

Maxor Heartburn Relief

omeprazole enteric capsules

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Maxor Heartburn Relief.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor or pharmacist has weighed the risks of you taking Maxor Heartburn Relief against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Maxor Heartburn Relief is used for

Gastro-oesophageal reflux disease (GORD)

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, 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.

How Maxor Heartburn Relief works

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. This helps reduce pain and also allows any damage to heal. 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.

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.

Before you take Maxor Heartburn Relief

When you must not take it

Do not take Maxor Heartburn Relief if you have an allergy to:

- medicines containing omeprazole or any of the ingredients listed at the end of this leaflet
- any medicine containing a proton-pump inhibitor.

Some of the symptoms of an allergic reaction may include skin rash, fever, wheezing, swelling of the face, lips, mouth,

tongue or throat which may cause difficulty in swallowing or breathing.

Do not take Maxor Heartburn Relief if you are currently taking cilostazol (Pletal), a medicine used to treat cramping pain and weakness in legs.

Please check with your doctor or pharmacist if you are taking cilostazol. This 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 or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if:

- you have allergies to any other medicines, foods, dyes or preservatives

- you have had to take other medication for indigestion or heartburn continuously for four or more weeks in order to control your symptoms
- you have recently (within the last two weeks) finished a course of Maxor Heartburn Relief or a similar medicine
- you have any problems with your liver
- you have any other medical conditions
- you have been diagnosed with osteoporosis
- if you have ever had a skin reaction after treatment with a medicine similar to Maxor that reduces stomach acid.

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.

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

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.

Taking other medicines

Do not take Maxor Heartburn Relief if you are taking the following medicine:

- cilostazol (Pletal), a medicine used to treat cramping pain and weakness in legs.

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

Some medicines and Maxor Heartburn Relief may interfere with each other. These include:

- 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 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 the above, tell them before you start taking Maxor.

How to take Maxor Heartburn Relief

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 box.

If you do not understand the instruction on the box, ask your doctor or pharmacist for help.

How much to take

The required dose is one Maxor Heartburn Relief capsule a day (every 24 hours).

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.

When to take it

Take Maxor Heartburn Relief at the same time each day.

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 or pharmacist if your symptoms return.

You may need further treatment with omeprazole.

If you forget to take it

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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Maxor Heartburn Relief. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking Maxor Heartburn 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 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.

Things you must 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.

Side effects

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

Like all other medicines, Maxor Heartburn Relief may have unwanted side effects in some people. Sometimes they are

serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

These side effects are usually mild and short-lived.

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

- muscle pain or weakness, joint pain
- tingling or numbness of the hands or feet, 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
- 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

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

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

- 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

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

Occasionally Maxor Heartburn Relief 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 also occur in some people.

Some health problems may arise from the condition being treated itself, rather than the treatment. For this reason, contact your doctor or pharmacist 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.

After taking Maxor Heartburn Relief

Storage

Keep your capsules in their original pack, until it is time to take them.

If you take the capsules out of the pack, they may not keep well.

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

Do not store Maxor Heartburn Relief or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where 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 or pharmacist tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Maxor Heartburn Relief is a pale white and pale pink enteric capsule marked G/OE 20.

Each blister pack contains 14 enteric capsules.

Ingredients

The active ingredient in Maxor Heartburn Relief is omeprazole. Each Maxor Heartburn Relief enteric capsule contains 20 mg of omeprazole.

The enteric capsules also contain:

- sucrose
- maize starch
- hypromellose
- purified talc

- dibasic sodium phosphate dihydrate
- methacrylic acid copolymer
- triethyl citrate
- gelatin
- iron oxide black CI77499
- iron oxide red CI77491
- erythrosine CI45430
- titanium dioxide
- TekPrint SW-9008 black ink.

Maxor Heartburn Relief enteric capsules are gluten free.

Supplier

Maxor Heartburn Relief is supplied in Australia by:

Alphapharm Pty Ltd

Level 1 - 30 The Bond

30 - 34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration number:

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