

PEMZO OMEPRAZOLE CAPSULES

Omeprazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about PEMZO OMEPRAZOLE.

It does not contain all the information that is known about PEMZO OMEPRAZOLE.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking PEMZO OMEPRAZOLE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What PEMZO OMEPRAZOLE is used for

Reflux Oesophagitis

PEMZO OMEPRAZOLE is used to treat the symptoms of reflux oesophagitis or reflux disease. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

PEMZO OMEPRAZOLE is also taken to help stop reflux oesophagitis coming back or relapsing.

Peptic Ulcers

PEMZO OMEPRAZOLE is used to treat peptic ulcers. Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

These ulcers can be caused by too much acid being made in the stomach.

PEMZO OMEPRAZOLE is also used to help stop gastric or duodenal ulcers coming back.

Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

When PEMZO OMEPRAZOLE is taken with antibiotics, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Peptic Ulcers Associated with Non-steroidal Anti-Inflammatory Drugs (NSAIDs)

Some peptic ulcers are caused by taking medicines called non-steroidal anti-inflammatory drugs (NSAIDs), a type of medicine used to treat pain or inflammation.

PEMZO OMEPRAZOLE is also used to heal and prevent ulcers associated with NSAIDs.

Zollinger-Ellison Syndrome

PEMZO OMEPRAZOLE is also used to treat a rare condition called Zollinger-Ellison syndrome, where

the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

How PEMZO OMEPRAZOLE Works

PEMZO OMEPRAZOLE is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may prescribe this medicine for another reason.

There is no evidence that PEMZO OMEPRAZOLE is addictive.

This medicine is only available on prescription.

Before you take PEMZO OMEPRAZOLE

When you must not take it

Do not take PEMZO OMEPRAZOLE if you have an allergy to:

- omeprazole or any ingredient listed at the end of this leaflet

- **any medicine containing a proton-pump inhibitor**

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take PEMZO Omeprazol if you are also taking cilostazol.

Please check with your doctor or pharmacist if you are taking cilostazol. This medicine will be affected by PEMZO OMEPRAZOLE.

Do not take PEMZO OMEPRAZOLE after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should take this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives.
- any problems with your liver
- any other medical conditions

Do not take PEMZO OMEPRAZOLE if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take PEMZO OMEPRAZOLE while you are pregnant. It may affect your baby.

It is not known if your baby can take in PEMZO OMEPRAZOLE from breast milk if you are breastfeeding.

Taking other medicines

Do not take PEMZO OMEPRAZOLE if you are taking the following medicine:

- cilostazol – a medicine used to treat intermittent claudication

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

Some medicines may interfere with PEMZO OMEPRAZOLE Capsules. These include:

- phenytoin - a medicine used to treat epilepsy or fits
- warfarin & clopidogrel - medicines used to prevent blood clots
- digoxin – a medicine used to treat heart conditions
- diazepam - a medicine used to treat anxiety and some other conditions
- St John’s Wort – a herbal remedy used to treat mood disorders
- ketoconazole, itraconazole, voriconazole - medicines used to treat fungal infection
- clarithromycin or rifampicin – medicines used to treat viral infections atazanavir and nelfinavir - medicines used to treat viral infections such as HIV
- tacrolimus - a medicine used to assist in organ transplants
- methotrexate – a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer

These medicines may be affected by PEMZO OMEPRAZOLE or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to

be careful with or avoid while taking this medicine.

If you have not told your doctor about any of these things, tell them before you take PEMZO OMEPRAZOLE.

How to take PEMZO OMEPRAZOLE

Follow all directions given to you by your doctor or 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.

How to take it

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 pack, ask your doctor or pharmacist for help.

How much to take

The dose for PEMZO OMEPRAZOLE varies from patient to patient. Your doctor will decide the right dose for you.

How to take it

Swallow the capsules with a glass of water.

Do not crush or chew the capsules.

If the granules or pellets contained in the capsules are crushed or chewed, they will not work properly.

When to take it

Take each dose of PEMZO OMEPRAZOLE at about the same time each day.

Taking each dose of PEMZO OMEPRAZOLE at the same time

each day will help you remember when to take it. PEMZO OMEPRAZOLE can be taken with food or on an empty stomach.

How long to take it

Keep taking PEMZO OMEPRAZOLE for as long as your doctor recommends.

If you are taking PEMZO OMEPRAZOLE to heal an ulcer or to treat reflux disease, you will usually need to take PEMZO OMEPRAZOLE for 4 to 8 weeks.

It is very important that you take the full course of PEMZO OMEPRAZOLE as prescribed by your doctor so that your condition is properly treated.

If you are taking PEMZO OMEPRAZOLE to stop an ulcer from coming back or to treat other conditions, your doctor will tell you how long you need to take the capsules.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much PEMZO

OMEPRAZOLE even if there are no signs of discomfort or poisoning.

While you are taking PEMZO OMEPRAZOLE

Things you must do:

Take PEMZO OMEPRAZOLE exactly as your doctor has prescribed.

If you are about to start any new medicine, remind your doctor and pharmacist that you are taking PEMZO OMEPRAZOLE.

Tell all doctors, dentists and pharmacists who are treating you that you are taking PEMZO OMEPRAZOLE.

Tell your doctor if you become pregnant while you are taking PEMZO OMEPRAZOLE.

Tell your doctor if your symptoms return.

Although PEMZO OMEPRAZOLE can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking PEMZO OMEPRAZOLE, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take PEMZO OMEPRAZOLE to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or change the dosage without checking with your doctor.

If you stop taking it suddenly or change the dose, your condition may worsen or you may have unwanted side effects.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PEMZO OMEPRAZOLE.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- constipation
- nausea or vomiting
- diarrhoea
- headache
- skin rash, itchy skin
- wind
- stomach pain
- dizziness
- dry or sore mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- muscle pain or weakness, joint pain
- "pins and needles"
- changes in sleep patterns
- mood changes, confusion or depression
- blurred vision
- increase in breast size (males)
- fever
- increased bruising
- increased sweating
- hair loss
- tremor

These are serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing
- shortness of breath or difficulty in breathing
- skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals
- blood in urine
- swelling of feet, hands and ankles
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Occasionally, PEMZO OMEPRAZOLE may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

Other problems are more likely to arise from the ulcer itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion that occurs during treatment with PEMZO OMEPRAZOLE
- you begin to vomit blood or food
- you pass black (blood-stained) motions.

After using it

Storage

Keep your PEMZO OMEPRAZOLE in the blister pack until it is time to take them. If you take PEMZO OMEPRAZOLE out of the blister pack they will not keep well.

Keep it in a cool, dry place where the temperature stays below 25 °C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking PEMZO OMEPRAZOLE or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What PEMZO OMEPRAZOLE looks like

PEMZO OMEPRAZOLE is an opaque yellow cap and body capsule containing off-white to cream-white spherical pellets.

Each bottle or carton (in blisters) contains 30 capsules.

Ingredients

Active ingredient:

Each capsule contains omeprazole 20mg.

Inactive ingredients:

Pellets

- sodium lauryl sulfate

- dibasic anhydrous sodium phosphate
- hypromellose
- mannitol
- macrogol 6000
- purified talc
- polysorbate-80
- titanium dioxide
- eudragit L30-D-55
- maize starch
- sucrose.

Capsule

- gelatin
- titanium dioxide
- quinoline yellow CI47005.

Sponsor

NAME AND ADDRESS OF THE SPONSOR

Pharmacor Pty Ltd
Suite 401, 7 Oaks Ave
Dee Why NSW 2099
Australia

NAME AND ADDRESS OF THE DISTRIBUTOR

Arrow Pharma Pty. Ltd.
Cremorne
Victoria 3121
Australia

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