Omeprazole 20 mg Capsules 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 20 mg Capsules are used to treat the following conditions:

- ‘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 20 mg 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-Ellson syndrome).

In children:
- Children over 1 year of age and ≥ 10 kg ‘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 20mg Capsules

Do not take Omeprazole 20mg Capsules:
- If you are allergic (hypersensitive) to omeprazole or any of the other ingredients of Omeprazole 20 mg Capsules (listed in section 4).
- If you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- If you are taking a medicine containing neftilinav (used for HIV infection).
- If you are not sure, talk to your doctor or pharmacist before taking Omeprazole 20 mg Capsules.

Warnings and precautions
Omeprazole may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Omeprazole 20 mg Capsules or while you are taking them, talk to your doctor straightaway:

- 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 vomit blood.
- You pass black stools (blood-stained faeces).
- You feel very sleepy.
- You have ever had a skin reaction after treatment with a medicine similar to Omeprazole that reduces stomach acid.

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).

If you take Omeprazole 20mg 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.

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.
Tell your doctor before taking this medicine if you are due to have a specific blood test (Chromogranin A).

Other medicines and Omeprazole 20mg Capsules
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is because Omeprazole 20mg Capsules can affect the way some medicines work and some medicines can have an effect on Omeprazole 20mg Capsules. Do not take Omeprazole 20mg Capsules if you are taking a medicine containing neftilinav (used for HIV infection).
Tell your doctor or pharmacist if you are taking any of the following medicines:
- Ketoconazole, itronoxazole, posaconazole or voriconazole (used to treat infections caused by a fungus).
- Dignox (used to treat heart problems).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Phenytin (used in epilepsy). If you are taking phenytin, your doctor will need to monitor you when you start or stop taking Omeprazole 20mg Capsules.
- Medicines used to treat HIV, such as warfarin or vitamin K blockers. Your doctor may need to monitor you when you start or stop taking Omeprazole 20mg Capsules.
- Rifampicin (used to treat tuberculosis).
- Atazanavir (used to treat HIV infection).
- Telithromycin (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 treatment.
- If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Omeprazole 20mg 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.

Omeprazole 20mg Capsules 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 breastfeeding, 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 20mg Capsules if you are breast-feeding.

Driving and using machines
Omeprazole 20mg 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.

1. How to take Omeprazole 20mg Capsules

Always take Omeprazole 20mg 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 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 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 6 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 you take the capsules with water, 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.
- 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 ulcers caused by Helicobacter pylori infection and to stop them coming back:
- The recommended dose is 20 mg omeprazole twice a day for 14 days.
- 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 (Czollar-Ellinger Syndrome):
- The recommended dose is 20 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.

Use in Children:
- Children aged over 4 years may take omeprazole. The dose for children is based on the child's weight and the doctor will decide the correct dose.
- Children over 1 year of age and with a body weight of more than 10 kg may take Omeprazole enteric-coated pelleted capsules. The doctor may decide how long you need to take the medicine for.

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 the capsules whole with 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.
- If you are taking Omeprazole 20mg Capsules and later on develop symptoms of GORD such as heartburn and acid regurgitation:
  - Children aged over 4 years may take omeprazole. Enteric-coated capsules are direct-swallow tablets with a sugar shell that stops the medicine from being broken down by stomach acid. The capsules are based on the child's weight and the doctor will decide the correct dose.

Taking the 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 the capsules whole with 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. The capsule shell is composed of gelatin, titanium dioxide E171, erythrosine E127, patent blue V E131, black iron oxide E172. The color in the capsule is made by shellac glaze, black iron oxide E172, black iron oxide E171. The cap and light grey body. Each capsule is printed with 'R158' on the neck and 'R159' at the neck of the capsule. The capsule contains 20 mg of omeprazole.
- 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 any acidic soft drink.
- 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.

If you take more Omeprazole 20mg Capsules than you should:
If you take more Omeprazole 20mg Capsules than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take Omeprazole 20mg Capsules:
If you forget to take a dose don't worry 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 20mg Capsules and contact a doctor immediately:
- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, breathing difficulties or swelling of the face (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be secondary blisters and sores in the lips, eyes, mouth 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):
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence),
- Feeling sick (nausea) or being sick (vomiting).

Rare side effects (may affect up to 1 in 1,000 people):
- Blood disorders: A lack of white blood cells can be seen as fatigue, involuntary muscle contractions, delirium, confusion, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Blood tests show 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.

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).
- Joint pains (arthritis) or muscle pains (myalgia).

Very rare side effects (may affect up to 1 in 100,000 people):
- Changes in blood count including aplastic anaemia.
- Low levels of magnesium in the blood.
- Severe kidney problems (interstitial nephritis).
- Muscle weakness.
- Enlarged breasts in men.

Not known (frequency cannot be estimated from the available data):
- 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.
- Ears and hearing problems.
- Feeling or seeing things that are not there (hallucinations).

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 lead to symptoms such as feeling tired, involuntary muscle contractions, delirium, confusion, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Blood tests show 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.

Very rare side effects may affect you:
- Changes in stomach blood 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).

5. How to store Omeprazole 20mg Capsules
Keep this medicine out of the sight and reach of children.

Do not change 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 25°C. Store this blister in the original package.

Do not throw away any medicines 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 20mg Capsules contain
- The active substance is omeprazole. Omeprazole 20mg Capsules contain 20 mg of omeprazole.
- The other ingredients are mannitol, crosspolyvose, hypromelllose, polysorbate 80, magnesium stearate, E1520 (ethyl acrylate copolymer), triethyl citrate and magnesium stearate.

What Omeprazole 20mg Capsules look like and contents of the pack
The capsules are supplied in a hard gelatin capsule shell with a purple cap and light grey body. Each capsule is printed with 'R158 Omeprazole 20mg' in black ink.

The capsule shell contains gelatin, titanium dioxide E171, prymethine E127, patent blue V E131, black iron oxide E172. The printing ink is composed of shellac glue, black iron oxide E172, propylene glycol and ammonium hydroxide.

Omeprazole 20mg Capsules are supplied in boxes containing 7, 14 or 28 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Dr. Reddy’s Laboratories (UK) Ltd
6 Riverview Road, Beverley, HU17 0LD, UK
Omeprazole 20mg Capsules, PL 085530126
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