk will drop into the medicine to help mix the powders and also mix the reconstituted suspension after addition of the water. It should remain in the bottle. The red cap is replaced by a grey cap after reconstitution. It is recommended that a pharmacist or other health care professional reconstitutes Omeprazole Oral Suspension prior to its dispensing to the patient.

Instructions for initial reconstitution.

Combination of powder in cap and bottle

- Shake the bottle for 10 seconds to loosen the powder.
- Twist the red cap anti-clockwise (see arrow on cap) until the seal is broken to release the powder in the red cap into the bottle.
- Twist the red cap back to the original position, securely fastening the red cap onto the bottle.

Reconstitution of the powder

- Shake the bottle vigorously for ten seconds to mix the powders.
- Tap the base of the bottle three times on a hard horizontal surface to make sure all powder is in the bottle and not in the cap.
- Remove the red cap from the bottle.
- Add 64 ml of water by using a suitable measuring device up to the line on the label.
- Securely fasten the red cap onto the bottle and shake vigorously for 30 seconds.

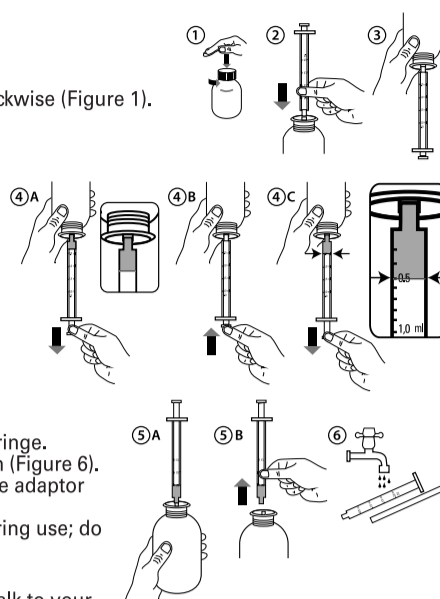
Placement of syringe adaptor

- Remove the red cap and red ring and throw away.
- Insert the colourless, transparent Bottle Adaptor and replace the red cap with the grey plastic screw-cap.
- Leave for fifteen minutes for product to reach final consistency.

Measuring your dose

Instructions for use of the syringe

1. Shake the bottle for 20 seconds immediately prior to each use
2. To open the bottle, press the grey cap down and turn it anti-clockwise (Figure 1). Do not remove the white cap portion.
3. Take the syringe and put it into the adaptor opening (Figure 2).
4. Turn the bottle upside down (Figure 3).
5. Fill the syringe with a small amount of suspension by pulling the plunger down (Figure 4A). Then push the plunger upward in order to remove any possible bubbles (Figure 4B). Finally, pull the plunger down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor. The top flat edge of the piston should be in line with the graduation mark you are measuring to (Figure 4C).
6. Turn the bottle the right way up (Figure 5A).
7. Remove the syringe from the adaptor (Figure 5B).
8. Put the end of the syringe into the mouth of the patient and push the plunger slowly back in to take the medicine. The suspension will be released slowly while the last portion will be released faster due to reduced resistance in the tip of the syringe.
9. Wash the syringe with water and let it dry before you use it again (Figure 6).
10. Close the bottle with the grey plastic screw cap - leave the bottle adaptor in the bottle.



Note: It is normal to have the red plastic disc in the suspension during use; do not attempt to remove it.

If you take more Omeprazole Oral Suspension than you should

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

If you forget to take Omeprazole Oral Suspension

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 Suspension

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

If you have 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 Suspension 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).
- 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.

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.

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.
- 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 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 Suspension 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 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 Oral Suspension

- 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 after EXP. The expiry date refers to the last day of that month.
- Dry Powders: 'This medicinal product does not require any special temperature storage conditions' and 'Store in the original foil pouch in order to protect from moisture'.
- Following reconstitution: Store in a refrigerator (2°C - 8°C). Store in the original container in order to protect from light. Keep the bottle tightly closed. The reconstituted suspension has a shelf life of 28 days. After this time, any remaining suspension should be discarded. For up to 2 days the suspension may be stored below 25°C.
- Do not use Omeprazole Oral Suspension if you notice anything wrong with the appearance of the medicine (See section 6). Tell your pharmacist.
- 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 to protect the environment.

6. Contents of the pack and other information

What Omeprazole Oral Suspension contains

- The active substance is omeprazole. Each ml of oral suspension contains 1 mg of omeprazole
- The other ingredients are Sodium hydrogen carbonate (E500), Potassium hydrogen carbonate (E501), Sodium alginate (E401), Maltitol (E965), Mannitol (E421), Sucralose (E955), Xanthan gum (E415), Natural Strawberry Flavouring containing Maltodextrin (Maize), Starch Modified Corn (E1450) and Acetic Acid (E260), Titanium dioxide (E171), Sodium benzoate (E211), Sodium methyl parahydroxybenzoate (E219)

What Omeprazole Oral Suspension looks like and contents of the pack

Before reconstitution: White / off-white / slightly yellow powder in a cap attached to a bottle containing white / off-white / slightly yellow powder, which may contain dark specks due to sweetener.

After reconstitution: White / off-white / brownish oral suspension. May contain dark specks due to sweetener.

Pack:

Amber plastic (PET) bottle with powder fitted with a red Polypropylene (PP) closure cap and a red Polypropylene (PP) mixing disk assembly containing powder, all enclosed in an aluminium foil pouch.

Each bottle contains 47 g of powder for oral suspension. Once reconstituted the bottle contains 90 ml of oral suspension, of which at least 75 ml is intended for dosing and administration.

Each pack also contains an opaque PP oral dosing syringe (5 ml, graduated at each 1 ml and intermediate marks every 0.1 ml) with white HDPE plunger, colourless, transparent LDPE press-in bottle adaptor and grey PP replacement cap.

Pack: 1 or 2 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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