

# PHARMACOR OMEPRAZOLE 20mg Enteric-coated Tablets

*Contain the active ingredient 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 PHARMACOR OMEPRAZOLE Enteric-coated tablets.

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 PHARMACOR OMEPRAZOLE Enteric-coated Tablets against the benefits expected 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 PHARMACOR OMEPRAZOLE Enteric-coated tablets is used for

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#### **Peptic Ulcers**

PHARMACOR OMEPRAZOLE Enteric-coated tablets are used to treat peptic ulcers and also to help prevent them from coming back.

These ulcers can be caused by the stomach producing too much acid. Depending on the location of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach and a duodenal ulcer occurs in the tube

leading out of the stomach, also known as the duodenum.

#### **Peptic Ulcers associated with Helicobacter pylori infection**

Most people with a peptic ulcer have been found to have the bacteria *Helicobacter pylori* in their stomach. PHARMACOR OMEPRAZOLE Enteric-coated tablets taken together with two antibiotics will kill the bacteria and let your ulcer heal. It is possible that the antibiotics may not always kill *Helicobacter pylori*.

#### **Peptic Ulcers associated with Non-steroidal Anti-inflammatory Drugs (NSAIDs)**

Some peptic ulcers are caused by taking medicines known as non-steroidal anti-inflammatory drugs. These medicines are commonly taken to treat arthritis and other inflammatory conditions.

PHARMACOR OMEPRAZOLE Enteric-coated tablets can be used to heal and prevent ulcers associated with NSAIDs.

#### **Reflux Oesophagitis**

PHARMACOR OMEPRAZOLE Enteric-coated tablets is used to treat and prevent the symptoms of reflux oesophagitis.

This condition is caused by the washing back, or reflux, of food and acid from the stomach into the oesophagus. Symptoms include a burning sensation in the chest rising up to the throat, also known as heartburn.

#### **Zollinger-Ellison Syndrome**

PHARMACOR OMEPRAZOLE Enteric-coated tablets is used to

treat this rare condition where the stomach produces excessive amounts of acid.

#### *How PHARMACOR OMEPRAZOLE Enteric-coated tablets works*

PHARMACOR OMEPRAZOLE Enteric-coated tablets belongs to a group of medicines called proton pump inhibitors. These medicines work by decreasing the amount of acid made by the stomach, to give relief from the symptoms and allow healing to take place. This does not stop food from being digested in the normal way.

**Ask your doctor if you have any questions about why PHARMACOR OMEPRAZOLE Enteric-coated tablets has been prescribed for you.**

Your doctor may have prescribed PHARMACOR OMEPRAZOLE Enteric-coated tablets for another reason.

PHARMACOR OMEPRAZOLE Enteric-coated tablets is available only with a doctor's prescription.

There is no evidence that PHARMACOR OMEPRAZOLE Enteric-coated tablets is addictive.

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## Before you take PHARMACOR OMEPRAZOLE Enteric-coated tablets

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### *When you must not take it*

#### **Do not take PHARMACOR OMEPRAZOLE Enteric-coated tablets if you are allergic to:**

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

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

#### **Do not take PHARMACOR OMEPRAZOLE Enteric-coated tablets if you are also taking a medicine containing cilostazol.**

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

#### **Do not take PHARMACOR OMEPRAZOLE Enteric-coated tablets if the expiry date (Exp.) printed on the pack has passed.**

#### **Do not take PHARMACOR OMEPRAZOLE Enteric-coated tablets if the packaging shows signs of tampering or the tablets do not look quite right.**

### *Before you start to take it*

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you are pregnant or plan to become pregnant.**

PHARMACOR OMEPRAZOLE Enteric-coated tablets may affect your unborn baby if taken during pregnancy. Your doctor will discuss the risks and benefits of taking PHARMACOR OMEPRAZOLE

Enteric-coated tablets during pregnancy.

**Tell your doctor if you are breastfeeding or wish to breastfeed.**

It is not known whether PHARMACOR OMEPRAZOLE Enteric-coated tablets passes into breast milk. Your doctor will discuss the risks and benefits of taking PHARMACOR OMEPRAZOLE Enteric-coated tablets when breastfeeding.

**Tell your doctor if you have any problems with your liver.**

**Tell your doctor if you have, or have had, any other medical conditions.**

**If you have not told your doctor about any of the above, tell them before you start taking PHARMACOR OMEPRAZOLE Enteric-coated tablets.**

### *Taking other medicines*

**Do not take PHARMACOR OMEPRAZOLE Enteric-coated tablets 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 a pharmacy, supermarket or health food shop.**

Some medicines may be affected by PHARMACOR OMEPRAZOLE Enteric-coated tablets, or may affect how well it works. These include:

- phenytoin, a medicine used to treat epilepsy or fits
- Methotrexate
- Mycophenolate mofetil, - a medicine used to treat arthritis and some types of cancer
- warfarin and clopidogrel, a medicine 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 or voriconazole, medicines used to treat certain fungal infections
- medicines to treat infections, such as clarithromycin or rifampicin
- anti-viral medicines such as atazanavir and nelfinavir, used to treat infections such as HIV
- tacrolimus, an immunosuppressant, a medicine used to assist in organ transplants
- erlotinib or related medicines used to treat cancer

These medicines may be affected by PHARMACOR OMEPRAZOLE Enteric-coated tablets 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 of these medicines.

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking PHARMACOR OMEPRAZOLE Enteric-coated tablets.

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## How to take PHARMACOR OMEPRAZOLE Enteric-coated tablets

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

They may differ from the information in this leaflet.

### *How much to take*

#### **Adults:**

The usual dose is 20 mg a day, but

may vary from 10 mg to 40 mg a day depending on your condition and whether or not you are taking any other medicines. Your doctor will advise you how much to take.

**Children 1 year or older:**

The usual dose for children 10 kg to 20 kg is 10 mg a day. This dose may be increased to 20 mg if required. For children more than 20 kg the dose is 20 mg a day which may be increased to 40 mg if required.

**Ask your doctor or pharmacist if you are not sure how to take PHARMACOR OMEPRAZOLE Enteric-coated tablets.**

*How to take PHARMACOR OMEPRAZOLE Enteric-coated tablets*

**Swallow the tablets whole with a glass of water. Do not crush or chew the tablets.**

If the tablets are crushed or chewed they will not work properly.

*When to take PHARMACOR OMEPRAZOLE Enteric-coated tablets*

PHARMACOR OMEPRAZOLE Enteric-coated can be taken with or without food.

**Take PHARMACOR OMEPRAZOLE Enteric-coated tablets at about the same time each day.**

Keeping a regular time for taking tablets will help to remind you to take them.

*If you forget to take PHARMACOR OMEPRAZOLE Enteric-coated tablets*

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

**Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.**

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

**If you are not sure what to do, ask your doctor or pharmacist.**

*How long to take PHARMACOR OMEPRAZOLE Enteric-coated tablets for*

**Keep taking PHARMACOR OMEPRAZOLE Enteric-coated tablets for as long as your doctor recommends.**

In most patients, PHARMACOR OMEPRAZOLE Enteric-coated tablets relieves symptoms rapidly and healing is usually complete within 4 weeks.

*If you take too much PHARMACOR OMEPRAZOLE Enteric-coated tablets (overdose)*

**Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) if you think you or anyone else may have taken too much PHARMACOR OMEPRAZOLE Enteric-coated tablets. Do this even if there are no signs of discomfort or poisoning.**

If you take too much PHARMACOR OMEPRAZOLE Enteric-coated tablets you may experience nausea, vomiting, dizziness, abdominal pain, diarrhoea and headache.

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**While you are taking PHARMACOR OMEPRAZOLE Enteric-coated tablets**

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*Things you must do*

**Before starting any new medicine, tell your doctor or pharmacist that you are taking PHARMACOR OMEPRAZOLE Enteric-coated tablets.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking**

**PHARMACOR OMEPRAZOLE Enteric-coated tablets.**

**If you become pregnant while taking PHARMACOR OMEPRAZOLE Enteric-coated tablets, tell your doctor.**

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

Although PHARMACOR OMEPRAZOLE Enteric-coated tablets heals ulcers very successfully, it may not prevent them recurring at a later date.

**If you need to have any medical tests while you are taking PHARMACOR OMEPRAZOLE Enteric-coated tablets, tell your doctor.**

PHARMACOR OMEPRAZOLE Enteric-coated tablets may affect the results of some tests.

*Things you must not do*

**Do not use PHARMACOR OMEPRAZOLE Enteric-coated tablets to treat any other conditions unless your doctor tells you to.**

**Do not give PHARMACOR OMEPRAZOLE Enteric-coated tablets to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or change the dose 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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**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 PHARMACOR OMEPRAZOLE Enteric-coated tablets.**

PHARMACOR OMEPRAZOLE Enteric-coated tablets helps most people with peptic ulcers or reflux disease, and is usually well tolerated, but it may have unwanted side effects in some 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 get 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 notice any of the following and they worry you:**

- diarrhoea
- constipation
- stomach pain
- nausea or vomiting
- dry or sore mouth
- flatulence
- skin rash, itchy skin
- headache
- dizziness
- Benign polyps in the stomach

These side effects are usually mild.

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

- muscle pain or weakness, joint pain
- tingling or numbness of the hands or feet
- changes in sleep patterns
- mood changes, confusion or depression
- blurred vision
- increase in breast size (males)
- fever
- increased bruising
- increased sweating
- hair loss
- tremor

These are serious side effects that may require medical attention. Serious side effects are rare.

**Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:**

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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

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

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

Other side effects not listed above may also 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 occurring during treatment with PHARMACOR OMEPRAZOLE Enteric-coated tablets
- vomiting of blood or food
- passing of black (blood-stained) motions.

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## After taking PHARMACOR OMEPRAZOLE Enteric-coated tablets

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### *Storage*

**Keep PHARMACOR OMEPRAZOLE Enteric-coated tablets 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.

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

If you take the tablets out of the blister pack, they may not keep well.

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

**Do not store PHARMACOR OMEPRAZOLE Enteric-coated tablets or any other medicine in the bathroom or near a sink.**

**Do not leave PHARMACOR OMEPRAZOLE Enteric-coated tablets in the car or on window sills.**

Heat and dampness can destroy some medicines.

### *Disposal*

**If your doctor tells you to stop taking PHARMACOR OMEPRAZOLE Enteric-coated tablets, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

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### *What it looks like*

PHARMACOR OMEPRAZOLE Enteric-coated tablets are brown capsule-shaped tablets.

Each blister contains 30 tablets.

## *Ingredients*

The active ingredient in PHARMACOR OMEPRAZOLE Enteric-coated tablets is omeprazole. Each PHARMACOR OMEPRAZOLE Enteric-coated tablets tablet contains 20 mg of omeprazole.

The tablets also contain:

- lactose
- sodium starch glycollate
- sodium stearate
- sodium stearyl fumarate
- hypromellose acetate succinate
- triethyl citrate
- sodium lauryl sulfate
- carnauba wax
- purified talc
- ethanolamine
- propylene glycol
- hypromellose
- titanium dioxide
- yellow iron oxide
- red iron oxide

## *Sponsor*

Medis Pharma Pty Ltd  
Suite 1002, 53 Walker  
Street, North Sydney, NSW  
2060,  
Australia

## *Distributor*

Pharmacor Pty Ltd.  
Suite 501, 7 Oaks Avenue  
Dee Why, NSW, 2099,  
Australia

Australian registration number:

### **Blister pack**

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