

Acimax(R)

Multiple Unit Pellet System

contains the active ingredient omeprazole magnesium

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Acimax.

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 Acimax against the benefits expected 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 Acimax is used for

Peptic Ulcers

Acimax 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. Acimax 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.

Acimax can be used to heal and prevent ulcers associated with NSAIDs.

Reflux Oesophagitis

Acimax 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

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

How Acimax works

Acimax 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 Acimax has been prescribed for you.

Your doctor may have prescribed Acimax for another reason.

Acimax is available only with a doctor's prescription.

There is no evidence that Acimax is addictive.

Before you take Acimax

When you must not take it

Do not take Acimax if you are allergic to medicines containing omeprazole magnesium 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.

Do not take Acimax if the expiry date (Exp.) printed on the pack has passed.

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

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

Acimax may affect your unborn baby if taken during pregnancy. Your doctor will discuss the risks and benefits of taking Acimax during pregnancy.

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

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

Tell your doctor if you have, or have had, any medical conditions.

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

Taking other medicines

Tell your doctor 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 may be affected by Acimax, or may affect how well it works. These include:

- * Phenytoin (Dilantin), a medicine used to treat epilepsy or fits
- * Warfarin (Coumadin, Marevan), a medicine used to prevent blood clots
- * Diazepam (eg. Valium, Antenex), a medicine used to treat anxiety and some other conditions
- * Ketoconazole (Nizoral) and itraconazole (Sporanox), medicines used to treat certain fungal infections
- * Atazanavir, an antiviral agent used to treat infections
- * Tacrolimus, an immunosuppressant.

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 Acimax.

How to take Acimax

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

They may differ from the information in this leaflet.

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 Acimax.

How to take Acimax

Swallow the tablets whole with a glass of water.

Acimax tablets can be gently mixed or dispersed in non-carbonated water or fruit juices if care is taken not to crush the pellets. Drink the liquid immediately or within 30 minutes.

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

When to take Acimax

Acimax can be taken with or without food.

Take Acimax tablets at about the same time each day.

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

If you forget to take Acimax

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 you missed.

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

How long to take Acimax for

Keep taking Acimax for as long as your doctor recommends.

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

Although Acimax heals ulcers very successfully, it may not prevent them recurring at a later date. Acimax can be taken long term to prevent these relapses.

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 take too much Acimax (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) if you think you or anyone else may have taken too much Acimax. Do this

even if there are no signs of discomfort or poisoning.

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

While you are taking Acimax

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Acimax.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Acimax.

If you become pregnant while taking Acimax, tell your doctor.

Visit your doctor regularly so they can check on your progress.

Things you must not do

Do not use Acimax to treat any other conditions unless your doctor tells you to.

Do not give Acimax to anyone else, even if they have the same condition as you.

Side effects

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

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

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

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

You may not experience any of them.

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

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

- * diarrhoea, constipation
- * abdominal pain
- * nausea, vomiting
- * dry mouth
- * flatulence
- * skin rash, itching
- * headache, dizziness
- * breast enlargement in men.

These side effects are usually mild.

Tell your doctor 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
- * changes in sleep patterns
- * mood changes
- * hallucinations, confusion
- * bleeding or bruising more easily than normal
- * signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers.

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

- * severe skin reaction which may include redness, blistering and peeling of the skin, accompanied with fever and chills, aching muscles
- * 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.

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

These side effects are very rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

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 Acimax
- * vomiting of blood or food
- * passing of black (blood-stained) motions.

After taking Acimax

Storage

Keep Acimax 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.

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

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

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

Do not store Acimax or any other medicine in the bathroom or near a sink.

Do not leave Acimax in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Acimax, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Acimax tablets are pink, oblong shaped, marked 20 mg on one side and a logo on the other.

Each pack contains 30 tablets.

Ingredients

The active ingredient in Acimax is omeprazole magnesium. Each Acimax tablet contains 20 mg of omeprazole (as magnesium) in enteric-coated pellets.

The tablets also contain:

- * glyceryl monostearate (E 471)
- * hydroxypropyl cellulose
- * hypromellose
- * magnesium stearate (E 572)
- * methylacrylic acid copolymer
- * microcrystalline cellulose (E 460)

- * paraffin hard
- * macrogol 6000
- * polysorbate 80 (E 433)
- * crospovidone
- * sodium stearyl fumarate
- * purified talc (E 553(b))
- * titanium dioxide (E 171)
- * triethyl citrate
- * sodium hydroxide
- * sugar spheres
- * iron oxide red CI 77491 (E173).

The tablets are gluten and lactose free.

Sponsor

Acimax is supplied by:
Alphapharm Pty Limited
(ABN 93 002 359 739)
Chase Building 2
Wentworth Park Road
Glebe NSW 2037
Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information
Phone: 1800 028 365

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This leaflet was prepared on
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