Gastro-resistant Tablets

Read all of this leaflet carefully before you start taking these tablets. It contains important information for you:

1. WHAT OMEPRAZOLE TABLETS ARE AND WHAT THEY ARE USED FOR

Omeprazole tablets contain the active substance omeprazole, which belongs to a group of medicines called ‘proton pump inhibitors’. They work by reducing the amount of acid that your stomach produces.

Omeprazole tablets are used to treat the following conditions:

- Ulcers caused by medicines called NSAIDs (Non-steroidal Anti-Inflammatory Drugs). Omeprazole tablets can also be used to stop ulcers from forming if you have been prescribed these medicines for use in the short term (less than 1 year).
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).
- 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 in the upper part of the intestine (duodenal ulcer). A duodenal ulcer is a sore in the lining of the small intestine (the tube which connects your throat to your stomach) where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE OMEPRAZOLE TABLETS

Do not take Omeprazole tablets:

- If you are allergic to omeprazole or any of the other ingredients of Omeprazole tablets.
- If you take to medicines containing another proton pump inhibitors (e.g. pantoprazole, lansoprazole, esomeprazole).
- If you are taking a medicine containing nelfinavir (used for HIV infection).
- If you get a rash on your skin, especially in areas exposed to sunlight.
- If you have any further questions, ask your doctor or pharmacist for advice before taking this medicine.

Other medicines and Omeprazole tablets

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Steroidal Anti-Inflammatory Drugs. Omeprazole tablets contain less than 1 mmol sodium (23 mg) per tablet, which is approximately 0.1% of the Daily Reference Value (DRV).
- 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.

3. HOW TO TAKE OMEPRAZOLE TABLETS

Omeprazole tablets are 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 tablets are not likely to affect the way that you use or react to any other medicines. If you are not sure, talk to your doctor or pharmacist.

Always take Omeprazole tablets as your doctor has prescribed them. Contact your doctor before taking this medicinal product.

Omeprazole tablets contain lactose and sodium. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Omeprazole tablets contain less than 1 mmol sodium (23 mg) per tablet, which is less than 0.1% of the Daily Reference Value (DRV) for sodium.

HOW TO TAKE OMEPRAZOLE TABLETS

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

Use in adults

To treat symptoms of GORD such as heartburn and indigestion:

- If your doctor has found that your food pipe (gullet) has been badly damaged, you may need to take a dose of 40 mg once a day for 4–8 weeks. Your doctor may tell you to take a dose of 40 mg for a further 4–8 weeks if your
The recommended 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 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 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 2 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 4 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 for 8 weeks.

To prevent 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 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 response, so decide how long you need to take the medicine for.

Children

This medication 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 crush or break 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 too many Omeprazole tablets as 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 the one you missed.

• If you stop taking Omeprazole tablets:

• Do not take Omeprazole tablets without taking advice from your doctor or pharmacist.

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 everyone using them will experience them.

If you notice any of the following rare (may affect up to 1 in 10,000 people) but serious side effects, stop taking the medicine and contact a doctor immediately:

• Sudden swelling, swelling of your lips, tongue and throat or body, rash, itching or difficulties in swallowing (severe allergic reaction); (rare)

• 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 shivering, which may be accompanied by "SEES syndrome or drug hypersensitivity syndrome"; (rare)

• A red or purple 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)

• Kidney problems, urine being dark and to a greater extent which can be symptoms of liver problems. (rare)

Other side effects include:

• Common side effects (may affect up to 1 in 10 people):

• Headache.

• Effects on your stomach or gut: diarrhea, stomach cramps, flatulence.

• Feeling sick (nausea) or being sick (vomiting).

• Bloating in the stomach.

• Uncommon side effects (may affect up to 1 in 100 people):

• Difficulty with the feet and ankles.

• Disturbed sleep (insomnia).

• Change in skin 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 or feeling energy, Fractures of the hip, wrist or spine.

Rare side effects (may affect up to 1 in 1,000 people):

• Blood problems such as reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely to occur.

• Low levels of sodium in the blood. This may cause weakness, being sick (vomiting), breathlessness.

• Feeling agitated, confused or depressed.

• Taste changes.

• Eyeball problems such as blurred vision.

• Suddenly feeling weak or short of breath (bronchospasm).

• Dry mouth.

• 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).

• Swelling of the feet and ankles.

• Enlarged breasts in men.

• Widespread rash, high body temperature and fever. If present, these symptoms may be accompanied by blisters or peeling. There may 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, potassium, calcium, sodium.

• Rash, possibly with pain in the joints.

Omeprazole tablets may in very rare cases affect the white blood cells causing 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 cough, sore throat, 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 by completing the Yellow Card Scheme Website: 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 to provide more information on the safety of this medicine.

5. HOW TO STORE OMEPRAZOLE TABLETS

• Keep out of the sight and reach of children.

• Do not use Omeprazole tablets after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

• Do not store above 25°C.

• Store the tablets in the original packaging 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 tablets contain

• The active substance is omeprazole. Omeprazole tablets contain 10 mg, 20 mg and 40 mg of omeprazole. The other ingredients are lactose monohydrate, sodium starch glycolate, sodium stearyl fumarate, microcrystalline cellulose, hypromellose (E462), hypromellose acetate succinate, brownish pink colouring (contains propylene glycol), titanium dioxide (E171), red iron oxide (E172), hypromellose and yellow iron oxide (E172). Citric acid, mononathanolamine, sodium laurylsulphate and traces of tricaprylin.

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.

2. Omeprazole 20 mg gastro-resistant tablets are brownish-pink film-coated capsule shaped tablets.

3. Omeprazole 40 mg gastro-resistant tablets are brownish-pink film-coated capsule shaped tablets.

Blisters of 7, 28 tablets and 140 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Dexcel Pharma Ltd, 7 Drayton Fields, Daventry, Northamptonshire, NN11 8BF.

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