Package leaflet: Information for the patient

Medoprazole 20 mg hard capsules

Omeprazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 Medoprazole is and what it is used for
2. What you need to know before you take Medoprazole
3. How to take Medoprazole
4. Possible side effects
5. How to store Medoprazole
6. Contents of the pack and other information

1. What Medoprazole is and what it is used for

Medoprazole 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.
Medoprazole 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). Medoprazole 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).

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 Medoprazole

Do not take Medoprazole:

- If you are allergic to omeprazole or any of the ingredients of this medicine (listed in section 6).
- 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)

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

Warnings and precautions

Talk to your doctor before taking Medoprazole:

- if you have ever had a skin reaction after treatment with a medicine similar to Medoprazole 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 Medoprazole. Remember to also mention any other ill-effects like pain in your joints.

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

If you take Medoprazole 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 a proton pump inhibitor like Medoprazole, 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).

When taking omeprazole, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

Other medicines and Medoprazole

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Medoprazole can affect the way some medicines work and some medicines can have an effect on Medoprazole.

Do not take Medoprazole 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 Medoprazole
- 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 Medoprazole

- 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))

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

Medoprazole with food and alcohol

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will decide whether you can take Medoprazole during this time.
Your doctor will decide whether you can take Medoprazole if you are breast-feeding.

Driving and using machines

Medoprazole 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.

Medoprazole contains mannitol and sucrose.

Medoprazole capsules contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Medoprazole capsules also contain mannitol which may have a mild laxative effect.

3. How to take Medoprazole

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 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:

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 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 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 do 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 tak**ing 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 Medoprazole 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.

Use in children:

To treat symptoms of GORD such as **heartburn and acid regurgitation**:

- Children over 1 year of age and with a body weight of more than 10 kg may take Medoprazole. The dose for children is based on the child's weight and the doctor will decide the correct dose.

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

- Children aged over 4 years may take Medoprazole. The dose for children is based on the child's weight and the doctor will decide the correct dose.
- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child.

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 coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

What to do if you or your child have trouble swallowing the capsules

If you, or your child, have trouble swallowing the capsules:

- 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 apple sauce.
- 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 Medoprazole than you should

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

If you forget to take Medoprazole

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, 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 Medoprazole 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.

Side effects may occur with certain frequencies, which are defined as follows:

Very common:	affects more than 1 user in 10
Common:	affects 1 to 10 users in 100
Uncommon:	affects 1 to 10 users in 1,000
Rare:	affects 1 to 10 users in 10,000
Very rare:	affects less than 1 user in 10,000
Not known:	frequency cannot be estimated from the available data

Other side effects include:

Common side effects

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

Uncommon side effects

- 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.

Rare side effects

- 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

- 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.
- Hypomagnesaemia.

Medoprazole 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.

Frequency not known

- Rash, possibly with pain in the joints

If you are on Medoprazole 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.

Do not be concerned by this list of possible side effects. You may not get any of them.

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 directly via the ADR Reporting website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Medoprazole

Keep this medicine out of the sight and reach of children.

Store below 25ºC, in the original package in order to protect from light.

Do not use this medicine 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 throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Medoprazole contains

- The active substance is omeprazole. Medoprazole capsules contain 20 mg of omeprazole.
- The other ingredients are: Sugar pellets (Manitol, Hydroxyl propyl methyl cellulose, Methacrylic acid copolymer dispersion, Sodium lauryl sulphate, Disodium hydrogen ortho phosphate, Diethyl phthalate, Sucrose, Titanium dioxide (E171), Povidone K-30, Calcium Carbonate, Talc, Polysorbate 80, Sodium hydroxide) gelatine and titanium dioxide (E171).

What Medoprazole looks like and contents of the pack

Medoprazole 20 mg hard capsules**:** gastro-resisant capsules: white hard gelatin capsules size "2" with opaque white cap and opaque white body.

Pack sizes:

PVC bottles, sealed with a PVC cap with 20 capsules.
PVC/Al blisters in carton boxes of 10, 20, 30 or 60 capsules.

Marketing Authorisation Holder and Manufacturer

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