

Omeprazole Gastro-resistant Capsules BP 20mg/40mg Taj Pharma

(Omeprazole)

Package leaflet: Information for the user

Read all of this leaflet carefully before you start taking this medicine.

- 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 Capsules are and what they are used for
2. What you need to know before you take Omeprazole Capsules
3. How to take Omeprazole Capsules
4. Possible side effects
5. How to store Omeprazole Capsules
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1. What Omeprazole Capsules are and what they are used for

Omeprazole Capsules 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 Capsules 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 Capsules 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).

2. What you need to know before you take Omeprazole Capsules

Do not take Omeprazole Capsules

- If you are allergic (hypersensitive) to omeprazole or any of the other ingredients of Omeprazole Capsules.
- 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 Omeprazole Capsules if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Omeprazole Capsules.

Warnings and precautions

Tell your doctor before taking this medicine, if:

- You are due to have a specific blood test (Chromogranin A)

Omeprazole Capsules may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Omeprazole Capsules 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 Capsules 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 Capsules. Remember to also mention any other ill-effects like pain in your joints.

Omeprazole may reduce magnesium level in blood, especially if you are taking it for more than 3 months; Talk to your doctor if you are taking Digoxin or water tablets, as they may increase the risk of low magnesium level.

Taking a proton pump inhibitor like Omeprazole Capsules, 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 take Omeprazole Capsules 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.**

Other medicines and Omeprazole Capsules

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is because Omeprazole Capsules can affect the way some medicines work and some medicines can have an effect on Omeprazole Capsules.

Do not take Omeprazole Capsules 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 Capsules
- 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 Capsules
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infection)
- Tacrolimus or mycophenolate mofetil (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 Capsules treatment

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

Taking Omeprazole Capsules with food and drink

You can take your Capsules with food or on an empty stomach.

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 Capsules if you are breast-feeding.

Driving and using machines

Omeprazole Capsules 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.

Important information about some of the ingredients of Omeprazole Capsules

Omeprazole Capsules contain lactose. 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 Omeprazole Capsules exactly as your doctor has told you. You should 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 doses are given below.

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 recommended 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 ulcer does 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 ulcer does 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 4–8 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 Capsules 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.

Children:

This formulation is not suitable for children.

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 tablets coated with enteric coating which stops the medicine from being broken down by the acid in your stomach. It is important not to damage the Capsules.

If you take more Omeprazole Capsules than you should

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

If you forget to take Omeprazole Capsules

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, Omeprazole Capsules can cause side effects, although not everybody gets them.

If you notice any of the following rare but serious side effects, stop taking Omeprazole Capsules 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.
- Fractures 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.
- 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 (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.
- 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).
- Hypomagnesaemia (low level of magnesium in the blood).
- Rash, possibly with pain in the joints.

If you are on Omeprazole Capsules 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.

Omeprazole Capsules 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.

Do not be concerned by this list of possible side effects. You may not get any of them. **If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

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.

5. How to store Omeprazole Capsules

- Keep out of the reach and sight of children.
- Do not use Omeprazole Capsules after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Store this blister in the original package or keep the bottle tightly closed in order to protect from moisture.
- Medicines should not be disposed of 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 Capsules contains

The active substance is omeprazole.

- a) Each hard gelatin capsule contains :
- | | |
|------------------------------|------|
| Omeprazole B.P. | 20mg |
| (as enteric coated granules) | |
| Excipients | q.s. |
- Approved colours used in empty capsule shells
- b) Each hard gelatin capsule contains :
- | | |
|------------------------------|------|
| Omeprazole B.P. | 40mg |
| (as enteric coated granules) | |
| Excipients | q.s. |
- Approved colours used in empty capsule shells

The other ingredients are: Lactose monohydrate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, hypromellose acetate succinate, talc, triethyl citrate, monoethanolamine, sodium laurilsulfate, carnauba wax, gelatin, titanium dioxide, red iron oxide.

What Omeprazole Capsules looks like and contents of the pack

Omeprazole gastro resistant Capsules are hard gelatin Capsules.

Aluminum blister.

Pack size: 7, 14, 28, 30, 50, 100 and 500 capsules.

Not all pack sizes may be marketed

7. Manufactured In India By:

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