

# OPRAZOL CAPSULES 20MG

Enteric-coated omeprazole pellets eq. to omeprazole 20mg

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## What *Oprazol* is used for

It is used in treatment of inflammation of the oesophagus, intestinal and non-cancerous gastric ulcers, and the Zollinger-Ellison syndrome (too much acid in the stomach caused by a growth in the pancreas).

## How *Oprazol* works

Omeprazole stops the secretion of gastric acid and is considered to do so by blocking the enzyme system (proton pump) of the gastric parietal cell. Acid secretions are inhibited. It is used in the management of gastrointestinal disorders thought to be related to an excess of stomach acid production. Omeprazole is non-reactive to acid. The product contains an enteric-coated granule formulation and appears to be dose-dependent, as increasing the dosage has been reported disproportionately to increase blood concentrations.

## Before you use *Oprazol*

### When you must not take it

- if you are allergic to omeprazole.

### Before you start to take it

The possibility of gastric cancer has excluded before giving *Oprazol*, since omeprazole may mask symptoms and delay diagnosis. Tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A).

### Taking other medications

As omeprazole is metabolised in the liver by liver enzymes, it may increase the blood concentrations of diazepam, phenytoin and warfarin, due to the decreased rate of metabolism by the liver. Due to increased pH of stomach by omeprazole, reduction of absorption of ampicillin esters, iron salts and ketoconazole may be noted.

## How to use *Oprazol*

### How much to take

Non-cancerous gastric ulcers: 20 – 40mg daily for 8 weeks. Intestinal ulcers: 20 – 40mg daily for 4 weeks. Long term treatment for patients with a history of recurrent duodenal ulcer is recommended at a dosage of 20mg omeprazole once daily,

up to one year. Healing of inflammation of oesophagus: 20 – 40mg once daily for 4 – 8 weeks. Zollinger-Ellison syndrome (too much acid in the stomach caused by a growth in the pancreas): 60mg once daily. Doses in the range of 20 – 120mg daily may be used. Doses above 80mg should be divided and given twice daily. The dosage should be adjusted individually and treatment continued as long as is clinically indicated. Note: Impaired renal function: Dosage adjustment is not required in patients with impaired renal function. Impaired hepatic function: A daily dose of 20mg may be sufficient. Elderly: Dose adjustments is not required.

### When to take it

Take *Oprazol* exactly as your doctor has told you.

### How long to take it

You should check with your doctor or pharmacist.

### If you forget to take 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 tablet.

### If you take too much (overdose)

If taken too much *Oprazol*, contact your doctor, an emergency department or a poisoning center immediately.

## While you are using *Oprazol*

### Things you must do

You must take your medication as directed.

### Things you must not do

Do not take other medications together with omeprazole without speaking to your doctor or pharmacist first.

### Things to be careful of

If you are pregnant or become pregnant or breast-feeding during treatment, you should inform your doctor prior to treatment.

## 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 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, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioral changes).

### a) Subacute Cutaneous Lupus Erythematosus (SCLE):

Frequency “not known”

### b) Interstitial Nephritis: Kidney problems (interstitial nephritis)

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

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

e) Clostridium Difficile Diarrhea: Severe diarrhoea which may be caused by infection (*Clostridium difficile*) in intestines.

f) Fundic Gland Polyps (Benign): Frequency “Common”: Benign polyps in the stomach

g) Vitamin B12 Deficiency: Proton pump inhibitors may cause vitamin B12 deficiency.

### h) Inflammation in the large bowel:

Frequency “not known”: Inflammation in the large bowel, that causes persistent watery diarrhea. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npa.gov.my](http://npa.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## After using *Oprazol*

### Storage

Store in cool, dry place below 30°C. Protect from light. Keep out of reach of children.

### Disposal

Ask your pharmacist how to dispose of medicines no longer required.

## Product description

### What it looks like

Dark peach cap/Light peach body capsules.

### Ingredients

Enteric-coated omeprazole pellets (omeprazole, hypromellose, sodium hydroxide, sugar, methacrylic acid copolymer dispersion liquid, talc, titanium dioxide, polyethylene glycol 6000 and polysorbate 80).

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**MAL No**

MAL14125127AZ

**Manufacturer & Product registration**

**Holder**

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