Package leaflet: Information for the patient

OMEPRAZOLE 10 mg CAPSULES
OMEPRAZOLE 20 mg CAPSULES
OMEPRAZOLE 40 mg 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 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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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 contains the active substance omeprazole. 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-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 recurrence.
- 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 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 to omeprazole or any of the other ingredients of this medicine (listed in section 6) .
- are allergic to other proton pump inhibitors (eg 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

Severe 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 and seek medical attention immediately if you notice any of the symptoms associated with these severe skin reactions described in section 4.

Talk to your doctor or pharmacist before taking Omeprazole if:

- You have reduced body stores or risk factors for reduced vitamin B_{12} and are to receive omeprazole long term. Omeprazole may reduce the absorption of vitamin B_{12}.
- 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).

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.

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.

This medicine may affect the way that your body absorbs vitamin B_{12}, 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 B_{12}:

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

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 stuff that you are taking this medicine. Your doctor may advice you to stop taking this medicine for at least 5 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.

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 infection)
- Tacrolimus (in cases of organ transplantation)
- Clarithromycin (an antibiotic) 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)
- Saquinavir (used to treat HIV infection)
- 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 and inflammatory conditions) – if you are taking a high dose of methotrexate, you 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
Pregnancy
Omeprazole can be used during pregnancy. 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.

Breast-feeding
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.

Omeprazole contains sucrose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

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

The recommended dose is given below.

Adults:
To treat of GORD with symptoms 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-40 mg once a day.
- If your gullet has not been damaged, the recommended dose is 10 mg to 20 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 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 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 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 4–8 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 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.

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 and adolescents:
To treat GORD with symptoms 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 may 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. However, it is recommended that you take it on an empty stomach unless otherwise asked by your doctor.
- 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 has 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.
    - You can also suck the capsule and swallow the pellets with half a glass of water. Do not chew the pellets.

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 taking your medicine unless your doctor tells you to.

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 serious side effects, stop taking Omeprazole and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing and breathing (severe allergic reaction).
- 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.
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- A red, scaly, widespread rash with bumps under the skin and blisters, accompanied by fever. Symptoms usually occur at the start of treatment (acute generalized exanthematous pustulosis).
- A reduction in your red or the 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.
- 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’
- 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), benign polyps in the stomach.
- 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 in the hip, wrist or spine.

Rare side effects: 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 restless, 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.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (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 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, 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 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 label after EXP. The expiry date refers to the last day of that month. Bottle packs: This medicine does not require any special temperature storage conditions. Keep the bottle tightly closed, in order to protect from moisture. After first opening of the bottle, the product should be used within 100 days.

Alu/Alu blister packs: Do not store above 30°C.

PVC-PVDC/Alu blister packs: Do not store above 25°C.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Omeprazole contains
Omeprazole 10 mg: The active substance is omeprazole.
The other ingredients are: hypromellose, talc, titanium dioxide (E171), disodium phosphate dihydrate, methacrylic acid ethyl acrylate copolymer, sodium lauril sulfate, polysorbate, triethyl citrate, sugar spheres.

The capsule shell contains: titanium dioxide (E171) and gelatin. The ink contains black iron oxide (E172) and shellac.

Omeprazole 20 mg / 40 mg:
The active substance is omeprazole.
The other ingredients are: hypromellose, talc, titanium dioxide (E171), disodium phosphate dihydrate, methacrylic acid ethyl acrylate copolymer, sodium lauril sulfate, polysorbate, triethyl citrate,sugar spheres.
The capsule shell contains titanium dioxide (E171), and gelatin. The ink also contains black iron oxide (E172) and shellac.

What Omeprazole looks like and contents of the pack
The 10 mg capsules are opaque white, containing white to slightly beige spherical pellets with "OM-10" printed on the capsule.
The 20 mg capsules are opaque white, containing white to slightly beige spherical pellets with "OM-20" printed on the capsule.
The 40 mg capsules are opaque white, containing white to slightly beige spherical pellets with "OM-40" printed on the capsule.
The capsule contains gastro-resistant microgranules.

The capsules are available in bottles or blister of 7, 14, 15, 28, 30, 50, 56, 60, 90, 100, 2x28 (they are also available in bottles of 50 capsules) and 500 capsules. Not all pack sizes may be marketed.

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