

OMESEC CAPSULE

Omeprazole (20mg)

What is in the leaflet

1. What Omesecc Capsule is used for
2. How Omesecc Capsule works
3. Before you use Omesecc Capsule
4. How to use Omesecc Capsule
5. While you are using it
6. Side effects
7. Storage and Disposal of Omesecc Capsule
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Omesecc Capsule is used for

Omesecc is used to treat the following conditions:

- ‘Gastro-oesophageal reflux disease’ (GERD). This is a condition where the acid from the stomach escapes into the throat.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Ulcers associated with ‘*Helicobacter pylori*’ infection in combination with other medications such as antibiotics.
- Zollinger-Ellison syndrome (overproduction of gastric acid due to tumours).

How Omesecc works

Omesecc 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 by your stomach.

Before you use Omesecc

- When you must not use it

Do not use Omesecc if you are

- allergic to omeprazole or any of the other ingredients of Omesecc.
- pregnant or planning to become pregnant
- breast-feeding

- Before you start to use it

Inform your doctor if:

- you have any liver disease.

Tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A). Omesecc Capsule treatment should be stopped for at least 5 days before the test.

Your doctor will prepare test to exclude cancer since Omeprazole may mask symptoms and delay diagnosis.

- Taking other medicines

Please inform your doctor if you are taking or have recently taken any other medications, as well as those you bought without a prescription, including but not limited to:

- Ketoconazole (for fungal infection)
- Digoxin (for heart problems)
- Diazepam (for anxiety)
- Phenytoin (for epilepsy),
- Warfarin (to prevent blood clot)
- Methotrexate (cancer medication)
- Clarithromycin, Ampicillin (antibiotic for bacterial infection)
- Iron salts

How to use Omesecc

- How much to use

Follow all instructions exactly as given to you by your doctor or pharmacist. The following information only serves as guidance, hence the dose and frequency for you may be different:

Benign Gastric & Duodenal Ulcer

Depending on the severity and location of the ulcer, the recommended dose is 20mg - 40mg once daily for 4 - 8 weeks.

The recommended dose for long term therapy for people with a history of repeated duodenal ulcer is 20mg once daily for up to one year.

The recommended dose for prevention of reoccurrence of duodenal ulcer is 10mg once daily. If needed, the dose can be increased to 20mg - 40mg once daily.

Gastro-Oesophageal Reflux Disease

The recommended dose is 20mg-40mg once daily for 4 - 8 weeks. The maintenance therapy can be continued with 10mg once daily.

Zollinger-Ellison Syndrome

The recommended dose is 60mg once daily initially with usual range 20mg - 120mg daily. Doses above 80mg should be divided and given twice daily.

Helicobacter Pylori Eradication

Omesecc should be given in combination with antibiotic(s). Depending on the regimen and duration of therapy, the recommended dose is 40mg once daily or 20mg twice daily.

Children and Elderly

Please consult your doctor before taking this medicine.

- When to use it

Omesecc should be taken immediately before meals, preferably in the morning or according to the time advised by your doctor or Pharmacist.

- How long to use it

The recommended duration for taking Omesecc will depend on your condition. Always take the medicine as per the instruction from your doctor or pharmacist.

- If you forget to use it

Take it as soon as you remember, then go back to taking your capsules as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose on time. Do not take a double dose to make up for the missed dose.

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

- If you use too much (overdose)

Some symptoms you may experience are drowsiness, headache and fast heart rate.

Alert 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 it

- Things you must do

Swallow your capsule as a whole with a glass of water. Do not chew or crush the capsule.

It is important not to damage the mini tablets in the capsules.

If you have difficulties in swallowing, the capsule can be opened and the content can be swallowed or suspended in a glass of juice, yoghurt or soured milk within half an hour. Alternatively, the contents can be swallowed by sucking the capsule.

- Things you must not do

Do not stop taking your medicine or change the dose without consulting your doctor.

Do not take Omesecc to treat any other complaints unless being instructed by your doctor.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Driving and using machines: Omesecc is not likely to affect your ability to drive or to operate machinery. However, side effects such as dizziness and visual disturbances may occur. If affected, you should not drive or operate machinery.

If you feel that the effect of Omesecc is too strong or too weak, consult your doctor for appropriate action.

Side effects

Like all medicines, Omesecc capsule can cause side effects.

The following side effects listed not all are common side effects have been reported:

- Headache
- Constipation, wind
- Nausea and/or vomiting

Other side effects:

- Subacute Cutaneous Lupus Erythematosus (SCLE, frequency “not known”)
- Kidney Problems (Interstitial Nephritis)
- 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 diarrhoea caused by an infection Clostridium difficile in your intestines.
- Fundic Gland Polyps (frequency “common”) benign polyps in the stomach.

- 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.

- 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 does not go away
- Anemic symptoms (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)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Omesecc

- Storage

Keep your medicine in its original packaging until it is time to take them.

Keep your medicine in a cool dry place below 25°C. Protect from light and moisture.

Keep out of reach of children.

- Disposal

Do not use Omesec after the expiry date. You may return any unused Omesec to your doctor or pharmacist.

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

Product Description

- What it looks like

Hard gelatin capsules with flesh opaque body and light brown opaque cap, each half printed with 'OMESEK 20' in black, holding enteric-coated mini-tablets.

Omesec comes in blister packs of 2x7's, 4x7's and 10x7's capsules.

- Ingredients

- Active ingredient:

Omeprazole

- Inactive ingredients:

- Povidone
- Disodium hydrogen phosphate
- Hydroxypropylmethylcellulose phthalate
- Sodium lauryl sulphate
- Sodium stearyl fumarate
- Dibutylphthalate
- Lactose anhydrous
- Crospovidone

Omesec capsules contain lactose. If you have intolerance to some sugars, contact your doctor.

- MAL number

MAL05041936ACZ

Manufacturer

Upha Pharmaceutical Mfg. (M)
Sdn Bhd (53667-M)
Lot 2&4, Jalan P/7, Section 13,
Bangi Industrial Estate, 43650
Bandar Baru Bangi, Selangor
Darul Ehsan

Product Registration Holder

CCM Pharmaceuticals Sdn Bhd
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Darul Ehsan

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