

Omeprazole (20mg)

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## What Probitor Capsules is used for

Probitor Capsules is used to treat the following conditions:

- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Ulcers which are infected with bacteria called '*Helicobacter pylori*'. If you have this condition, your doctor may also prescribed antibiotics to treat the infection and allow the ulcer to heal.
- Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs).
- Reflux oesophagitis. This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).
- Prevention in people with in increased risk of NSAIDs associated ulcer, gastroduodenal erosions or indigestion symptoms.

## How Probitor Capsules works

Probitor Capsules contains the active substance omeprazole. It belongs to a group of medicine called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

## Before you use Probitor Capsules

- When you must not use it

### Do NOT take Probitor Capsules

- if you are allergic (hypersensitive) to omeprazole or any of the other ingredients of Probitor.
- if you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole,

esomeprazole).

- If you are taking a medicine containing nelfinavir (for HIV infection).

If you are not sure, talk to your doctor or pharmacist before taking Probitor Capsules.

- Before you start to use it

Tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A).

Tell your doctor if you have or have had any medical condition especially the following:

- You lose a lot of weight for no reason and have problems swallowing.
- You begin to vomit food or blood.
- You pass black stools (blood-stained faeces).
- You experience severe or persistent diarrhea, as omeprazole has been associated with a small increase in infectious diarrhea.

Your doctor may ask you to do additional tests to diagnose cancer, as treatment may alleviate symptoms and delay diagnosis.

If you take Probitor Capsules on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

For long term treatment, Probitor Capsule may reduce the absorption of vitamin B12 (cyanocobalamin), reduce magnesium level in the blood and increase risk of hip, wrist and spine fracture.

## Pregnancy and breast-feeding

### Pregnancy

You must tell your doctor if you think that you are (or might become) pregnant.

Your doctor will decide whether you can take Probitor Capsules during this time.

### Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding.

Your doctor will decide whether you can take Probitor Capsules if you are breastfeeding.

Probitor Capsules can be used during pregnancy and breastfeeding.

- Taking other medicines

Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription. This is because Probitor Capsules can affect the way some medicines work and some medicine can have an effect on Probitor Capsules.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Atazanavir and nelfinavir (used to treat HIV infections).
- Digoxin (used to treat heart problem).
- Clopidogrel (used to prevent blood clots).
- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus).
- Erlotinib (used to treat cancers).
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers.
- Diazepam (used to treat anxiety, relax muscles or in epilepsy)
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking Probitor.
- Cilostazol (used to treat intermittent claudication (blood circulation in the legs).
- Saquinavir (used to treat HIV infection).
- Tacrolimus (in cases of organ transplantation).
- Methotrexate (a chemotherapy agent).
- Rifampicin (used to treat tuberculosis).
- St John's wort (*Hypericum perforatum*) (used to treat depression).

If your doctor has prescribed the antibiotics amoxicillin and

Omeprazole (20mg)

clarithromycin as well as Probitor to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

## How to use Probitor Capsules

- How much to take

### To treat ulcers in the upper part of the intestine (duodenal ulcer)

- The usual dose is 20 mg once a day for 2 - 4 weeks.
- If the ulcer does not fully heal, the dose can be increased to 40 mg once a day for 4 weeks.

### To prevent the duodenal ulcers from coming back

- The usual dose 20 mg once a day.

### To treat ulcers in the stomach (gastric ulcer)

- The usual dose is 20 mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your ulcer has not yet healed.
- If the ulcer does not fully heal, the dose can be increased to 40 mg once a day and healing is usually achieved within 8 weeks.

### To prevent the gastric ulcers from coming back

- The usual dose 20 mg once a day.

### To treat ulcers caused by *Helicobacter pylori* infection

For the eradication of *H. pylori* the selection of antibiotics should consider the individual patient's drug tolerance, and should be undertaken in accordance with national, regional and local resistance patterns and treatment guidelines.

### To treat duodenal and stomach ulcers and erosions caused by NSAIDs (Non-Steroidal Anti-Inflammatory)

- The usual dose is 20 mg once a day for 4 to 8 weeks.

### To prevent duodenal and stomach ulcers, erosion and indigestion symptoms if you are taking NSAIDs

- The usual dose is 20 mg once a day.

### To treat reflux oesophagitis

- The usual dose is 20 mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if not yet healed.

- For severe oesophagitis, the dose can be increased to 40 mg once a day and healing is usually achieved within 8 weeks.

### To treat Zollinger-Ellison Syndrome

- The initial dose is 60 mg daily.
- In case of dose exceeding 80 mg, it should be taken in divided doses and given twice daily.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine.

- When to take it

It is recommended to take the capsules in the morning, preferably without food.

Swallow your capsules whole with half a glass of water. Do not chew or crush the capsules. This is because the capsules contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

*If you have swallowing difficulties*

Open the capsule and swallow the contents with half a glass of water or after mixing the contents in a slightly acidic fluid e.g., fruit juice or applesauce, or in non-carbonated water. This should be taken immediately (or within 15 minutes) and always be stirred just before drinking and rinsed down with half a glass of water.

Alternatively you can suck the capsule and swallow the pellets with half a glass of water. The enteric-coated pellets must not be chewed.

- How long to take it

Do not stop treatment before talking to your doctor, as this will reduce the treatments effect. Follow your doctor's advice.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up a forgotten dose.

- If you use too much (overdose)

Contact your doctor or the nearest hospital casualty department

immediately.

Take this leaflet or some medicines with you so that people will know what you have taken.

If you have any further questions on the use of this product, ask your doctor or pharmacist

### While you are using it

- Things you must do

- Take your medicine exactly as your doctor or pharmacist has told you.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give Probitor Capsules to anyone else, even if they have the same symptoms are condition as you.
- Do not stop taking the medicine unless advised by your doctor.

- Things to be careful of

### Driving and using machines

Probitor Capsules is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur. If affected, you should not drive or operate machinery.

### Side effects

Like all medicines, Probitor Capsules can cause side effects, although not everybody gets them.

Side effects can occur with the following frequencies:

**Common** side effects are:

- Headache
- Effects on your stomach or gut: diarrhea, stomach pain, constipation, wind (flatulence)
- Feeling sick (nausea) or being sick (vomiting)
- Fundic gland polyps (Benign): Benign polyps in the stomach

**Uncommon** side effects are:

- Disturbed sleep (insomnia)
- Dizziness, tingling feelings such as 'pins and needles', feeling sleepy

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- Spinning feeling (vertigo)
- Changes in blood tests that check how the liver is working
- Skin rash and itchy skin
- Generally feeling unwell and lacking energy
- Swelling of the feet and ankles
- Fracture: Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis)

#### Rare side effects are:

- Blood disorders (reduced number of cells in the blood i.e., leukopenia, thrombocytopenia, agranulocytosis and pancytopenia)
- Low levels of sodium in the blood. This may cause being sick (vomiting) and cramps
- Feeling agitated, confused or depressed
- Aggression
- Seeing, feeling or hearing things that are not there (hallucinations)
- Taste changes
- Eyesight problems such as blurred vision
- Suddenly feeling wheezy or short of breath (bronchospasm)
- Dry mouth
- An inflammation of the inside of the mouth
- Inflammation in the large bowel, that causes persistent watery diarrhea
- Liver inflammation, including jaundice which can cause yellow skin, dark urine, and tiredness
- Severe liver problems leading to liver failure and affecting the brain
- Hair loss (alopecia)
- Sensitivity to light
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains [erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN), acute generalized exanthematous pustulosis (AGEP), drug rash with eosinophilia and systemic symptoms (DRESS)]
- Joint pains (arthralgia) or muscle pains (myalgia)
- Muscle weakness
- Kidney problems (interstitial nephritis)
- Increased sweating
- Swelling of legs, feet, ankles or hands (peripheral oedema)

#### Very rare side effects are:

- Hypomagnesaemia: Low levels of magnesium can also lead to a reduction in potassium or calcium levels in blood
- Enlarged breasts in men

#### Frequency “Not Known” side effects are:

- Subacute Cutaneous Lupus Erythematosus (SCLE)

#### Other side effects reported are:

- *Clostridium difficile* diarrhea: Severe diarrhea which may be caused by an infection (*Clostridium difficile*) in your intestines
- Vitamin B12 deficiency: Proton pump inhibitors may cause vitamin B12 deficiency

When you are taking this medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Please tell your doctor promptly if you get any of the symptoms below:

- Rash (especially in areas exposed to the sun), possibly with pain in the joints (Subacute Cutaneous Lupus Erythematosus, SCLE).
- Fever, extreme tiredness, pus/blood in urine.
- Involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate.
- Fracture in the hip, wrist or spine.
- Watery stool, stomach pain and fever that do not go away.
- Anaemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioural changes).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or

pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

#### Storage and disposal of Probitor Capsules

##### - Storage

Keep out of the reach and sight of children.

Do not use Probitor Capsules after the expiry date “EXP” which is stated on the packaging.

Do not store above 30°C. Store in the original package to protect from moisture.

##### - Disposal

Medicinal should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### Product Description

##### - What it looks like

White cap, white body capsules containing almost white to light brown pellets.

##### - Ingredients

#### Active ingredients

The active substance is omeprazole. Each capsule contains 20 mg omeprazole.

#### Inactive ingredients

##### Capsule content

Sugar spheres  
Hypromellose  
Sodium Lauryl Sulphate  
Magnesium Oxide Heavy  
Povidone  
Talc  
Methacrylic Acid-Ethyl Acrylate Copolymer 1:1 Dispersion 30%  
Triethyl Citrate  
Magnesium Stearate

##### Capsule shell

Titanium dioxide  
Gelatine

##### - MAL No.

MAL09122031AZ

# PROBITOR<sup>®</sup> CAPSULES

*Consumer Medication Information Leaflet (RiMUP)*

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**Manufacturer**

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**Product Registration Holder**

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