

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking MAXOR?

MAXOR contains the active ingredient omeprazole. MAXOR is used to treat and prevent gastro-oesophageal reflux disease (GORD) and reflux oesophagitis from returning. It is also used to treat peptic ulcers; peptic ulcers associated with helicobacter pylori infection; peptic ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs); and a rare condition called Zollinger-Ellison syndrome. For more information, see Section [1. Why am I taking MAXOR?](#) in the full CMI.

2. What should I know before I take MAXOR?

Do not take if you have ever had an allergic reaction to omeprazole or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take MAXOR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MAXOR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take MAXOR?

- Take one MAXOR capsule at the same time each day, unless your doctor has told you otherwise.
- Swallow the capsules whole with a glass of water. Do not crush or chew the capsules.

More instructions can be found in Section [4. How do I take MAXOR?](#) in the full CMI.

5. What should I know while taking MAXOR?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking MAXOR.

	<ul style="list-style-type: none"> • Tell your doctor if you become pregnant while you are taking MAXOR. • Tell your doctor if your symptoms return.
Things you should not do	<ul style="list-style-type: none"> • Do not take MAXOR to treat any other complaints unless your doctor tells you to. • Do not stop taking your medicine or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how MAXOR affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • Keep it in a cool, dry place where the temperature stays below 25°C. • Keep your MAXOR in the blister pack until it is time to take them.

For more information, see Section [5. What should I know while taking MAXOR?](#) in the full CMI.

6. Are there any side effects?

Mild side effects: constipation, nausea or vomiting, diarrhoea, wind, stomach pain, headache, dizziness, skin rash, itchy skin, dry or sore mouth.

Serious side effects (Call your doctor straight away, or go straight to the Emergency Department): swelling of the face, lips, mouth, tongue or throat, shortness of breath or difficulty in breathing, skin reaction (which may include rash, itching, redness, blistering or peeling of the skin) especially in sun-exposed areas with joint pain, ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals, blood in the urine, swelling of hands, feet or ankles, yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

MAXOR®

Active ingredient(s): omeprazole

Consumer Medicine Information (CMI)

This leaflet provides important information about using MAXOR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MAXOR.**

Where to find information in this leaflet:

- [1. Why am I taking MAXOR?](#)
- [2. What should I know before I take MAXOR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take MAXOR?](#)
- [5. What should I know while taking MAXOR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking MAXOR?

MAXOR contains the active ingredient omeprazole. MAXOR belongs to a group of medicines called proton pump inhibitors. It works by reducing 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.

Gastro-oesophageal reflux disease (GORD)

MAXOR is used to treat and prevent gastro-oesophageal reflux disease (GORD) from returning.

This can be caused by "washing back" (reflux) of food and acid from the stomach into the oesophagus (food pipe).

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

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

Peptic Ulcers

MAXOR is used to treat peptic ulcers.

Depending on the position of the peptic 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.

Ulcers can be caused in part by too much acid being made in the stomach.

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

Peptic Ulcers Associated with *Helicobacter pylori* Infection

MAXOR is used to treat peptic ulcers associated with *helicobacter pylori* infection.

Most people who have a peptic ulcer also have a bacterium called *Helicobacter pylori* in their stomach. MAXOR can be taken with antibiotics to treat this

infection. The antibiotics are used to kill the bacteria while MAXOR allows the ulcers to heal.

You may need further treatment with antibiotics.

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

MAXOR is used to treat 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.

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

Zollinger-Ellison Syndrome

MAXOR is used to treat a rare condition called Zollinger-Ellison syndrome.

In this condition, the stomach produces very large amounts of acid, much more than in ulcers and reflux disease.

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

MAXOR is not recommended for use in children, as there is no experience with MAXOR capsules in children.

There is no evidence that MAXOR is addictive.

2. What should I know before I take MAXOR?

Warnings

Do not use MAXOR if:

- you are allergic to omeprazole, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any medicines containing a proton-pump inhibitor.
- Always check the ingredients to make sure you can use this medicine.

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

- you are also taking cilostazol. Please check with your doctor or pharmacist if you are taking cilostazol. The medicine will be affected by MAXOR.

Do not take this medicine after the 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 start taking this medicine, talk to your doctor.

Check with your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives.
- any problems with your liver
- been diagnosed with osteoporosis
- have any other medical conditions
- take any medicines for any other condition
- if you have ever had a skin reaction after treatment with a medicine similar to MAXOR that reduces stomach acid.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Serious skin reactions including erythema multiforme (EM), Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with omeprazole treatment. Stop using MAXOR and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

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

Do not take MAXOR if you are taking the following medicine:

- cilostazol - a medicine used to treat intermittent claudication

Some medicines may interfere with MAXOR and affect how it works.

- phenytoin - a medicine used to treat epilepsy or fits
- warfarin and 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 or voriconazole - medicines used to treat certain fungal infections
- clarithromycin or rifampicin - medicines used to treat bacterial infections
- atazanavir or nelfinavir - medicines used to treat viral infections such as HIV
- tacrolimus and mycophenolate mofetil - medicines used to reduce the risk of rejection of a transplanted organ
- 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 MAXOR 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 can tell you what to do if you are taking any other medicines.

If you have not told your doctor about any of the above, tell them before you start taking MAXOR.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MAXOR.

4. How do I take MAXOR?

How much to take

- The usual dose is 20 mg a day. Your doctor may vary this dose depending on your condition. The dose varies from patient to patient. Your doctor will decide the right dose for you.
- 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 carton, ask your doctor or pharmacist for help.
- Follow the instructions provided and take MAXOR until your doctor tells you to stop.

When to take MAXOR

- MAXOR should be taken at the same time each day.
- Keeping a regular time for taking MAXOR will help to remind you to take it.
- MAXOR can be taken with or without food.

How to take it

- Swallow the capsules whole with a glass of water.
- Do not crush or chew the capsules.
- If the granules in the capsules are crushed or chewed they will not work properly.

How long to take it for

- Continue taking your medicine for as long as your doctor tell you to.
- To properly heal an ulcer or to treat reflux disease, you will need to take MAXOR for 4 to 8 weeks.
- If you are taking MAXOR to stop an ulcer from coming back or to treat other conditions, your doctor will tell you for how long you need to take the tablets.
- Tell your doctor if your symptoms return. You may need further treatment with omeprazole.
- If your condition is associated with Helicobacter pylori, you may need a repeat course of antibiotics plus omeprazole.

If you forget to take MAXOR

MAXOR should be used regularly at the same time each day. If you miss your dose at the usual time, take the missed dose as soon as you remember, and then go back to taking your capsules 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 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 MAXOR

If you think that you or anyone else may have taken too much MAXOR, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include nausea, vomiting, dizziness, stomach pain, diarrhoea, headache and confusion.

5. What should I know while taking MAXOR?

Things you should do

- Take MAXOR exactly as your doctor has prescribed
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MAXOR.

- Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.
- If you become pregnant while taking MAXOR, tell your doctor immediately.
- Tell your doctor if your symptoms return. Although MAXOR can heal ulcers successfully, it may not prevent them recurring at a later date.
- Tell your doctor if you need to have any medical tests while you are taking MAXOR. It may affect the results of some tests.

Remind any doctor, dentist or pharmacist you visit that you are taking MAXOR.

Things you should not do

- Do not stop taking this 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.
- Do not take MAXOR 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.

Things that may help your condition

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

- Alcohol - your doctor may advise you to limit your alcohol intake

- Aspirin and similar medicines used to treat, for example, arthritis, period pain or headache - these medicines may irritate the stomach and may make your condition worse. Your doctor or pharmacist can suggest other medicines you may take
- Caffeine - your doctor may advise you to limit the number of drinks you take which contain caffeine, such as coffee, tea, cocoa and cola drinks because they contain ingredients that may irritate the stomach
- Eating habits - consider eating smaller quantities at regular meal times. Do not skip meals. Eat slowly and chew your food carefully. Try not to rush at meal times
- Smoking - your doctor is likely to advise you to stop smoking or at least cut down the number of cigarettes you smoke. Ask for advice on how they can help you do this
- Weight - if you are overweight, your doctor may suggest that you lose some weight to help your condition.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MAXOR affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your capsules in the blister pack, until it is time to take them. If you take the capsules out of the blister, they may not keep well.
- Keep your capsules in a cool, dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

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.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or if you no longer need it or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Less serious side effects

Less serious side effects	What to do
<p>These side effects are usually mild.</p> <ul style="list-style-type: none">● constipation● diarrhoea● nausea or vomiting● wind● stomach pain● headache● dizziness	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● skin rash, itchy skin ● dry or sore mouth 	

Serious side effects

Serious side effects	What to do
<p>These are serious side effects which may require medical attention. Serious side effects are rare.</p> <ul style="list-style-type: none"> ● 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 or bleeding ● increased sweating ● hair loss ● tremor 	<p>Tell your doctor immediately if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● pain or indigestion which occurs during treatment with MAXOR ● vomiting blood or food ● passing black or blood-stained motions. <p>treatment > 3 month possibly decrease magnesium blood levels resulting in fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate</p> <ul style="list-style-type: none"> ● low magnesium blood levels may cause decrease of potassium or calcium levels in blood 	
<p>These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.</p> <ul style="list-style-type: none"> ● swelling of the face, lips, mouth, tongue or throat which may cause 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>difficulty in swallowing or breathing</p> <ul style="list-style-type: none"> • shortness of breath or difficulty in breathing • severe skin reaction which may include rash, itching, redness, blistering and peeling of the skin • ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals • widespread rash, high body temperature and enlarged lymph nodes • blood in the urine • swelling of hands, feet or ankles • signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite. • skin reaction, especially in sun-exposed areas, with joint pain 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

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

When taking MAXOR, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

Some health problems may arise from the condition being treated itself, rather than the treatment. For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion which occurs during treatment with MAXOR
- vomiting blood or food
- passing black or blood-stained motions.

Tell your doctor if your reflux symptoms return after you stop taking MAXOR.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What MAXOR contains

Active ingredient (main ingredient)	Omeprazole
Other ingredients (inactive ingredients)	Sucrose Maize starch Hypromellose Purified talc Methacrylic acid copolymer Triethyl citrate Dibasic disodium Phosphate dihydrate Gelatin Purified water

	Iron oxide black Iron oxide red Erythrosine Titanium dioxide TekPrint SW-9008 Black Ink (ARTG PI No: 2328)
Potential allergens	Sugars and trace quantities of sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What MAXOR looks like

MAXOR 20 mg enteric capsules are size 2 hard gelatin capsule with pale pink cap and white body, containing white to pink/beige spherical pellets, and printed 'G' and 'OE20' in black ink (AUST R 173994).

MAXOR 20 mg is available in packs of 30 capsules.

Who distributes MAXOR

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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