

OMETAC CAPSULE

Omeprazole (20mg)

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What Ometac is used for

Ometac is used to treat the following conditions:

- Ulcers in the upper part of the intestine (Duodenal ulcer).
- Stomach ulcers (Gastric ulcer).
- Stomach ulcers or ulcers in the upper part of the intestine caused by your medicine for pain and inflammation (NSAID associated gastric and duodenal ulcers or erosions).
- Ulcers which are infected with bacteria called *Helicobacter pylori* (*Helicobacter pylori* eradication in peptic ulcer disease).
- Disease with symptoms caused by a return flow of fluid from the stomach (Symptomatic gastro-oesophageal reflux disease or reflux oesophagitis).
- Acid related upper abdominal pain or discomfort (Acid related indigestion).
- Hormone producing tumours in the pancreas causing excess acid in the stomach (Zollinger-Ellison syndrome).

How Ometac works

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

Before you use Ometac

- When you must not use it

Do not take Ometac:

- If you are allergic to omeprazole or any other ingredients in Ometac.

- Before you start use it

Inform your health care professional if,

- you have any alarming symptoms (e.g. significant unintentional weight loss, recurrent vomiting, difficulty swallowing, severe or persistent diarrhoea, vomiting blood or blood in your stools).
- you are taking medicines for Human Immunodeficiency Virus (HIV), such as atazanavir or if you have reduced vitamin B12 (cyanocobalamin) absorption or body stores.
- you have hereditary problems of sugar intolerance such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.
- you are due to have a specific blood test (Chromogranin A)

Some population studies have indicated that the use of proton pump inhibitors (like Ometac capsule) may be associated

with a small increased risk for osteoporotic bone fractures (osteoporosis is a condition where certain bones become brittle). Please inform your doctor if you have been diagnosed with osteoporosis.

Treatment with proton pump inhibitors may lead to slightly increased risk of gastrointestinal infections. If you are undergoing long-term treatments, especially when exceeding a treatment period of 1 year, the doctor may arrange regular appointments for you.

Pregnancy

Tell your doctor if you are pregnant or trying to become pregnant. Ometac capsule can be used in pregnancy. If you are pregnant, only take Ometac capsule on the advice of your doctor.

Breast-feeding

Tell your doctor if you are breast-feeding.

Ometac capsule may be used during breastfeeding. If you are breastfeeding, only take Ometac capsule on the advice of your doctor.

- Taking other medicines

Please inform your doctor if you are currently taking or have recently taken any other medications, including over-the-counter drugs, such as:

- Ketoconazole (for fungal infections)
- Digoxin (for heart problems)
- Diazepam (for anxiety)
- Phenytoin (for epilepsy)
- Warfarin (to prevent blood clotting)
- Methotrexate (cancer medication)
- Clarithromycin, Ampicillin (antibiotics for bacterial infections)
- Iron supplements.

How to use Ometac

- How much to use

Always take Ometac capsule exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell how many capsules to take and when to take them.

You can take your capsules with food or on an empty stomach. The capsules should not be chewed or crushed. They should be swallowed whole, with half a glass of water. This is because the capsules contain coated pellets which stop the medicine from being broken down by the acid in your stomach.

If you have problems with swallowing capsules, break the capsule and mix it with some water or fruit juice. You can drink immediately or within 30 minutes. Always stir just before drinking. Rinse it down with half a glass of water.

- When to use it

Duodenal ulcer, Gastric ulcer, Reflux oesophagitis. Depending on the severity of the ulcer or reflux oesophagitis, the recommended dose is 20-40mg taken once a day, for 2-8 weeks. To prevent a duodenal ulcer from coming back and people with healed reflux oesophagitis are being treated for a long time, the recommended dose is 10-40mg taken once a day. To prevent a gastric ulcer from coming back, the recommended dose is 20-40mg taken once a day.

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Symptomatic gastro-oesophageal reflux disease. The recommended dose is 10-20mg taken once a day for 4 weeks.

Acid related indigestion.

For relief of symptoms with abdominal pain or discomfort the recommended dose is 10-20mg once a day for 4 weeks.

NSAID associated gastric and duodenal ulcers or erosions.

To heal your ulcer caused by your medicine for the pain and inflammation, the recommended dose is 20mg taken once a day for 4-8 weeks. To prevent the ulcer or pain from coming back when you continue to take your medicine for the pain and inflammation the recommended dose is also 20mg once a day.

Helicobacter pylori eradication in peptic ulcer disease

Ometac capsule taken with two antibiotics.

Ometac capsule 20mg with amoxicillin 1g and clarithromycin 500mg each twice daily for 1 week or

Ometac capsule 20mg with metronidazole 400mg (or tinidazole 500mg) and 250mg clarithromycin each twice daily for 1 week or

Ometac capsule 40mg once daily with amoxicillin 500mg and metronidazole 400mg both three times a day for 1 week.

Ometac capsule taken with one antibiotic. Ometac capsule 40-80mg daily with amoxicillin 1.5g (doses up to 3g) in divided doses a day for 2 weeks or Ometac capsule 40mg once daily with 500mg clarithromycin three times a day for 2 weeks. If your symptoms do not go away after you have been given one of these treatments, your doctor may repeat the same treatment, or try one of the other treatments.

Zollinger-Ellison syndrome.

The recommended start dose is 60mg daily. Your doctor will adjust the dose according to your needs and also decide for how long you should take the medicine. With doses above 80mg

daily, the dose should be divided and taken twice a day.

Elderly.

The dose does not need to be adjusted in the elderly.

People with impaired kidney or liver Function People with severe liver disease rarely need more than 10-20mg per day. The dose does not need to be adjusted in people with impaired kidney function. If you have the impression that the effect is too strong or too weak, talk to your doctor or pharmacist.

Children

Ometac capsule 20mg are not recommended to be used in children

- How long to use it

Always take Ometac exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many capsules to take and how long to take them for. This will depend on your condition and how old you are.

- 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 for a forgotten dose.

- If you use too much (overdose)

If you suspect an overdosage, contact your nearest hospital casualty department or tell your doctor immediately.

Symptoms of an overdose may include:

- Blurred vision
- Confusion
- Diaphoresis
- Drowsiness
- Dryness of mouth
- Flushing
- Headache
- Nausea
- Abnormally rapid heart rate (tachycardia).

Since there is no specific antidote, treatment should be symptomatic and supportive.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

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

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Ometac to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Taking omeprazole is unlikely to make you unable to drive or use machines.

However, it's possible to experience side effects like dizziness and changes in vision. If these side effects occur, it's important not to drive or operate machinery until you feel better.

Side effects

Like all medicines, Ometac capsule can have side effects.

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

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• Anemic (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 behavioral changes)

The following undesirable effects have been reported: headache, diarrhoea, constipation, stomach ache, feel sick / be sick, wind, and fundic gland polyps (benign polyps in the stomach).

On uncommon occasions, there have been reports of: skin rash, skin inflammation, itchiness (hives), sensation of burning / prickling / numbness, dizziness, difficulty sleeping, feeling sleepy, sensation of movement of one's self or of one's surroundings, feeling ill.) and fracture (tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

There have been a few isolated cases of: inflammation in the gut (leading to diarrhoea), sensitivity to sunlight, severe skin reactions (including StephensJohnson syndrome (SJS), toxic epidermal necrolysis (TEN), hair loss, sore joints and muscles, muscular weakness, dry mouth, inflammation in the mouth, gastrointestinal fungal infection, disorientation/aggression/ confusion/decreased consciousness (if you already have severe liver disease), kidney and liver problems (i.e., inflammation of the kidney (interstitial nephritis), inflammation of the liver with or without jaundice, impaired liver function), blood disorders (reduced number of cells in the blood i.e., leukopenia, thrombocytopenia, agranulocytosis and pancytopenia), development of breasts in males, swelling, fever, discomfort / tightness in the chest, severe allergic reaction (anaphylactic reaction/ shock), increased sweating, blurred vision, taste disorders, low blood sodium, low blood magnesium (which may result in low blood calcium and/or low blood potassium), subacute cutaneous lupus erythematosus (SCLE), severe

diarrhoea which may be caused by an infection (Clostridium difficile) in your intestines and Vitamin B12 deficiency. Inflammation in the large bowel Frequency 'not known': Inflammation in the large bowel, that causes persistent watery diarrhea. If you are very ill, you may feel confused, nervous, depressed or hallucinate.

If you suffer from any of these reactions, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Other undesirable effects may occur. If you have any bothersome or unusual reaction while taking Ometac capsule, check with your doctor or pharmacist right away.

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 Ometac

- Storage

- Store in a dry place below 30° C.

- 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

Ometac 20 capsule
Opaque pink / reddish brown hard gelatin capsule with 'OMETAC 20' printed on body and cap.

- Ingredients

Active ingredient
- Omeprazole.

Inactive ingredients
- Disodium hydrogen Phosphate
- Sodium Lauryl sulphate
- Lactose monohydrate
- Corn starch

- Manitol
- Sucrose
- Hydroxypropylmethylcellulose
- Propylene Glycol
- Sodium hydroxide
- Methacrylic Acid
- Polysorbate 80
- Titanium Dioxide
- Cetyl alcohol
- Isopropyl alcohol
- Purified water

- MAL number
MAL19992754AZ

Manufacturer and Registration Holder

Noripharma Sdn. Bhd.
Lot 5030, Jalan Teratai,
5 ½ Miles off Jalan Meru,
41050 Klang, Selangor.

Date of revision

26/02/2024

Serial number

NPRA(R2/1)240213/1206