

Omeprazole-WGR

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 using OMEPRAZOLE-WGR?

OMEPRAZOLE-WGR contains the active ingredient omeprazole. OMEPRAZOLE-WGR 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 using Omeprazole-WGR?](#) in the full CMI.

2. What should I know before I use OMEPRAZOLE-WGR?

Do not use if you have ever had an allergic reaction to OMEPRAZOLE-WGR 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 use OMEPRAZOLE-WGR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OMEPRAZOLE-WGR 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 use OMEPRAZOLE-WGR?

- Follow all directions given to you by your doctor or pharmacist
- Take one OMEPRAZOLE-WGR tablet at the same time each day
- Swallow the tablet whole with a glass of water. Do not crush or chew the tablet

More instructions can be found in Section [4. How do I use OMEPRAZOLE-WGR?](#) in the full CMI.

5. What should I know while using OMEPRAZOLE-WGR?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using OMEPRAZOLE-WGR • Tell your doctor if you become pregnant whilst taking OMEPRAZOLE-WGR • Tell your doctor if your symptoms return
Things you should not do	• Do not take OMEPRAZOLE-WGR to treat any other complaints unless your doctor tells you to • Do not stop taking OMEPRAZOLE-WGR or change the dosage without checking with your doctor
Driving or using machines	• Be careful before you drive or operate machinery until you know how OMEPRAZOLE-WGR affects you
Drinking alcohol	• Tell your doctor if you drink alcohol
Looking after your medicine	• Keep OMEPRAZOLE-WGR in a cool, dry place where the temperature stays below 25°C • Keep OMEPRAZOLE-WGR tablets in the blister pack until it is time to take them

For more information, see Section [5. What should I know while using OMEPRAZOLE-WGR?](#) in the full CMI.

6. Are there any side effects?

Common side effects include diarrhoea, constipation, abdominal pain, nausea/vomiting, flatulence and headache. Call your doctor straight away, or go straight to the Emergency Department if you have swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing; skin reaction including rash, redness, blistering or peeling of the skin; ulcers, blisters or bleeding of the lips, eyes, mouth, nose or genitals; swelling of hands, feet or ankles; blood in the urine; 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.

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.

Omeprazole-WGR

Active ingredient: *omeprazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using OMEPRAZOLE-WGR. **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 OMEPRAZOLE-WGR.**

Where to find information in this leaflet:

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

1. Why am I using OMEPRAZOLE-WGR?

OMEPRAZOLE-WGR contains the active ingredient **omeprazole**. OMEPRAZOLE-WGR 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.

OMEPRAZOLE-WGR is used to treat the following:

Peptic Ulcers

OMEPRAZOLE-WGR tablets are used to treat peptic ulcers and also to help prevent them from coming back.

These ulcers can be caused by the stomach producing too much acid. Depending on the location of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach and a duodenal ulcer occurs in the tube leading out of the stomach, also known as the duodenum.

Peptic Ulcers associated with *Helicobacter pylori* infection

Most people with a peptic ulcer have been found to have the bacteria *Helicobacter pylori* in their stomach. OMEPRAZOLE-WGR taken together with two antibiotics will kill the bacteria and let your ulcer heal. It is possible that the antibiotics may not always kill *Helicobacter pylori*.

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

Some peptic ulcers are caused by taking medicines known as non-steroidal anti-inflammatory drugs. These medicines are commonly taken to treat arthritis and other inflammatory conditions.

OMEPRAZOLE-WGR can be used to heal and prevent ulcers associated with NSAIDs.

Reflux Oesophagitis

OMEPRAZOLE-WGR is used to treat and prevent the symptoms of reflux oesophagitis.

This condition is caused by the washing back, or reflux, of food and acid from the stomach into the oesophagus. Symptoms include a burning sensation in the chest rising up to the throat, also known as heartburn.

Zollinger-Ellison Syndrome

OMEPRAZOLE-WGR is used to treat this rare condition where the stomach produces excessive amounts of acid.

Your doctor may have prescribed OMEPRAZOLE-WGR for another reason.

OMEPRAZOLE-WGR is available only with a doctor's prescription.

There is no evidence that OMEPRAZOLE-WGR is addictive.

2. What should I know before I use OMEPRAZOLE-WGR?

Warnings

Do not use OMEPRAZOLE-WGR if:

- You are allergic to omeprazole, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.
- Always check the ingredients to make sure you can use this medicine.
- You are allergic to medicines containing a proton pump inhibitor
- You are taking cilostazol (a medicine used to treat intermittent claudication) as it will be affected by OZEMP

Do not take OMEPRAZOLE-WGR if the expiry date printed on the pack has passed.

Do not take OMEPRAZOLE-WGR if the packaging shows signs of tampering or the tablets do not look quite right.

Check with your doctor if you:

- take any medicines for any other condition
- are allergic to any other medicines, foods, dyes or preservatives
- any problems with your liver
- been diagnosed with osteoporosis
- have any other medical conditions

- if you have ever had a skin reaction after treatment with a medicine similar to OMEPRAZOLE-WGR 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 OMEPRAZOLE-WGR 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 OMEPRAZOLE-WGR 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 OMEPRAZOLE-WGR 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 OMEPRAZOLE-WGR if you are taking the following medicine:

- Cilostazol (medicine used to treat intermittent claudication)

Some medicines may interfere with OMEPRAZOLE-WGR and affect how it works.

- phenytoin (a medicine used to treat epilepsy or fits)
- methotrexate (a medicine used to treat arthritis and some types of cancer)
- warfarin and clopidogrel (a medicine 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)
- medicines to treat infections such as clarithromycin or rifampicin
- anti-viral medicines such as atazanavir and nelfinavir, used to treat infections such as HIV
- tacrolimus and mycophenolate, immunosuppressants, medicines used to assist in organ transplants
- erlotinib or related medicines used to treat cancer

These medicines may be affected by OMEPRAZOLE-WGR 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 OMEPRAZOLE-WGR.

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

4. How do I use OMEPRAZOLE-WGR?

How much to take / use

- 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.
- Follow the instructions provided and take OMEPRAZOLE-WGR until your doctor tells you to stop.
- Swallow the tablets whole with a glass of water. Do not crush or chew the tablets.

When to take / use OMEPRAZOLE-WGR

- OMEPRAZOLE-WGR should be taken at the same time each day.
- Keeping a regular time for tablets will help to remind you to take them
- OMEPRAZOLE-WGR can be taken with or without food

Keep taking OMEPRAZOLE-WGR for as long as your doctor recommends. In most patients, OMEPRAZOLE-WGR relieves symptoms rapidly and healing is usually complete within 4 weeks.

If you forget to use OMEPRAZOLE-WGR

OMEPRAZOLE-WGR 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 tablets 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 use too much OMEPRAZOLE-WGR

If you think that you have used too much OMEPRAZOLE-WGR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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.

If you take too much OMEPRAZOLE-WGR you may experience nausea, vomiting, dizziness, abdominal pain, diarrhoea and/or headache.

5. What should I know while using OMEPRAZOLE-WGR?

Things you should do

- Take OMEPRAZOLE-WGR 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 OMEPRAZOLE-WGR.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.
- If you become pregnant while taking OMEPRAZOLE-WGR, tell your doctor immediately.
- Tell your doctor if your symptoms return. Although OMEPRAZOLE-WGR 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 OMEPRAZOLE-WGR. It may affect the results of some tests.

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 OMEPRAZOLE-WGR 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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how OMEPRAZOLE-WGR affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

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.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine 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?

All medicines can have side effects. 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.

Less serious side effects

Less serious side effects	What to do
These side effects are usually mild: • constipation • diarrhoea • nausea or vomiting • wind • stomach pain • headache • dizziness • skin rash, itchy skin • dry or sore mouth • flatulence	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
These are serious side effects which may require medical attention. Serious side effects are rare. • muscle pain or weakness, joint pain • tingling or numbness of the hands or feet • changes in sleep patterns • mood changes, confusion or depression • blurred vision • increase in breast size (males) • fever • increased bruising • increased sweating • hair loss • tremor • pain or indigestion that occurs during treatment with OMEPRAZOLE-WGR. • vomiting blood or food • blood in your stool (a dark black stool can be an indicator of this) • low magnesium blood levels may cause decrease of	Tell your doctor immediately if you notice any of these serious side effects

potassium or calcium levels in blood • involuntary muscle contraction, disorientation, convulsions, dizziness or increased heart rate caused by decrease in magnesium which may occur if you have been taking OMEPRAZOLE-WGR for a period of 3 or more months. • needing to urinate more frequently, lower back pain, fatigue can be signs of inflammation in your kidney.	
These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare: • skin reaction which may include rash, redness, blistering or peeling of the skin • 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 • swelling of hands, feet or ankles • shortness of breath or difficulty in breathing • blood in the urine • 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	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.

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

When taking OMEPRAZOLE-WGR, 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 OMEPRAZOLE-WGR
- vomiting blood or food
- passing black or blood-stained motions. Tell your doctor if your reflux symptoms return after you stop taking OMEPRAZOLE-WGR.

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 OMEPRAZOLE-WGR contains

Active ingredient (main ingredient)	omeprazole
Other ingredients (inactive ingredients)	• lactose monohydrate • sodium starch glycollate • sodium stearate • sodium stearyl fumarate • hypromellose acetate succinate • triethyl citrate • sodium lauryl sulfate • carnauba wax • purified talc • monoethanolamine • propylene glycol • hypromellose • titanium dioxide • iron oxide yellow • iron oxide red
Potential allergens	sugars (as lactose)

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

What OMEPRAZOLE-WGR looks like

OMEPRAZOLE-WGR tablets are brown capsule-shaped tablets debossed with '20' on one side.

Each bottle or blister contains 30 tablets.

AUST R 444390 (blisters); AUST R 444410 (bottles)

Who distributes OMEPRAZOLE-WGR

Sponsor

Medis Pharma Pty Ltd
Level 1, 37 Epping Road
Macquarie Park, NSW 2113
Australia

Distributor

Arrotex Pharmaceuticals
15-17 Chapel Street
Cremorne, VIC 3121
Australia

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