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

The usual dose is 20 mg Omeprazole capsules twice a day.

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 pancrace (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 capsules in the morning.

You can take your capsules with or without food or an empty stomach.

Swallow your capsules whole with a half 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.

Do not take Omeprazole capsules

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, do not take a double dose to make up for a forgotten dose.

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:

• Nausea or vomiting, swelling in the face, throat or lips or palate.

• Low levels of sodium in the blood. This may cause weakness, cramps or nausea.

• Joint pains (arthralgia) or muscle pains (myalgia)

• Disturbed sleep (insomnia)

• Low levels of magnesium in the blood. This may cause weakness, being sick (vomiting) and cramps.

• 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 10,000)

• Rash:

• Efficacy on your stomach or gut, diarrhea, 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 face and ankles

• Disturbed sleep (insomnia).

• Difficulty breathing especially with a high fever (shortness of breath, wheezing).

• Skin rash, lumpy rash (hives) and itchy skin.

• Joint pain and stiffness (arthritis) or muscle pain (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 anaemia (lack of white blood cells)

• Agitation

• Sewing, 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 itching 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

Not Known (frequency cannot be estimated from the available data)

• Hyperglycaemia (low level of magnesium in the blood).

The usual dose is 20 mg Omeprazole capsules twice a day for one week.

If you are on Omeprazole capsules for more than three months it is possible that the levels of magnesium in your body will fall.

Low levels of magnesium can be as severe as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heat rate. If you get any of these symptoms, please tell your doctor.

Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the body. 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 discharge, be sure to consult your doctor as soon as possible as that is the worst white blood cell count (granulocytes) can be reduced or even by a blood test. It is important for you to give information about your medication 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.

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 light.

6. Further information

What Omeprazole capsules contain

The active substance is omeprazole. Omeprazole capsules contain 10 mg, 20 mg omeprazole.

The other ingredients are lactose monohydrate, sodium citrate, sodium hydrogen carbonate, magnesium stearate, gelatin, black iron oxide (E172) and titanium dioxide (E171) and talc, sodium carboxymethylcellulose, hydroxypropyl methylcellulose, glycerol.

What Omeprazole capsules looks like and contents of the pack

• Omeprazole 10 mg gastro resistant capsules are hard gelatin capsules with an opaque beige body, marked “10”, and an opaque beige cap, marked “DP”.

• Blisters of 28 capsules

• Omeprazole 20 mg gastro-resistant capsules are hard gelatin capsules with an opaque beige body, marked “20”, and a caramel beige cap, marked “DP”.

• Blisters of 28 capsules

Marketing Authorisation Holder and Manufacturer:

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

Distributed by Discovery Pharmaceutics, The Old Vicarage, Market Place, Castle Donington, DE74 2US, UK.

This leaflet was last revised in September 2012.