

# PROBITOR®

omeprazole enteric capsules

## Consumer Medicine Information

### WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Probitor.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

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

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

**Keep this leaflet with the medicine.**

You may need to read it again.

### WHAT PROBITOR IS USED FOR

The name of your medicine is Probitor. It contains the active ingredient omeprazole.

#### Peptic Ulcers

This medicine 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 of the stomach.

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

This medicine is also used to stop gastric or duodenal ulcers from coming back.

#### Reflux oesophagitis

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

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

#### Peptic ulcers associated with *Helicobacter pylori*

Many people who have a peptic ulcer also have bacteria called *Helicobacter pylori* in their stomach. When Probitor is taken together with antibiotics, it will help kill the bacteria and allow your peptic ulcer to heal. However, it is possible that the antibiotics might not always be able to kill *Helicobacter pylori*. 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. These medicines are commonly taken to treat pain or inflammation.

This medicine is also used to heal and prevent ulcers developing which are associated with NSAIDs.

#### Zollinger-Ellison syndrome

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

#### How Probitor works

Probitor belongs to a group of medicines called proton pump inhibitors (PPIs).

**It works by decreasing the amount of acid made by the stomach. This does not stop food being digested in the normal way. It helps reduce the pain and also allows the ulcer to heal. Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

There is no evidence that this medicine is addictive.

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

There is not enough information to recommend the use of this medicine for children.

### BEFORE YOU TAKE PROBITOR

#### When you must not take it

**Do not take this medicine if you have an allergy to:**

- omeprazole, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines especially if they are in the same drug class as omeprazole (proton pump inhibitors), e.g. esomeprazole, lansoprazole, pantoprazole and rabeprazole.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**Do not take this medicine if you are also taking cilostazol.**

Check with your doctor or pharmacist if you are taking cilostazol. This medicine will be affected by Probitor.

**Do not take this medicine if you are also taking nelfinavir, used to treat HIV infections.**

Check with your doctor or pharmacist if you are taking any other medicines used to treat HIV infections, such as atazanavir.

**Do not take this medicine after the expiry date printed on the pack has passed.**

**Do not use this medicine if the packaging is torn or shows signs of tampering.**

If it has expired, is damaged or shows any signs of deterioration (e.g. darkening of the capsules), return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

*Before you start to take it*

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

**Tell your doctor if you have or have had any problems with your liver or any other medical conditions.**

**Tell your doctor if you have been diagnosed with osteoporosis.**

**Tell your doctor if you have ever had a skin reaction after treatment with a medicine similar to Probitor that reduces stomach acid.**

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

Your doctor can discuss with you the risks and benefits involved.

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

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

*Taking other medicines*

**Do not take Probitor 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 and Probitor may interfere with each other. These include:

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

These medicines may be affected by Probitor, 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 the above, tell them before you start taking Probitor.**

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## HOW TO TAKE PROBITOR

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**Follow all directions given to you by your doctor and 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*

Take one Probitor capsule each day, unless your doctor has told you otherwise.

The dose for Probitor varies from patient to patient. Your doctor will decide the right dose for you.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

If you take the wrong dose, Probitor may not work as well and your problem may not improve.

*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 Probitor*

**Take each dose of Probitor at about the same time each day.**

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

This medicine can be taken with food or on an empty stomach.

### *How long to take Probitor*

**Keep taking your medicine for as long as your doctor recommends.**

In most patients, Probitor relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking Probitor for as long as your doctor tells you to.

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

### *If you forget to take it*

**Take your dose as soon as you remember, and continue to take 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.**

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering 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 Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766), for advice, or go to Accident and Emergency at your nearest hospital, if you think**

**that you or anyone else has taken too much Probitor. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

Symptoms of an overdose may include nausea, vomiting, dizziness, abdominal pain, diarrhoea and headache.

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## WHILE YOU ARE TAKING PROBITOR

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### *Things you must do*

**Take Probitor exactly as your doctor has prescribed.**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Probitor.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you become pregnant while taking this medicine, tell your doctor immediately.**

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

Although Probitor 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 Probitor, tell your doctor.**

It may affect the results of some tests.

### *Things you must not do*

**Do not take Probitor to treat any other complaints unless your doctor tells you.**

**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 may have unwanted side effects.

### *Things to be careful of*

Be careful driving or operating machinery until you know how Probitor affects you.

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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 Probitor.**

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need urgent medical attention 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 any questions you may have.**

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

- constipation
- diarrhoea
- nausea (feeling sick)
- vomiting
- headache
- stomach pain
- wind
- dry or sore mouth
- skin rash, itchy skin.

These side effects are usually mild.

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

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

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

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- swelling of 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
- severe skin reaction, especially in sun-exposed areas, with joint pain

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

Occasionally, Probitor may be associated with change 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 people.

Other health problems may arise from the condition being treated itself rather than the treatment.

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

- pain or indigestion during treatment with this medicine
- vomiting blood or food
- passing black or blood-stained motions

Tell your doctor if your reflux return after you stop taking Probitor.

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## AFTER TAKING PROBITOR

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### *Storage*

**Keep your medicine in the original container.**

If you take it out of its original container, it may not keep well.

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

**Do not store Probitor or any other medicine in a bathroom or near a sink. Do not leave it in the car or on a window sill.**

Heat and dampness can destroy some medicines.

**Keep it 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## PRODUCT DESCRIPTION

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### *What it looks like*

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

Available in bottles of 5, 30 and 100 enteric capsules and in blister packs of 6, 7, 28, 30 and 35 enteric capsules.

*Not all presentations are available in Australia.*

## *Ingredients*

### **Active ingredient:**

- Probitor 20 mg - 20 mg omeprazole.

### **Inactive ingredients:**

#### *Pellets*

- sodium lauryl sulfate
- dibasic anhydrous sodium phosphate
- hypromellose
- mannitol
- macrogol 6000
- purified talc
- polysorbate-80
- titanium dioxide
- eudragit L30D-55 (PI 3700)
- maize starch
- sucrose

#### *Capsule*

- gelatin
- titanium dioxide
- quinoline yellow.

Probitor contains: sugars.

This medicine does not contain lactose, gluten, tartrazine, or any other azo dyes.

## *Supplier*

Sandoz Pty Ltd  
ABN 60 075 449 553  
54 Waterloo Road  
Macquarie Park, NSW 2113  
Australia  
Tel: 1800 726 369

Novartis New Zealand Ltd  
PO Box 99102, Newmarket  
Auckland 1149  
New Zealand  
Tel: 0800 354 335

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### **Australian Registration Numbers:**

Bottle: AUST R 78186

Blister: AUST R 82757