PACKAGE LEAFLET: INFORMATION FOR THE USER

Omeprazole 20 mg Gastro-resistant Capsules

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

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 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 in adults for the short-term treatment of reflux symptoms (for example, heartburn, acid regurgitation).

Reflux is the backflow of acid from the stomach into the gullet “foodpipe”, which may become inflamed and painful. This may cause you symptoms such as a painful burning sensation in the chest rising up to the throat (heartburn) and a sour taste in the mouth (acid regurgitation).
It might be necessary to take the capsules for 2-3 consecutive days to achieve improvement of symptoms.

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).
- if you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- if you are taking a medicine containing nefifinavir (for HIV infection).
If you are not sure, talk to your doctor or pharmacist before taking Omeprazole.

Warnings and precautions

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Do not take Omeprazole for more than 14 days without consulting a doctor. If you do not experience relief, or if you experience a worsening of symptoms, consult your doctor.

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 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 had previous gastric ulcer or gastrointestinal surgery.
- You are on continuous symptomatic treatment of indigestion or heartburn for 4 or more weeks.
- You continuously suffer from indigestion or heartburn for 4 or more weeks.
- You have jaundice or severe liver disease.
- You are aged over 55 years with new or recently changed symptoms.
- You are due to have a specific blood test (Chromogranin A).
- You have ever had a skin reaction after treatment with a medicine similar to Omeprazole that reduces stomach acid.

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.

Patients should not take omeprazole as a preventative medication.

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 20 mg Gastro-resistant Capsules.

Do not take Omeprazole if you are taking a medicine containing nelfinavir (used to treat HIV infection). You should specifically tell your doctor or pharmacist if you are taking clopidogrel (used to prevent blood clots (thrombi)).

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)
- 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.

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Omeprazole with food and drink
You can take your capsules with food or on an empty stomach.

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 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 contains 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
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told
you. You should check with your doctor or pharmacist if you are not sure.
The usual dose is one 20 mg capsule or two 10 mg capsules once a day for 14 days. Contact your doctor
if you are not free from symptoms after this period.
It might be necessary to take the capsules for 2-3 consecutive days to achieve improvement of symptoms.

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 have trouble swallowing the capsules
- If you have trouble swallowing the capsules:
  - Open the capsule 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. Do not use milk or fizzy water. The solid pieces contain the medicine
    - do not chew or crush them.

Children
This medicine should not be used in children and adolescents under the age of 18 years.

If you take more Omeprazole than you should
If you take more Omeprazole than recommended, talk to your doctor or pharmacist straight away.

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.
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:

- 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’.
- 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.
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing.
- 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.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthritis) 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.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- 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 take 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 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 (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 out of the reach and sight of children.

Do not use Omeprazole after the expiry date which is stated on the blister and outer carton. The expiry date refers to the last day of that month.

In – use shelf life in HDPE bottles
100 days Do not store above 25ºC.
Store in the original package, in order to protect from light and moisture.

Keep the tablet container tightly closed in order to protect from moisture.

Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Omeprazole 20 mg Gastro-resistant Capsules contains
The active substance is omeprazole.

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Each gastro-resistant capsule, hard contains 20mg of omeprazole.

The other ingredients are:

**Capsule content:**
Sugar spheres (Sucrose and Maize starch), Hypromellose, Sodium Lauryl Sulfate, Magnesium oxide heavy, Povidone K25, talc, Methacrylic acid copolymer dispersion type C, 30 % water dispersion, Triethyl Citrate.

**Capsule shell:**
gelatine, titanium dioxide (E171),

**What Omeprazole 20 mg Gastro-resistant Capsules looks like and contents of the pack**
White cap, white body, containing almost white to light brown pellets.

**Pack sizes:**
Blisters: 7 and 14 gastro-resistant capsules, hard
White plastic tablet container with tamper-evident screw cap and (integrated) desiccant: 7, 10 and 14 gastro-resistant capsules, hard.

Not all pack sizes may be marketed.

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