

OMEZOLE CAPSULE

Omeprazole (20 mg)

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What Omezone is used for

- Treatment of reflux oesophagitis. This is where acid from the stomach leaks backward to the food pipe causing pain, inflammation and heartburn.
- Treatment of ulcers in the upper part of the intestine (duodenal ulcer) or stomach (benign gastric ulcer).
- Long term treatment for too much acid secreted in the stomach caused by Zollinger-Ellison syndrome

How Omezone works

Omezone contains the active substance omeprazole. It belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid produced in the stomach.

Before you use Omezone

- When you must not use it

Do not take this medicine:

- if you are allergic to omeprazole or any of the other ingredients listed at the end of the leaflet.
- if you are allergic to medicines containing other proton pump inhibitors (eg pantoprazole, lansoprazole, rabeprazole, esomeprazole)

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

- Before you start to use it

Tell your doctor/pharmacist if:

- you have allergies to any other medicines, foods, dyes or preservatives
- you have liver problems or history of it.
- you have problem swallowing
- you have osteoporosis
- you are breastfeeding
- you are pregnant
- you are due to have a specific blood test (Chromogranin A)
- you are taking diuretic or digoxin medicine for heart problem

- Taking other medicines

Omezone may affect or be affected by other medicines you are taking. Talk to your doctor or pharmacist if you are taking any other medicines in any form including any that you buy or obtained without a prescription.

Tell the doctor if you are taking the following medicines:

- Antifungal medicines (e.g. ketoconazole)
- Antibiotic (e.g. ampicillin)
- Medicines that are used for seizure (e.g. diazepam, phenytoin)
- Medicines that are used to thin your blood
- Iron salts

Other interactions not stated may occur. Talk to your doctor or pharmacist if you have any other concerns.

How to use Omezone

Omezone is preferably swallowed whole with liquid. If you have swallowing difficulties, you can open the capsule and swallow the content or dissolve the content in a slightly acidic fluid e.g. juice, soured milk, or non-carbonated water. The dispersion should be taken immediately or within 30 minutes.

Alternatively you can suck the capsule content and swallow the pellets with liquid.

Do not chew or crush the content.

- How much to use

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 label, ask your doctor or pharmacist for help.

Reflux Oesophagitis

The usual dose is one capsule once a day. Your doctor may tell you to take a dose of two capsules if your condition has not yet healed.

Duodenal Ulcer/ Benign Gastric Ulcer

The usual dose is one capsule once a day. Your doctor may increase the dose to two capsules once a day.

Gastric hypersecretory (e.g., Zollinger-Ellison)

The usual dose is three capsules once a day. Your doctor will adjust the dose depending on your needs.

If you have liver problems, one capsule once a day may be sufficient.

- When to use it

Recommended to be taken immediately before meals, preferably in the morning

- How long to use it

Reflux Oesophagitis

The usual treatment regime is 4 weeks. Your doctor may tell you to take a further 4 weeks if your condition has not yet healed.

Duodenal Ulcer/ Benign Gastric Ulcer

The usual treatment regime is 4 weeks. Your doctor may tell you to take for a further 4 weeks if your ulcer has not yet healed.

Your doctor may tell you to take up to one year if you have history of recurrent duodenal ulcer.

Gastric hypersecretory (e.g., Zollinger-Ellison)

You are advised to take it as long as your doctor tells you to.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Omeazole

- Things you must do

Tell your doctor: .

- If you become pregnant while taking this medication

Tell all the doctors, dentists and pharmacists treating you that you are taking Omeazole.

- Things you must not do

Do not:

- give your medicine to anyone else even if they have the same condition as you
- take your medicine to treat any other complaints unless you are told by your doctor or pharmacist
- take more than the recommended dose unless your pharmacist or doctor tells you to
- stop taking the medicine unless advised by your doctor.

- Things to be careful of

Tell your doctor if:

- you are having any new and exceptional symptoms or circumstances when taking Omeazole on long term basis

Side effects

Like all medicines, Omeazole can cause side effects, although not everybody gets them. These effects can be serious but most of the time, they are mild and temporary.

Stop taking Omeazole and tell your doctor immediately if you notice:

- Severe allergic reactions such as sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing

Other side effects

- Headache.
- Constipation, wind (flatulence).
- Nausea
- Chest pain
- Heartburn

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
- Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioral changes).

Subacute Cutaneous Lupus Erythematosus (SCLE)

Frequency “not known”.

Interstitial Nephritis

Kidney problems.

Hypomagnesaemia

Frequency “not known”. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood.

Fracture

Frequency “uncommon”. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Clostridium Difficile Diarrhea

Severe diarrhea which may be caused by an infection (*Clostridium difficile*) in your intestines.

Fundic Gland Polyps (Benign)

Frequency “Common”. Benign polyps in the stomach.

Vitamin B12 Deficiency

Proton pump inhibitors may cause vitamin B12 deficiency.

Other unwanted side effects not listed may occur. Tell your doctor immediately.

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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Omeazole

- Storage

Keep out of reach of children.

Store below 25°C. Protect from moisture.

- Disposal

Medicines 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

Light caramel and flesh opaque capsule with "OMEZOLE 20" printed on one end and "hovid" printed on the other end of the capsule.

- Ingredients

- Active ingredients

Each capsule contains Omeprazole pellets equivalent to omeprazole 20 mg

- Inactive ingredients

None

- MAL Number:

MAL20000377AZ

Manufacturer

HOVID Bhd.

Lot 56442, 7 ½ Miles, Jalan Ipoh/
Chemor, 31200 Chemor, Perak,
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Product Registration Holder

HOVID Bhd.

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