

OMEZOL RELIEF

Omeprazole modified release capsules

10 mg, 20 mg and 40 mg



What is in this leaflet

This leaflet answers some of the common questions about **OMEZOL RELIEF**.

It does not contain all the information. 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 **OMEZOL RELIEF** 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 OMEZOL RELIEF is used for

OMEZOL RELIEF is used to treat the following conditions:

Reflux Oesophagitis

OMEZOL RELIEF is used to treat the symptoms of reflux oesophagitis or reflux disease in adults and in children. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe also known as the oesophagus.

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn, which usually occurs after eating or at night and which worsens when bending over.

OMEZOL RELIEF is also used to help stop reflux oesophagitis coming back or relapsing.

Acid-Related Dyspepsia

OMEZOL RELIEF is used to treat acid-related dyspepsia.

Dyspepsia is an uncomfortable feeling in the stomach or belching after eating. It is also known as indigestion.

Peptic Ulcers

OMEZOL RELIEF 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. They can cause pain and discomfort (indigestion) which is felt between the naval and the breast bone.

OMEZOL RELIEF 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 bacteria called *Helicobacter pylori* in their stomach. When **OMEZOL RELIEF** is taken with antibiotics, they will kill *Helicobacter pylori* and let your peptic ulcer heal. When **OMEZOL RELIEF** is taken together with two antibiotics, they are more effective than taken one or two at a time. It is possible that the antibiotics may not always kill *Helicobacter pylori*. You may need further treatment.

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). These medicines are commonly taken to relieve pain, swelling and other symptoms of inflammation, including arthritis. **OMEZOL RELIEF** is also used to heal and prevent ulcers associated with NSAIDs.

Zollinger-Ellison Syndrome

OMEZOL RELIEF 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 OMEZOL RELIEF works

OMEZOL RELIEF contains the active ingredient omeprazole, which belongs to a group of medicines called proton pump inhibitors.

OMEZOL RELIEF 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you take OMEZOL RELIEF

When you must not take it

Do not use **OMEZOL RELIEF** if you have an allergy to:

- any medicine containing omeprazole
- any of the ingredients listed at the end of this leaflet
- 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 OMEZOL RELIEF after the expiry date printed on the label or if the packaging 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 start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if:

- you are pregnant or planning to become pregnant
- you are breastfeeding or plan to breastfeed
- you have or have had liver disease or liver problems
- you have or have had any medical conditions
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor of any of the above, tell him/her

before you start taking OMEZOL RELIEF.

Taking other medicines

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

Some medicines and **OMEZOL RELIEF** may interfere with each other. These include:

- phenytoin (a medicine used to treat epilepsy)
- warfarin, clopidogrel or vitamin K antagonists (medicines used to treat or prevent blood clots)
- diazepam (a medicine used to treat anxiety or tension)
- ketoconazole, itraconazole or voriconazole (medicines used to treat fungal infections)
- cilostazol (a medicine used to treat intermittent claudication)
- clarithromycin or rifampicin (antibiotics)
- atazanavir, nelfinavir or saquinavir (antiretroviral medicines used to treat HIV)
- tacrolimus (an immunosuppressant used in organ transplants)
- digoxin (a medicine used to treat various heart conditions)
- St John's Wort (a herbal remedy taken for depression)
- methotrexate (a medicine used to treat some cancers and psoriasis)
- other medicines that you buy at the chemist, supermarket or health food shop.

These medicines may be affected by **OMEZOL RELIEF** or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take OMEZOL RELIEF

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 bottle ask your doctor or pharmacist for help.

How much to take

Take **OMEZOL RELIEF** capsules as instructed by your doctor.

Adults

The usual doses of **OMEZOL RELIEF** can vary from 10 mg to 40 mg daily, but can be higher. The dose is dependant on the condition being treated and how severe it is. Maintenance therapy is usually at a lower dose than the initial treatment.

Children

The recommended dose in children with severe reflux oesophagitis is 10 mg once a day in children weighing 10-20 kg and 20 mg in children weighing more than 20 kg. The dosage may be increased if needed.

How to take it

Swallow **OMEZOL RELIEF** capsules whole with a glass of water. Do not crush or chew.

If you have trouble swallowing **OMEZOL RELIEF** capsules, open the capsule over an empty glass or cup and swallow the pellets with half a glass of liquid, or mix the pellets in a slightly acidic fluid e.g. fruit juice, yoghurt or non carbonated water and take within 30 minutes. You can also suck the capsule until it opens (1-2 minutes) and swallow the pellets with liquid. **Do not crush or chew the capsules or the pellets. If the pellets in the capsules are chewed or crushed they will not work properly.**

When to take it

Take **OMEZOL RELIEF** at the same time each day in the morning.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter whether you take **OMEZOL RELIEF** with food or on an empty stomach.

How long to take it

Continue taking your medicine for as long as your doctor tells you. This medicine helps to treat your condition and where it does not cure it, it helps to control it. It is important to keep taking your medicine even if you feel well.

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 are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much OMEZOL RELIEF. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking OMEZOL RELIEF

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking OMEZOL RELIEF.

Tell all doctors, dentists and pharmacists who treat you that you are taking OMEZOL RELIEF.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if you become pregnant or intend to breastfeed while you are taking OMEZOL RELIEF.

OMEZOL RELIEF can be taken during pregnancy as studies have shown that there is no adverse effect on the pregnancy or the health of the unborn or newborn baby.

Although **OMEZOL RELIEF** appears in breast milk it is unlikely that there will be any effect on a nursing infant when taken at the recommended doses.

Things you must not do

Do not take OMEZOL RELIEF 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.

Things that may help your condition

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- **Alcohol** - your doctor may advise you to limit your alcohol intake.
- **Aspirin and many other medicines used to treat arthritis/period pain/headaches** - these medicines may irritate the stomach and may make your condition worse. Your doctor or pharmacist may suggest other medicines you can take.
- **Caffeine** - your doctor may advise you to limit the number of drinks which contain caffeine, such as coffee, tea, cocoa and cola drinks, because they contain ingredients that may irritate your stomach.
- **Eating habits** - eat smaller, more frequent meals. Eat slowly and chew your food carefully. Try not to rush at meal times.
- **Smoking** - your doctor may advise you to stop smoking or at least cut down.
- **Weight** - your doctor may suggest losing some weight to help your condition.

Side effects

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

OMEZOL RELIEF helps most people with stomach or duodenal ulcers, acid related dyspepsia, reflux disease or Zollinger-Ellison syndrome, but it may have unwanted side effects in a few people. 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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:

- diarrhoea, wind (flatulence) or constipation
- nausea and/or vomiting
- dry mouth
- blurred vision
- altered taste
- increased sweating
- headache and/or dizziness
- "pins and needles" (tingling or numbness of the hands and feet)
- changes in sleep patterns
- breast enlargement in men
- unusual hair thinning or loss.

The above list includes the more common side effects of **OMEZOL RELIEF**.

Tell your doctor as soon as possible if you notice any of the following:

- stomach pain or discomfort
- skin rash, itching
- muscle pain or weakness, joint pain
- changes in mood
- hallucinations or confusion
- bleeding or bruising more easily than normal, nose bleeds
- yellowing of the skin and eyes and dark coloured urine.
- frequent infections such as fever, severe chills, sore throat or mouth ulcers.

The above list includes less common side effects some of which may require medical attention. Serious side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if any of the following occurs:

- severe skin reaction which may include redness, blistering and peeling of the skin, accompanied by fever and chills, aching muscles
- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- impaired consciousness, memory loss, personality

change, tremors, seizures, stupor and coma.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you think you have any of these effects or notice anything else that is making you feel unwell.

Some people may get other side effects while taking **OMEZOL RELIEF**.

Other problems may arise from the condition being treated rather than the treatment.

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

- pain or indigestion occurs during treatment with **OMEZOL RELIEF**
- you begin to vomit blood or food
- you pass black (blood-stained) motions.

After taking OMEZOL RELIEF

Storage

Keep your **OMEZOL RELIEF** capsules in the bottle with the lid tightly closed until it is time to take them. If you take **OMEZOL RELIEF** out of the bottle they may not keep well.

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

Do not store **OMEZOL RELIEF** 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.

Do not use **OMEZOL RELIEF** after the expiry date printed on the label.

Keep your medicines where children cannot reach them. A locked cupboard at least one and a half meters above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking **OMEZOL RELIEF** or the capsules have passed their expiry date, ask your pharmacist what to do with any capsules you have left over.

Product description

What OMEZOL RELIEF looks like

10 mg: Hard gelatin capsule with an opaque light pink cap and opaque white body containing white to off white pellets. The capsule is printed with 'MYLAN' over 'OM 10'.

20 mg: Hard gelatin capsule with an opaque dark pink cap and opaque white body containing white to off white pellets. The capsule is printed with 'MYLAN' over 'OM 20'.

40 mg: Hard gelatin capsule with an opaque dark pink cap and body containing white to off-white pellets. The capsule is printed with 'MYLAN' over 'OM 40'.

Ingredients

Each **OMEZOL RELIEF** capsule contains omeprazole 10, 20 or 40 mg as the active ingredient plus:

- Gelatin
- Sodium lauryl sulfate
- Hypromellose
- Methacrylic acid – ethyl acrylate copolymer
- Purified talc
- Sodium hydroxide
- Polysorbate 80
- Macrogol
- Base pellets (made of sucrose, corn starch and water)
- Titanium dioxide (E171)
- TekPrint SW-9008 Black Ink.

Only present in the 10 mg capsule shells

- Red iron oxide (E172).

Only present in the 20 mg capsule shells

- Tartrazine (E102).

Only present in 20 mg and 40 mg capsule shells

- Brilliant Blue (E133)
- Allura Red (E129).

Only present in the 40 mg capsule shells

- Sunset Yellow (E110).

OMEZOL RELIEF is supplied as capsules of enteric-coated pellets in bottles of 90 capsules.

OMEZOL RELIEF does not contain lactose or gluten.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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8 February 2012
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