

Maxor

contains the active ingredient omeprazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Maxor.

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 has weighed the risks of you taking Maxor 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 is used for

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 of 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

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)

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.

How Maxor works

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.

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

Maxor is available only with a doctor's prescription.

There is no evidence that Maxor is addictive.

Before you take Maxor

When you must not take it

Do not take Maxor 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 if 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.

Before you start to take it

Tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives.
- any problems with your liver
- any other medical conditions

Do not take Maxor 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 while you are pregnant. It may affect your baby.

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

Taking other medicines

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

- cilostazol, a medicine used to treat intermittent claudication

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 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, a medicine 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 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

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.

How much to take

The dose varies from patient to patient. Your doctor will decide the right dose for you.

The usual dose is 20 mg a day. Your doctor may vary this dose depending on your condition.

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.

When to take it

Take Maxor 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 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 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 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. 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

Things you must 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.

Things you must not do

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.

Do not stop taking our 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.

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.

Side effects

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

Like all other medicines, Maxor 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 or vomiting
- headache
- skin rash, itchy skin
- wind
- stomach pain
- dizziness
- dry or sore mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- 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

The above list includes serious side effects 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 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.

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

Occasionally, Maxor 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 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.

After taking Maxor

Storage

Keep your capsules in the original container, 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.

Do not store Maxor or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a windowsill.

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 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 is a pale white and pale pink capsule marked G/OE 20.

Each blister pack contains 30 capsules.

Ingredients

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

The capsules also contain:

- sucrose
- maize-starch
- hypromellose
- purified talc
- methacrylic acid copolymer
- triethyl citrate
- dibasic dihydrate disodium phosphate
- gelatin
- iron oxide black
- iron oxide red
- erythrosine
- titanium dioxide
- TekPrint SW-9008 black ink.

Maxor capsules are gluten free.

Supplier

Maxor is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian Registration Number:

Blister Pack: Aust R 173994

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