

Rabeprazole Mylan

rabeprazole sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about RABEPRAZOLE MYLAN. 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 RABEPRAZOLE MYLAN 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 RABEPRAZOLE MYLAN is used for

RABEPRAZOLE MYLAN contains the active ingredient rabeprazole sodium.

RABEPRAZOLE MYLAN belongs to a group of medicines called proton pump inhibitors (PPIs).

RABEPRAZOLE MYLAN works by decreasing the amount of acid the stomach makes, to give relief from the symptoms and allow healing to take place. Your food will still be digested in the same way.

Gastro-oesophageal reflux disease

RABEPRAZOLE MYLAN is used to treat gastro-oesophageal reflux disease (GORD), commonly known as 'reflux'. This can be caused by food and acid from the stomach flowing the wrong way (reflux) back up the food pipe, also known as the oesophagus.

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

RABEPRAZOLE MYLAN is also used to help stop gastro-oesophageal reflux disease from coming back or relapsing.

Peptic Ulcers

RABEPRAZOLE MYLAN is used to treat peptic ulcers. Depending on the position of the 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.

These ulcers can be caused by too much acid being made in the stomach.

Most people who have a peptic ulcer also have a bacteria called *Helicobacter pylori* in their stomach. Your doctor may also prescribe a course of antibiotics (clarithromycin and amoxicillin) for you. When RABEPRAZOLE MYLAN is taken with antibiotics, the combination therapy will kill the *Helicobacter pylori* and let your ulcer heal.

Chronic Gastritis

The presence of the bacteria *Helicobacter pylori* may cause the stomach to become inflamed, resulting in pain, nausea and vomiting; all of which are signs of chronic gastritis.

When RABEPRAZOLE MYLAN tablets are taken with antibiotics, they will help kill *Helicobacter pylori* and allow the stomach to heal.

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.

Before you take RABEPRAZOLE MYLAN

When you must not take it

Do not take RABEPRAZOLE MYLAN if you have an allergy to:

- any medicine containing rabeprazole sodium
- any of the ingredients listed at the end of this leaflet
- other proton pump inhibitors (omeprazole, esomeprazole, lansoprazole, pantoprazole)

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 give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

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, preservatives or dyes.

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

- liver disease

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

It is not known whether RABEPRAZOLE MYLAN passes into breast milk.

If you have not told your doctor about any of the above, tell him/her before you start taking RABEPRAZOLE MYLAN.

Taking other medicines

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.

Do not take RABEPRAZOLE MYLAN and tell your doctor or pharmacist if you are taking any of the following:

- atazanavir, a medicine used (with other antiretrovirals) to treat HIV-1 infection
- clopidogrel, an antiplatelet medicine

Some medicines and RABEPRAZOLE MYLAN may interfere with each other. These include:

- ciclosporin, a medicine used to treat several conditions including prevention of graft rejection following kidney, liver or heart transplantation; severe, active rheumatoid arthritis, severe skin diseases where other treatments have failed
- methotrexate, a medicine used to treat some kinds of cancer. It is also used to treat psoriasis (skin disease) and rheumatoid arthritis
- digoxin, a medicine used to treat heart problems
- mycophenolate mofetil, a medicine used to prevent organ rejection following kidney, liver or heart transplants
- clarithromycin, a medicine used to treat infections

These medicines may be affected by RABEPRAZOLE MYLAN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking RABEPRAZOLE MYLAN.

How to take RABEPRAZOLE MYLAN

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 one tablet at the same time each day. The dose of RABEPRAZOLE MYLAN tablets is usually 20 mg, but may vary from 10 mg to 40 mg per day depending on what condition you are being treated for and how severe it is.

For treating *Helicobacter pylori* infections in combination with antibiotics (clarithromycin and amoxicillin), the dose is one 20 mg tablet twice daily, morning and evening, for 7 days.

How to take it

Swallow the tablets whole, with a glass of water or other liquid.

Do NOT crush or chew the tablets. They have a special coating, which protects them from the acid in your stomach. If the coating is broken by chewing, the tablets may not work.

When to take it

It does not matter if you take RABEPRAZOLE MYLAN with food or an empty stomach.

If you forget to take it

If you forget to take your tablet take it as soon as you remember, and then go back to taking your medicine as you would normally.

However, 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 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

RABEPRAZOLE MYLAN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using RABEPRAZOLE MYLAN

Things you must do

Use RABEPRAZOLE MYLAN exactly as your doctor has prescribed.

Always swallow RABEPRAZOLE MYLAN tablets whole.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking RABEPRAZOLE MYLAN.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor if you need to have a specific blood test (Chromogranin A) while you are taking RABEPRAZOLE MYLAN.

It may affect the results of this test.

Things you must not do

Do not take RABEPRAZOLE MYLAN 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 crush or chew the tablets.

Do not give RABEPRAZOLE MYLAN to children.

Side effects

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

RABEPRAZOLE MYLAN is usually well tolerated.

This medicine helps most people with peptic ulcers or reflux disease, 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:

- headache
- dizziness

- diarrhoea
- constipation
- stomach pain
- wind
- vomiting
- constipation
- runny or blocked nose
- sore throat and discomfort when swallowing
- cough
- pain (including back, chest or joint pain)
- muscle weakness, physical weakness or lack of energy
- rash or itchy rash accompanied by skin eruptions or blisters
- flu-like symptoms
- sleeplessness (insomnia)
- indigestion
- belching
- dry mouth

- leg cramps
- swelling of the arms or legs
- nervousness
- sleepiness (somnolence)
- loss of appetite for food (anorexia)
- weight gain
- sweating

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:

- painful and/or frequent urination (common symptoms of a urinary tract infection)
- vision or taste disturbance
- depression
- feeling dizzy, faint, lightheaded or weak (hypotension)
- shortness of breath
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers

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 and do not take your next dose of RABEPRAZOLE MYLAN if you experience:

- signs of allergy such as skin rash, reddening, blisters or itching, swelling of the face, lips or other parts of the body, shortness of breath or wheezing
- pass black (blood-stained) stools

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

If you experience symptoms such as severe (water or bloody) diarrhoea, fever, abdominal pain or tenderness, you may have Clostridium difficile colitis (bowel inflammation).

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

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

- pain or indigestion
- vomiting blood or food
- pass black (blood-stained) motions

Under rare circumstances supervised by the doctor, proton pump inhibitors (PPIs) might be used for long periods of time.

Low magnesium can occur in some people who take a proton pump inhibitor. Symptoms of low magnesium can include seizures, dizziness, spasms, cramps or muscle weakness.

Withdrawal of long-term PPI therapy may lead to worsening of acid-related symptoms.

People who take proton pump inhibitor medicines at high doses for a long period of time (1 year or longer) may have an increased risk of fractures of the hip, wrist, or spine.

Proton pump inhibitors may reduce the amount of acid in your stomach. Stomach acid is needed to absorb vitamin B-12 properly. Talk with your doctor or pharmacist about the possibility of vitamin B-12 deficiency if you have been taking a proton pump inhibitor for a long time (i.e. more than 3 years).

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

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

After using RABEPRAZOLE MYLAN

Storage

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

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

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

Do not store RABEPRAZOLE MYLAN 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

RABEPRAZOLE MYLAN 10 mg tablets: pink, biconvex, enteric-coated tablets, plain on both sides.

RABEPRAZOLE MYLAN 20 mg tablets: yellow, biconvex, enteric-coated tablets, plain on both sides.

RABEPRAZOLE MYLAN 10 mg tablets are supplied in Alu/Alu blister packs of 28 tablets.

RABEPRAZOLE MYLAN 20 mg tablets are supplied in Alu/Alu blister packs of 30 tablets.

Ingredients

RABEPRAZOLE MYLAN contains 10 mg or 20 mg of rabeprazole sodium as the active ingredient.

The tablets also contain the following inactive ingredients:

- light magnesium oxide
- mannitol
- sodium starch glycollate
- povidone (K-30)
- magnesium stearate
- ethylcellulose
- hypromellose phthalate
- titanium dioxide
- purified talc
- 10 mg tablet contains iron oxide red
- 20 mg tablet contains iron oxide yellow

This medicine does not contain lactose or gluten.

Supplier

Alphapharm Pty Ltd

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