

# Omeprazole AN tablets

Omeprazole

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about Omeprazole AN.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Omeprazole AN against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

**Keep this leaflet with your medicine.**

You may need to read it again.

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### What Omeprazole AN is used for

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#### Peptic Ulcers

Omeprazole AN is used to treat peptic ulcers. Depending on the position of the ulcer it is called a gastric or duodenal ulcer.

A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

These ulcers can be caused by too much acid being made in the stomach.

Omeprazole AN is also used to help stop peptic or duodenal ulcers coming back.

#### Peptic Ulcers Associated with *Helicobacter pylori* Infection

Most peptic ulcers are caused by an infection with the bacterium *Helicobacter pylori* in the stomach.

*H. pylorus* weakens the protective mucous coating of the stomach and duodenum, which allows acid to get through to the sensitive lining beneath. Both the acid and the bacteria irritate the lining and cause a sore, or ulcer.

When Omeprazole AN is taken together with an antibiotic, the combination will kill *H. pylori* and let your peptic ulcer heal.

#### Peptic Ulcers Associated with Non-Steroidal Anti-Inflammatory Drugs (NSAID's)

Some peptic ulcers are caused by medicines called non-steroidal anti-inflammatory drugs. These medicines are commonly taken to treat joint disease or arthritis.

Omeprazole AN is also used to heal and prevent ulcers associated with NSAIDs.

#### Reflux Oesophagitis

Omeprazole AN is used to treat the symptoms of reflux oesophagitis or reflux disease. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

Omeprazole AN is also used to help stop reflux oesophagitis coming back or relapsing.

#### Zollinger-Ellison Syndrome

Omeprazole AN is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

Your doctor will have explained why you are being treated with Omeprazole AN and advised you what dose to take. Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another purpose. Ask your doctor if you have any questions about why Omeprazole AN has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is no evidence that Omeprazole AN is addictive.

#### How does Omeprazole AN work?

Omeprazole AN is a type of medicine called a proton pump inhibitor. Your stomach produces acid to help break down food so it is easier to digest. In certain circumstances, this acid can irritate the lining of your stomach and duodenum (the tube leading out from the stomach) causing indigestion and even ulceration and bleeding.

The proton pump inhibitors work by decreasing the production of stomach acid, to give relief of symptoms and allow healing to take place. They do this by inhibiting a system in the stomach known as the proton pump. This does not stop food being digested in the normal way.

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## Before you take Omeprazole AN

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### *When you must not take it*

- 1. Do not take Omeprazole AN if you have an allergy to medicines that contain omeprazole or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction to omeprazole may include skin rash, difficulty breathing, and hayfever, swelling of the face and fainting.**
- 2. Do not take Omeprazole AN if you are pregnant or suspect that you are pregnant.**
- 3. Do not take Omeprazole AN if you are breast-feeding. Your baby may absorb omeprazole from breast milk and there is a chance of harm to the baby.**
- 4. Do not take Omeprazole AN if the packaging is torn or shows signs of tampering.**
- 5. Do not take Omeprazole AN if the expiry date (EXP) printed on the bottle has passed. If you take this medicine after the expiry date has passed, it may not work as well.**

**If you are not sure whether you should start taking Omeprazole AN, contact your doctor.**

### *Before you start to take it*

**You must tell your doctor or pharmacist:**

- **If you are allergic to any other medicines, foods, dyes, or preservatives**
- **If you have any other medical conditions**
- **If you are pregnant or intend to become pregnant.** Your doctor or pharmacist will discuss the possible risks of using Omeprazole AN during pregnancy.
- **If you are breast-feeding or wish to breast-feed.** Your doctor or pharmacist will discuss the possible risks of using Omeprazole AN during breast-feeding.
- **If you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may interfere with Omeprazole AN. These include:

- phenytoin
- warfarin
- diazepam
- ketoconazole, itraconazole, voriconazole
- clarithromycin
- antiretroviral drugs (atazanavir, nelfinavir)
- tacrolimus
- clopidogrel

These medicines may be affected by Omeprazole AN or may affect how well it works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

**If you have not told your doctor about any of the above, tell them before you start taking Omeprazole AN.**

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## How to take Omeprazole AN

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.**

### *How much to take*

Your doctor will tell you how much to take and when to take it. Take Omeprazole AN tablets exactly as your doctor has prescribed.

### *How to take it*

**Swallow the prescribed dose whole with a glass of water. If the tablets are chewed or crushed, they will not work properly.**

### *When to take it*

Take Omeprazole AN at about the same time each day. A consistent routine can help you to remember to take it.

In most patients, Omeprazole AN relieves symptoms rapidly and healing is usually complete within 4 weeks.

Tell your doctor if your symptoms return. It is possible that the antibiotics may not kill *H. pylori*. You may need treatment with further antibiotics.

### *If you forget to take it*

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

### *If you take too much (overdose)*

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Omeprazole AN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include slowed heart rate, difficulty breathing, marked drop in blood pressure, severe heart failure, or a decrease in blood sugar. Keep telephone numbers for these places handy.

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## While you are taking Omeprazole AN

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### *Things you must do*

Tell your doctors, dentists and pharmacists who are treating you that you are taking Omeprazole AN.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking Omeprazole AN.

Tell your doctor if you become pregnant while you are taking Omeprazole AN.

**Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.**

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

### *Things you must not do*

**Do not stop taking Omeprazole AN or change the dose without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.**

**Do not give this medicine to anyone else even if they have the same condition as you.**

**Do not use Omeprazole AN to treat any other complaints unless your doctor says to.**

### *Things to be careful of*

**Be careful driving or operating machinery until you know how Omeprazole AN affects you.**

**Omeprazole AN generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Omeprazole AN may cause dizziness in some people.**

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## Side Effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Omeprazole AN.**

Omeprazole AN helps most people with stomach or duodenal ulcers or reflux disease, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you experience some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

Tell your doctor if you experience any of the following common side effects and they worry you:

- constipation

- nausea
- abdominal pain
- diarrhoea
- headache
- skin rash

These are all mild side effects of Omeprazole AN.

**Tell your doctor immediately if you notice any of the following:**

- Muscle pain or weakness
- Dizziness
- 'Pins and needles'
- Changes in sleep patterns
- Mood changes
- Increase in breast size (males)
- Fever
- Increased bruising

**These side effects are usually rare but may be serious and need urgent medical attention.**

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion during treatment with Omeprazole AN
- you begin to bleed or vomit
- you pass black (blood stained) motions

Some people may experience other side effects while taking Omeprazole AN.

Other problems are more likely to arise from the ulcer itself rather than the treatment.

This is not a complete list of all possible side effects. Other side effects not listed above may occur in some patients.

**Tell your doctor if you notice anything else that is making you feel unwell while you are taking or soon after you have finished taking Omeprazole AN, even if it is not mentioned in this list.**

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## After taking Omeprazole AN

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### *Storage*

**Keep your tablets in the bottle or blister pack until it is time to take them.**

If you take the tablets out of the container they may not keep as well.

**Keep it in a cool, dry place where the temperature stays below 25°C.**

**Do not store the tablets or any other medicine in the bathroom or near a sink. Do not leave them in the car or on windowsills.**

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### *Disposal*

**If your doctor tells you to stop taking Omeprazole AN, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.**

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## Product description

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### *What it looks like*

Omeprazole AN 20 mg tablets are red brown, oblong, enteric coated tablets.

It is available in an Al blister pack of 5, 10 or 30 tablets (AUST R 159688) and HDPE bottles of 30 tablets (AUST R 149424).

### *Ingredients*

#### **Active Ingredient:**

Each tablet contains 20 mg of Omeprazole.

#### **Other Ingredients:**

- ascorbyl palmitate

- microcrystalline cellulose
- crospovidone
- magnesium stearate
- povidone
- lactose
- hypromellose phthalate
- glycerol triacetate
- purified talc
- iron oxide red
- iron oxide black

### *Name and Address of the Sponsor*

#### **Scentia Pharmaceuticals Pty Ltd**

8 - 12 Ordish Road  
Dandenong South,  
VIC - 3175  
Australia

#### **Date of Preparation**

February 2014

Doc ID: 83.AN.M.1.0