

# APO-Omeprazole Capsules

Contains the active ingredient Omeprazole

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## Consumer Medicine Information

For a copy of a large print leaflet,  
Ph: 1800 195 055

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### What is in this leaflet

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#### Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about Omeprazole. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

#### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

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### What this medicine is used for

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#### Reflux Oesophagitis

APO-OMEPRAZOLE 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.

APO-OMEPRAZOLE is also taken to help stop reflux oesophagitis coming back or relapsing.

#### Peptic Ulcers

APO-OMEPRAZOLE 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.

APO-OMEPRAZOLE is also used to help stop gastric or duodenal ulcers coming back.

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

Most people who have a peptic ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

When APO-OMEPRAZOLE is taken with antibiotics, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

#### Peptic Ulcers Associated with Non-steroidal Anti-Inflammatory Drugs (NSAIDs)

Some peptic ulcers are caused by taking medicines called non-steroidal anti-inflammatory drugs (NSAIDs), a type of medicine used to treat pain or inflammation. APO-OMEPRAZOLE is also used to heal and prevent ulcers associated with NSAIDs.

#### Zollinger-Ellison Syndrome

APO-OMEPRAZOLE 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.

#### How it works

APO-OMEPRAZOLE is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

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

There is no evidence that this medicine is addictive.

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

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## Before you take this medicine

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### *When you must not take it*

#### **Do not take APO-OMEPRAZOLE if you have an allergy to:**

- omeprazole or any ingredient listed at the end of this leaflet
- any medicine containing a proton-pump inhibitor

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

#### **Do not take APO-Omeprazole if you are also taking cilostazol.**

Please check with your doctor or pharmacist if you are taking cilostazol. This medicine will be affected by APO-OMEPRAZOLE.

#### **Do not take this medicine if:**

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.  
If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should take this medicine, talk to your doctor.

### *Before you start to take it*

#### **Before you start taking this medicine, tell your doctor if:**

You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes
- any problems with your liver
- any other medical conditions

#### **Do not take APO-OMEPRAZOLE if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.**

It is not known if it is safe for you to take APO-OMEPRAZOLE while you are pregnant. It may affect your baby.

It is not known if your baby can take in APO-OMEPRAZOLE from breast milk if you are breastfeeding.

### *Taking other medicines*

#### **Do not take APO-OMEPRAZOLE if you are taking the following medicine:**

- cilostazol - a medicine used to treat intermittent claudication

Tell your doctor if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with APO-OMEPRAZOLE Capsules.

These include:

- phenytoin - a medicine used to treat epilepsy or fits
- warfarin & clopidogrel - medicines used to prevent blood clots
- digoxin - a medicine used to treat heart conditions
- diazepam - a medicine used to treat anxiety and some other conditions
- St John's Wort - a herbal remedy used to treat mood disorders
- ketoconazole, itraconazole, voriconazole - medicines used to treat fungal infection
- clarithromycin or rifampicin - medicines used to treat viral infections atazanavir and nelfinavir - medicines used to treat viral infections such as HIV
- tacrolimus - a medicine used to assist in organ transplants
- methotrexate - a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer

These medicines may be affected by APO-OMEPRAZOLE or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

#### **If you have not told your doctor about any of these medicines, tell them before you take APO-OMEPRAZOLE.**

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## How to take this medicine

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Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

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

### *How much to take*

The dose for APO-OMEPRAZOLE varies from patient to patient. Your doctor will decide the right dose for you.

### *How to take it*

**Swallow the capsules with a glass of water.**

**Do not crush or chew the capsules.**

**If the granules or pellets contained in the capsules are crushed or chewed, they will not work properly.**

### *When to take it*

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

APO-OMEPRAZOLE can be taken with food or on an empty stomach.

### *How long to take it for*

Keep taking APO-OMEPRAZOLE for as long as your doctor recommends.

If you are taking APO-OMEPRAZOLE to heal an ulcer or to treat reflux disease, you will usually need to take APO-OMEPRAZOLE for 4 to 8 weeks.

It is very important that you take the full course of APO-OMEPRAZOLE as prescribed by your doctor so that your condition is properly treated.

If you are taking APO-OMEPRAZOLE to stop an ulcer from coming back or to treat other conditions, your doctor will tell you how long you need to take the capsules.

### *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 missed doses.**

This may increase the chance of you experiencing side effects.

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

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

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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## While you are taking this medicine

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### *Things you must do*

**Take APO-OMEPRAZOLE exactly as your doctor has prescribed.**

**If you are about to start any new medicine, remind your doctor and pharmacist that you are taking APO-OMEPRAZOLE.**

**Tell all doctors, dentists and pharmacists who are treating you that you are taking APO-OMEPRAZOLE.**

**Tell your doctor if you become pregnant while you are taking APO-OMEPRAZOLE.**

**Tell your doctor if your symptoms return.**

Although APO-OMEPRAZOLE can heal ulcers successfully, it may not prevent them recurring at a later date.

**If you need to have any medical tests while you are taking APO-OMEPRAZOLE, tell your doctor.**

It may affect the results of some tests.

### *Things you must not do*

**Do not take APO-OMEPRAZOLE to treat any other complaints unless your doctor tells you to.**

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

**Do not stop taking your medicine or change the dosage without checking with your doctor.**

If you stop taking it suddenly or change the dose, your condition may worsen or you may have unwanted side effects.

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## Possible 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 APO-OMEPRAZOLE.**

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

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

**Tell your doctor if you notice any of the following and they worry you:**

- constipation
- nausea or vomiting
- diarrhoea
- headache
- skin rash, itchy skin
- wind
- stomach pain
- dizziness
- dry or sore mouth

These side effects are usually mild.

**Tell your doctor as soon as possible if you notice any of the following.**

These may be serious side effects and you may need medical attention: Serious side effects are rare.

- muscle pain or weakness, joint pain
- "pins and needles"
- changes in sleep patterns
- mood changes, confusion or depression
- blurred vision
- increase in breast size (males)
- fever
- increased bruising
- increased sweating
- hair loss
- tremor

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

These are very serious side effects and you may need urgent medical attention or hospitalisation. These side effects are rare.

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing
- shortness of breath or difficulty in breathing
- skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals
- blood in urine
- swelling of feet, hands and ankles
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite

Occasionally, APO-OMEPRAZOLE may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may occur in some patients.

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

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

- pain or indigestion that occurs during treatment with APO-OMEPRAZOLE
- you begin to vomit blood or food
- you pass black (blood-stained) motions.

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## Storage and disposal

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### Storage

**Keep your medicine in its original packaging until it is time to take it.**

If you take your medicine out of its original packaging it may not keep well.

**Keep your medicine in a cool dry place where the temperature will stay below 25°C.**

**Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.** Heat and dampness can destroy some medicines.

**Keep this medicine where 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 this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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## Product description

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### *What APO-Omeprazole Capsules looks like*

APO-OMEPRAZOLE is an opaque yellow cap and body capsule containing off-white to cream-white spherical pellets.

Each bottle or carton (in blisters) contains 30 capsules.

### *Ingredients*

Each tablet contains 20mg of omeprazole as the active ingredient.

It also contains the following inactive ingredients:

### **Pellets**

- sodium lauryl sulfate
- dibasic anhydrous sodium phosphate
- hypromellose
- mannitol
- macrogol 6000
- purified talc
- polysorbate-80
- titanium dioxide
- eudragit L30-D-55
- maize starch
- sucrose

### **Capsule**

- gelatin
- titanium dioxide
- quinoline yellow CI47005.

### *Australian Registration Numbers*

- APO-Omeprazole 20mg Capsules (Blister Pack)  
AUST R 149518
- APO-Omeprazole 20mg Capsules (Bottle)  
AUST R 167316

### *Sponsor*

**Pharmacor Pty Ltd**  
Suite 401, 7 Oaks Ave  
Dee Why NSW 2099  
Australia

### *Distributor*

**Apotex Pty Ltd**  
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Macquarie Park NSW 2113  
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