

**OMEPRAZOLE 10mg / 20mg / 40mg GASTRO-RESISTANT TABLETS**

## Omeprazole

(Referred to as Omeprazole tablets throughout this leaflet)

**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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this tell your doctor or pharmacist.

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**1. What Omeprazole Tablets are and what are they used for**

Omeprazole Tablets 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 Tablets 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 Tablets 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. Before you take Omeprazole Tablets**

Do not take Omeprazole tablets

- If you are allergic (hypersensitive) to omeprazole or any of the other ingredients of Omeprazole Tablets.
- 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 (used for HIV infection)

If you are not sure, talk to your doctor or pharmacist before taking Omeprazole Tablets.

**Take special care with Omeprazole Tablets and check with your doctor or pharmacist before taking your medicine**

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

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 Tablets, 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 Tablets 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 other medicines**

**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 Tablets can affect the way some medicines work and some medicines can have an effect on Omeprazole Tablets.

Do not take Omeprazole Tablets 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 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 Tablets
- 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 Tablets
- 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 Tablets treatment

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Omeprazole Tablets 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 Tablets with food and drink:**

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

**Pregnancy and breast-feeding:**

Before taking Omeprazole Tablets, tell your doctor if you are pregnant or trying to get pregnant. Your doctor will decide whether you can take Omeprazole Tablets during this time.

Your doctor will decide whether you can take Omeprazole Tablets if you are breast-feeding.

**Driving and using machines:**

Omeprazole Tablets 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 Tablets:**

Omeprazole Tablets 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 Tablets**

Always take Omeprazole Tablets 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 tablets to take and how long to take them for. This will depend on your condition and how old you are.

The usual 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 usual 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 usual 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 usual 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 usual 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 usual 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 usual dose is 20 mg once a day for 4-8 weeks.

To **prevent duodenal and stomach ulcers** if you are taking **NSAIDs**:

- The usual dose is 20 mg once a day.

To treat **ulcers caused by *Helicobacter pylori*** infection and to stop them coming back:

- The usual dose is 20 mg Omeprazole Tablets 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 usual 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 tablets in the morning.
- You can take your tablets with food or on an empty stomach.
- Swallow your tablets whole with half a glass of water. Do not chew or crush the tablets. This is because the tablets are 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 tablets

**If you take more Omeprazole Tablets than you should**

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

**If you forget to take Omeprazole Tablets**

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 Tablets can cause side effects, although not everybody gets them.

**If you notice any of the following rare but serious side effects, stop taking Omeprazole Tablets 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** (*These may affect 1 to 10 users in 100*)

- Headache.
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).

**Uncommon side effects** (*These may affect 1 to 10 users in 1,000*)

- 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 and spine

**Rare side effects** (*These may affect 1 to 10 users in 10,000*)

- 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** (*These may affect less than 1 user in 10,000*)

- 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).

If you are on Omeprazole Tablets 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 Tablets 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**

Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Alternatively you can call Freephone 0800 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy.

#### 5. How to store Omeprazole Tablets

- Keep out of the reach and sight of children.
- Do not use Omeprazole Tablets 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. Further information

**What Omeprazole Tablets contains**

The active substance is omeprazole. Omeprazole Tablets contain 10 mg, 20 mg and 40mg of omeprazole.

The other ingredients are lactose monohydrate, sodium starch glycolate, sodium stearyl fumarate, sodium stearate, hypromellose acetate succinate, brownish pink colour [contains propylene glycol, titanium dioxide (E171), red iron oxide (E172), hypromellose and yellow iron oxide (E172)], talc, triethyl citrate, monoethanolamine, sodium laurilsulfate and traces of carnauba wax.

**What Omeprazole Tablets looks like and contents of the pack**

1. Omeprazole 10 mg Gastro-Resistant Tablets are brownish-pink film coated capsule shaped tablets. Blisters of 28 tablets
  2. Omeprazole 20 mg Gastro-Resistant Tablets are brownish-pink film coated capsule shaped tablets. Blisters of 28 tablets
  3. Omeprazole 40 mg Gastro-Resistant Tablets are brownish-pink film coated capsule shaped tablets. Blisters of 7, 28 tablets
- Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer:**

Dexcel® - Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB, UK.

This leaflet was last revised in May 2013

155mm x 480mm