

Maxor EC Tabs

omeprazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Maxor EC Tabs. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Maxor EC Tabs against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Maxor EC Tabs is used for

Peptic Ulcers

Maxor EC Tabs is 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. Maxor EC Tabs 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 nonsteroidal anti-inflammatory drugs. These medicines are commonly taken to treat arthritis and other inflammatory conditions.

Maxor EC Tabs can be used to heal and prevent ulcers associated with NSAIDs.

Reflux Oesophagitis

Maxor EC Tabs 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. Maxor EC Tabs is also taken to help stop reflux oesophagitis coming back or relapsing.

Zollinger-Ellison Syndrome

Maxor EC Tabs is used to treat this rare condition where the stomach produces excessive amounts of acid.

How Maxor EC Tabs works

Maxor EC Tabs belongs to a group of medicines called proton pump inhibitors. These medicines work by decreasing the amount of acid made by the stomach, to give relief from the symptoms and allow healing to take place. This does not stop food from being digested in the normal way.

Ask your doctor if you have any questions about why this

medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that Maxor EC Tabs is addictive.

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

Before you take Maxor EC Tabs

When you must not take it

Do not take Maxor EC Tabs if you have an allergy to:

- any medicine containing omeprazole
- 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:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take Maxor EC Tabs if you are also taking a medicine containing cilostazol.

Please check with your doctor or pharmacist if you are taking cilostazol. This medicine will be affected by Maxor EC Tabs.

Do not take this medicine after the expiry date printed on the pack/bottle 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, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- any problems with your liver
- any other medical conditions
- been diagnosed with osteoporosis
- if you have ever had a skin reaction after treatment with a medicine similar to Maxor EC Tabs that reduces stomach acid

Tell your doctor if you are pregnant or plan to become pregnant.

It is not known if it is safe to take Maxor EC Tabs during pregnancy. It may affect your baby. Your doctor will discuss the risks and benefits of taking Maxor EC Tabs during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

It is not known whether Maxor EC Tabs passes into breast milk. Your doctor will discuss the risks and benefits of taking Maxor EC Tabs when breastfeeding.

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

Taking other medicines

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

- cilostazol, a medicine used to treat intermittent claudication

It is not recommended that you take Maxor EC Tabs if you are taking atazanavir and nelfinavir, medicines (used to treat viral infections such as HIV).

Tell your doctor or pharmacist if you are taking any other

medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Maxor EC Tabs may interfere with each other. These include:

- phenytoin, a medicine used to treat epilepsy or fits
- 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
- clarithromycin or rifampicin, medicines used to treat infections
- atazanavir and nelfinavir, medicines used to treat viral infections such as HIV as their use is not recommended (see above).
- 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 EC Tabs 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 of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to

be careful with or avoid while taking this medicine.

How to take Maxor EC Tabs

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

Adults

The usual dose is 20 mg a day, but may vary from 10 mg to 40 mg a day depending on your condition and whether or not you are taking any other medicines. Your doctor will advise you how much to take.

Children 1 year or older

The usual dose for children 10 kg to 20 kg is 10 mg a day. This dose may be increased to 20 mg if required. For children more than 20 kg the dose is 20 mg a day which may be increased to 40 mg if required.

Ask your doctor or pharmacist if you are not sure how to take Maxor EC Tabs.

How to take it

Swallow the tablets whole with a glass of water. Do not crush or chew the tablets.

If the tablets are crushed or chewed they will not work properly.

When to take it

If the tablets are crushed or chewed they will not work properly.

Take your medicine at about the same time each day.

Keeping a regular time for taking tablets will help to remind you to take them.

The tablets can be taken with food or on an empty stomach.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

In most patients, Maxor EC Tabs relieves symptoms rapidly and healing is usually complete within 4 weeks.

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 tablets as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering 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 that you or anyone else may have taken too much Maxor EC Tabs. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Maxor EC Tabs you may experience nausea, vomiting, dizziness, abdominal pain, diarrhoea and headache.

While you are using Maxor EC Tabs

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 EC Tabs.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking Maxor EC Tabs, tell your doctor.

Tell your doctor if your symptoms return.

Although Maxor EC Tabs heals ulcers very successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking Maxor EC Tabs, tell your doctor.

Maxor EC Tabs may affect the results of some tests.

Things you must not do

Do not take Maxor EC Tabs 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 your medicine or change the dose 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.

Side effects

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

This medicine helps most people with peptic ulcers or reflux disease, and is usually well tolerated, but it may have unwanted side effects in a few people.

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- diarrhoea
- constipation
- stomach pain
- nausea or vomiting
- dry or sore mouth
- flatulence
- skin rash, itchy skin
- headache
- dizziness
- weight gain
- drowsiness
- insomnia
- changes in taste
- tiredness

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- muscle pain or weakness, joint pain
- tingling, 'pins and needles' or numbness of the hands or feet
- fever
- changes in sleep patterns
- mood changes, agitation, confusion, hallucinations or depression
- hallucinations
- blurred vision
- increase in breast size (males)
- increased bruising or bleeding
- increased sweating
- hair loss
- tremor
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- inability to get or maintain erection

- fractures, for example hip, wrist or spine

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

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- severe 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

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

Occasionally, Maxor EC Tabs 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.

Other problems are more likely to arise from the ulcer itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion occurring during treatment with Maxor EC Tabs
- vomiting of blood or food
- passing of black (bloodstained) motions

Tell your doctor if your reflux symptoms return after you stop taking Maxor EC Tabs.

After using Maxor EC Tabs

Storage

Keep your tablets in the pack/box until it is time to take them.

If you take the tablets out of the pack/box they may not keep well.

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

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

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 EC Tabs tablets are red brown, oblong, enteric coated tablets.

They are available in packs of 30 tablets in aluminium/aluminium blisters.

Ingredients

Maxor EC Tabs contains 20 mg of omeprazole as the active ingredient.

The tablets also contain the following inactive ingredients:

- ascorbyl palmitate
- triacetin
- microcrystalline cellulose
- crospovidone
- magnesium stearate
- povidone
- lactose monohydrate
- hypromellose phthalate
- purified talc
- iron oxide red
- iron oxide black

Sponsor

Southern Cross Pharma Pty Ltd
Suite 5/118 Church Street
Hawthorn VIC 3122
Contact: info@southernxp.com

Distributor

Maxor EC Tabs is distributed in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au

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