

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.

Ulcers

This medicine is used to treat and help heal 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 in part by too much acid being made in the stomach.

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

Reflux oesophagitis

This medicine is used to treat and prevent reflux oesophagitis. 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.

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 joint disease or arthritis.

This medicine is also used to heal and prevent ulcers 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.

How Probitor works

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

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 are taking other medicines that may cause low levels of magnesium in the blood (hypomagnesaemia). For example diuretics.

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.

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

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 - a medicine used to assist in organ transplants
- St. John's wort - a medicine used to treat anxiety, stress, nervous tension and some other conditions.
- digoxin - a medicine used to treat heart problems.

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

How to take Probitor

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

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

Continue taking your medicine for as long as your doctor tells you.

If you are taking this medicine to heal an ulcer or to treat reflux disease, you will usually need to take it for 4 to 8 weeks.

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 are taking this medicine 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

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.

While you are taking Probitor

Things you must do

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.

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.

Things to be careful of

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

Side effects

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
- abdominal pain
- excessive gas in stomach or bowel
- 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
- dizziness
- tingling or numbness in the hands or feet
- changes in sleep patterns
- blurred vision
- increased sweating
- hair loss
- increase in breast size (males)
- sleepiness or drowsiness
- depression, agitation, confusion, mood changes or hallucinations
- bruising or bleeding more easily than normal
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite.
- Inability to get or maintain erection.
- Fractures, for example hip, wrist or spine.

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.

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

Tell your doctor 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
- unexpected weight loss.

After taking Probitor

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.

Product description

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 30 enteric capsules and in blister packs of 6, 7 and 30 enteric capsules.

Ingredients

Active ingredient:

- Probitor 20mg - 20mg omeprazole.

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.

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
 Private Bag 65904 Mairangi Bay
 Auckland 0754
 New Zealand
 Tel: 0800 354 335

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