

MAXOR® HEARTBURN RELIEF

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 HEARTBURN RELIEF?

MAXOR HEARTBURN RELIEF contains the active ingredient omeprazole. MAXOR HEARTBURN RELIEF is used for the relief of heartburn and stomach acid complaints due to gastro-oesophageal reflux disease (GORD).

For more information, see Section [1. Why am I taking MAXOR HEARTBURN RELIEF?](#) in the full CMI.

2. What should I know before I take MAXOR HEARTBURN RELIEF?

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 or pharmacist 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 HEARTBURN RELIEF?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MAXOR HEARTBURN RELIEF 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 HEARTBURN RELIEF?

- Take one MAXOR HEARTBURN RELIEF 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 HEARTBURN RELIEF?](#) in the full CMI.

5. What should I know while taking MAXOR HEARTBURN RELIEF?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking MAXOR HEARTBURN RELIEF.• Tell your doctor or pharmacist if you become pregnant while you are taking MAXOR HEARTBURN RELIEF.• MAXOR HEARTBURN RELIEF should be taken for at least 7 days, and up to 14 days.• Tell your doctor or pharmacist if your symptoms return.
Things you should not do	<ul style="list-style-type: none">• Do not take MAXOR HEARTBURN RELIEF to treat any other complaints unless your doctor tells you to.• You should not take it for more than 14 days unless directed by a 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 HEARTBURN RELIEF affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor or pharmacist 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 HEARTBURN RELIEF in the blister pack until it is time to take them.

For more information, see Section [5. What should I know while taking MAXOR HEARTBURN RELIEF?](#) 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® HEARTBURN RELIEF

Active ingredient(s): *omeprazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MAXOR HEARTBURN RELIEF. **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 HEARTBURN RELIEF.**

Where to find information in this leaflet:

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

1. Why am I taking MAXOR HEARTBURN RELIEF?

MAXOR HEARTBURN RELIEF contains the active ingredient omeprazole. MAXOR HEARTBURN RELIEF 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.

MAXOR HEARTBURN RELIEF is used for the relief of heartburn and stomach acid complaints due to gastro-oesophageal reflux disease (GORD).

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.

Who should use MAXOR HEARTBURN RELIEF

MAXOR HEARTBURN RELIEF is recommended for:

- adults 18 years of age and over who suffer from heartburn at least 2 times a week.

MAXOR HEARTBURN RELIEF is not the right medicine for you if you suffer heartburn only occasionally (one episode of heartburn a week or less), or if you want immediate relief of heartburn.

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

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

MAXOR HEARTBURN RELIEF is available only from your pharmacist or doctor. It can be purchased directly from your local pharmacy without a doctor's prescription.

There is no evidence that MAXOR HEARTBURN RELIEF is addictive.

2. What should I know before I take MAXOR HEARTBURN RELIEF?

Warnings

Do not use MAXOR HEARTBURN RELIEF 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, a medicine used to treat cramping pain and weakness in legs. Please check with your doctor or pharmacist if you are taking cilostazol. The medicine will be affected by MAXOR HEARTBURN RELIEF
- Do not give MAXOR HEARTBURN RELIEF to children and adolescents under 18 years of age.

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 or pharmacist if you have:

- allergies to any other medicines, foods, dyes or preservatives
- had to take other medication for indigestion or heartburn continuously for four or more weeks in order to control your symptoms
- recently (within the last two weeks) finished a course of MAXOR HEARTBURN RELIEF or a similar medicine
- any problems with your liver
- been diagnosed with osteoporosis
- any other medical conditions
- take any medicines for any other condition
- ever had a skin reaction after treatment with a medicine similar to MAXOR HEARTBURN RELIEF 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?](#)

Pregnancy and breastfeeding

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

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

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

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

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

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

If you have suffered from frequent heartburn/indigestion symptoms for some time you should see your doctor.

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 HEARTBURN RELIEF if you are taking the following medicine:

- cilostazol - a medicine used to treat intermittent claudication such as cramping pain and weakness in legs.

Some medicines may interfere with MAXOR HEARTBURN RELIEF 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 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 MAXOR HEARTBURN 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 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 HEARTBURN RELIEF.

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 HEARTBURN RELIEF.

4. How do I take MAXOR HEARTBURN RELIEF?

How much to take

- The required dose is one MAXOR HEARTBURN RELIEF capsule a day (every 24 hours)
- Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet or the instructions on the carton
- If you do not understand the instructions on the carton, ask your doctor or pharmacist for help
- Do not exceed the recommended dosage.

When to take MAXOR HEARTBURN RELIEF

- MAXOR HEARTBURN RELIEF should be taken at the same time each day.
- Keeping a regular time for taking MAXOR HEARTBURN RELIEF will help to remind you to take it.

How to take it

- Swallow the capsules whole with a glass of water with or without food
- 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

- MAXOR HEARTBURN RELIEF should be taken for at least 7 days, and up to 14 days.
- You should not take it for more than 14 days unless directed by a doctor.
- Tell your doctor if your symptoms return. You may need further treatment with omeprazole.

If you forget to take MAXOR HEARTBURN RELIEF

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

Otherwise, take the missed dose as soon as you remember, and then go back to taking your capsules as you would normally.

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 HEARTBURN RELIEF

If you think that you or anyone else may have taken too much MAXOR HEARTBURN RELIEF, 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 HEARTBURN RELIEF?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MAXOR HEARTBURN RELIEF
- Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine
- If you become pregnant while taking MAXOR HEARTBURN RELIEF, tell your doctor or pharmacist immediately
- If you need to have any medical tests while you are taking MAXOR HEARTBURN RELIEF, tell your doctor. It may affect the results of some tests.

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

Things you should not do

- Do not take MAXOR HEARTBURN RELIEF to treat any other complaints unless your doctor or pharmacist 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 or pharmacist 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 or pharmacist 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 or pharmacist 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 or pharmacist 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 HEARTBURN RELIEF affects you.

Drinking alcohol

Tell your doctor or pharmacist 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 or pharmacist 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 HEARTBURN RELIEF.

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 and short-lived.</p> <ul style="list-style-type: none"> • constipation • diarrhoea • nausea (feeling sick) or vomiting • headache • skin rash, itchy skin • wind • stomach pain • dizziness • dry or sore mouth 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

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 • tingling or numbness of the hands or feet, pins and needles • changes in sleep patterns 	<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"> ● mood changes, confusion or depression ● blurred vision ● increase in breast size (males) ● fever ● increased bruising or bleeding ● increased sweating ● hair loss ● tremor ● signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers ● worsening of acid related symptoms as a result of stopping your heartburn medicine ● pain or indigestion which occurs during treatment with MAXOR HEARTBURN RELIEF ● vomiting blood or food ● passing black or blood-stained motions ● treatment > 3 month possibly decrease magnesium blood levels resulting in fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate ● 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 difficulty in swallowing or breathing ● 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 ● 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 	<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>

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

When taking MAXOR HEARTBURN RELIEF, 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 HEARTBURN RELIEF
- vomiting blood or food
- passing black or blood-stained motions.

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

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.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What MAXOR HEARTBURN RELIEF contains

Active ingredient (main ingredient)	Omeprazole
Other ingredients (inactive ingredients)	sucrose maize starch hypromellose purified talc dibasic sodium phosphate dihydrate methacrylic acid copolymer triethyl citrate 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 HEARTBURN RELIEF looks like

MAXOR HEARTBURN RELIEF omeprazole 20 mg enteric capsule: Opaque pink cap and opaque white body capsule #2, printed G/OE20 containing white to slightly beige spherical pellets (AUST R 180913).

MAXOR HEARTBURN RELIEF is available in packs of 14 enteric capsules.

Who distributes MAXOR HEARTBURN RELIEF

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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