

OMELON ENTERIC MICROENCAPSULATED CAPSULE

Omeprazole (20mg)

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What OMELON is used for

Treatment of duodenal and benign gastric ulcers including those complicating NSAID therapy. Treatment of acid reflux of oesophagus inflammation due to the stomach acid, Zollinger-Ellison syndrome (due to overproduction of gastric acid), and treatment for bacterial infection of *Helicobacter pylori*. Long term treatment for recurrent duodenal ulcer.

How OMELON works

Omeprazole acts as a specific inhibitor of the gastric acid pump and reduces gastric acid secretion through a unique mechanism of action. Omeprazole is a weak base and is concentrated and converted to the active form in the acid environment.

Before you use OMELON

-When you must not use it

If you have shown hypersensitivity to omeprazole or any ingredients in this medicine.

-Before you start to use it

Tell your doctor or pharmacist if you are allergic to any other medicines or you have any other health related problems.

-Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

OMELON may cause unwanted effect if it is use together with other medicines, such as:

- Diazepam, phenytoin (medicine for seizure)

- Digoxin (medicine to treat heart diseases)
- Amoxicillin (medicine to treat bacterial infection)
- Antacid (medicine to relieve heartburn)
- Clarithromycin (medicine to treat bacterial infection)
- Ketoconazole (medicine to treat fungal infection)

How to use OMELON

-How much to use

Duodenal and benign gastric ulcers: 20mg once daily for 4 weeks in duodenal ulceration or 8 weeks in gastric ulceration; in severe or recurrent cases increase to 40mg daily.

Maintenance for recurrent duodenal ulcer: 20mg once daily.

Reflux oesophagitis: 20mg once daily for 4 – 8 weeks

Zollinger-Ellison syndrome: Initially 60mg once daily; usual range 20-120mg daily (above 80mg in 2 divided doses).

H. pylori eradication:

Triple therapy regimens: Omelon 20mg, amoxicillin 1g and clarithromycin 500mg, all twice a day for 1 week; or Omelon 20mg, clarithromycin 250mg and metronidazole 400mg, all twice a day for 1 week; or Omelon 40mg once daily with amoxicillin 500mg and metronidazole 400mg, both 3 times a day for 1 week.

Dual therapy regimens: Omelon 40mg daily with amoxicillin 1.5g daily in divided doses for 2 weeks.

Kidney and liver impairment: No dosage adjustment necessary.

-When to use it

OMELON should be taken according to the time advised by your doctor.

-How long to use it

OMELON should be taken as your doctor advised you to do so.

-If you forget to use it

If you miss a dose of OMELON and you are taking it regularly, take it as soon as possible. If it is approaching time for the next dose, do not double the dose to make up for the forgotten dose, unless advised by your health care provider. Do not take 2 doses at once.

-If you use too much (overdose)

Seek for medical attention.

While you are using OMELON

-Things you must do

Follow your doctor's instruction when you are taking OMELON.

-Things you must not do

Do not stop taking this medicine or change the dosing regimen without instruction from your doctor. Do not give OMELON to anyone else, even if they have the same condition as you.

-Things to be careful of

There is no evidence on the safety of omeprazole used in pregnancy and lactation. Avoid in pregnancy and breastfeeding unless there is no safer alternative.

Dose adjustment is not required in the elderly, people with impaired kidney or liver function. There is no experience on the use of omeprazole in children. People with severe liver disease should not require >20mg of omeprazole daily. Cautions should be taken for people with gastric ulcer.

Side effects

Omeprazole is well tolerated and adverse reactions have generally been mild and reversible. Side effects might happen such rashes, hives, and itching, arthralgia (joint pain), muscle weakness, myalgia (muscle pain), headache, dizziness, insomnia (sleep disorder), vertigo (spinning sensation), depression, hallucinations, diarrhea, constipation, vomiting, increased liver enzyme, leucopenia (deficiency of white blood cell), malaise, and hypersensitivity reactions such blurred vision and taste disturbance.

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 CLARIMYCIN FILM COATED TABLET

-Storage

Keep in a tight container. Store at temperature below 25°C. Protect from light and moisture.

-Disposal

OMELON should be disposed when your doctor or pharmacist tells you to stop taking this tablet or it has passed the expiry date. Ask your pharmacist how to dispose medicines that are no longer required

Product description

What it looks like

Pale brown cap and pink body hard gelatin capsule, containing milky white pellets, and both cap and body impressed with a mark “ YSP
OMCp ”.

-Ingredients

Active ingredient-
Omeprazole

-MAL number

MAL20040810AZ

Manufacturer

Y.S.P. Industries (M) Sdn. Bhd.
Lot 3,5 & 7, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru
Bangi, 43000 Kajang, Selangor Darul
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Product Registration Holder

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