

PROBITOR CAPSULES

Omeprazole (20mg)

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What Probitor Capsules is used for
Probitor Capsules is used to treat the following conditions:

- 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.
- 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.
- Erosions caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs).
- 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 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.
- You have severe liver problem.

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 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 pine 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.

Lactation

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 taken 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:

- Ketoconazole, itraconazole, or voriconazole (used to treat infections caused by a fungus)
- Digoxin (used to treat heart problem)
- 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

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Probitor.

- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking Probitor Capsules.
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infections)
- Tacrolimus (in cases of organ transplantation)
- St John's wort (*Hypericum perforatum*) (used to treat depression)
- Cilostazol (used to treat intermittent claudication (blood circulation in the legs))
- Saquinavir (used to treat HIV infection)
- Clopidogrel (used to prevent blood clots)

If your doctor has prescribed the antibiotics amoxicillin and 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 20mg once a day for 4-8 weeks
- If the ulcer do not fully heal, the dose can be increased to 40mg once a day for 4 weeks.

To treat ulcers in the stomach (gastric ulcer):

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

To prevent the duodenal ulcers from coming back:

- The usual dose 20mg once a day, up to one year.

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

- The usual dose is 20mg 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 20mg once a day.

To treat ulcers caused by *Helicobacter pylori* infection:

- The usual dose is 40mg Probitor once a day in the morning
- Your doctor will also tell you to take antibiotics among amoxicillin, clarithromycin and metronidazole.

To treat Zollinger-Ellison Syndrome

- The initial dose is 60mg daily.
- In case of dosage exceeding 80mg, it should be taken in divided doses.
- 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

You can take take your capsules with food or on an empty stomach. 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.

- How long to take it

Do not stop treatment before talking to your doctor, as this will reduce the treatments effect

- 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 tablets 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.

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Side effects can occur with the following frequencies:

Common, occurs in 1 to 10 per 100 users:

- Headache
- Effects on your stomach or gut: diarrhea, stomach pain, constipation, wind (flatulence)
- Feeling sick (nausea) or being sick (vomiting)

Uncommon, occurs in 1 to 10 per 1000 users:

- Swelling of the feet and ankles
- Disturbed sleep (insomnia)
- Dizziness, tingling feelings such as 'pins and needles', feeling sleepy
- Spinning feeling (vertigo)
- Changes in blood tests that check how the liver is working
- Skin rash, lumpy rash (hives) and itchy skin
- Generally feeling unwell and lacking energy

Rare, occurs in 1 to 10 per 10 000 users:

- Blood problems such as a reduced number of white cells or platelets. This can cause bruising or make infections more likely
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing
- Low levels of sodium in the blood. This may cause being sick (vomiting) and cramps
- Feeling agitated, confused or depressed
- 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
- An infection called 'thrush' which can affect the gut and is caused by a fungus
- Liver inflammation, including jaundice which can cause

yellow skin, dark urine, and tiredness

- Hair loss (alopecia)
- Joint pains (arthralgia) or muscle pains (myalgia)
- Severe kidney problems (interstitial nephritis)
- Increased sweating

Very rare, occurs in less than 1 of 10 000 users:

- Changes in blood count including agranulocytosis (lack of white blood cells)
- Aggression
- Seeing, feeling or hearing things that are not there (hallucinations)
- Severe liver problems leading to liver failure and affecting the brain
- 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)
- Muscle weakness
- Enlarged breasts in men

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 calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

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. The expiry date refers to the last day of that month.

Blister:

Store below 25°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

Probitor Capsules are white, with imprint "OME 20" containing dull yellowish, brown granules.

- Ingredients

Active ingredients

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

Inactive ingredients

The other ingredients are low substituted hydroxypropyl cellulose, microcrystalline cellulose, lactose anhydrous, croscarmellose sodium, povidone,, polysorbate 80, hypromellose phthalate, dibutyl sebacate, talc, anhydrous ethanol, acetone.

- MAL No.

MAL09122031AZ

Manufacturer

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Product registration holder

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