

RABEPRAZOLE MYLAN Tablets

Rabeprazole-Sodium

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about RABEPRAZOLE MYLAN tablets. 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 this medicine is expected to have for you.

If you have any concerns about using RABEPRAZOLE MYLAN ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

WHAT RABEPRAZOLE MYLAN IS USED FOR

The name of your medicine is RABEPRAZOLE MYLAN. It 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 gastrooesophageal 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.

Your doctor may have prescribed RABEPRAZOLE MYLAN for another reason. Ask your doctor if you have any questions about why RABEPRAZOLE MYLAN has been prescribed for you.

HOW RABEPRAZOLE MYLAN WORKS

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 normal way.

Your doctor may have prescribed RABEPRAZOLE MYLAN for another reason. Ask your doctor if you have any questions about why RABEPRAZOLE MYLAN has been prescribed for you.

RABEPRAZOLE MYLAN is only available with a doctor's prescription.

BEFORE YOU TAKE RABEPRAZOLE MYLAN

When you must not take it:

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

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

Symptoms of an allergic reaction may include:

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

Do not take RABEPRAZOLE MYLAN if:

- the packaging is torn or shows signs of tampering.
- the expiry date (month and year) printed on the pack has passed. If you take RABEPRAZOLE MYLAN after the expiry date it may not work.

Before you start to take it

You must tell your doctor if:

- you are pregnant or intend to become pregnant.
- you are breast-feeding or intend to breast-feed. It is not known if RABEPRAZOLE MYLAN passes into breast milk.
- you have or have ever had liver disease.

Taking other medicines:

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

Do not take PARIET 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

You should not take RABEPRAZOLE MYLAN while taking these medicines.

Also tell your doctor or pharmacist if you are taking any of the following:

- 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 kidney disease 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.
- ketoconazole, a medicine used to treat fungal infections.
- 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 RABEPRAZOLE MYLAN works. Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

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

Your doctor will advise you whether or not to take RABEPRAZOLE MYLAN or if

you need to have your dose adjusted.

TAKING RABEPRAZOLE MYLAN

Follow the directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

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.

Children

RABEPRAZOLE MYLAN should not be given to children under 18 years of age. Safety and effectiveness of RABEPRAZOLE MYLAN in children has not been established.

How to take it:

RABEPRAZOLE MYLAN should be swallowed 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.

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

Ask your doctor or pharmacist for help if you do not understand the instructions provided with this medicine.

If you forget to take it:

If you forget to take your tablet take it as soon as you remember, and then continue to take it 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 you missed.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you have taken too much (overdose):

Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 for advice, or go to Accident and Emergency at your nearest hospital.

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.
- Tell your doctor if you become pregnant while you are taking RABEPRAZOLE MYLAN

Tell your doctor or pharmacist that you are taking RABEPRAZOLE MYLAN if you are about to start taking a new medicine.

Things you must not do:

- **Do not use RABEPRAZOLE MYLAN to treat any other complaint unless your doctor says to.**
- **Do not give this medicine to anyone else, even if they have the same symptoms as you.**
- **Do not crush or chew the tablets.**
- **Do not give RABEPRAZOLE MYLAN to children.**

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.

SIDE EFFECTS

RABEPRAZOLE MYLAN is usually well tolerated but tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking RABEPRAZOLE MYLAN.

RABEPRAZOLE MYLAN 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 treatment if you get some 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 experience 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

These side effects are usually mild.

Tell your doctor immediately 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.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

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

If you experience symptoms such as severe (watery 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 rather than the treatment. **For this reason contact your doctor immediately if you notice any of the following:**

- pain or indigestion
- you begin to vomit blood or food
- you 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 B12 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 if you notice anything making you feel unwell when you are taking, or soon after you have finished taking RABEPRAZOLE MYLAN.

Ask your doctor or pharmacist if you do not understand anything in this list.

AFTER USING RABEPRAZOLE MYLAN

Storage

RABEPRAZOLE MYLAN tablets are packaged in blister packs. **Do not take RABEPRAZOLE MYLAN tablets out of the blister pack until it is time to take them.** If you take them out of the blister they may not keep well.

Keep RABEPRAZOLE MYLAN tablets in a cool dry place where the temperature is below 25°C. Do not keep RABEPRAZOLE MYLAN in the refrigerator.

Do not store RABEPRAZOLE MYLAN, or any other medicine, in the bathroom or near a sink.

Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your medicines where children cannot reach them.

A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Disposal

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

PRODUCT DESCRIPTION

What RABEPRAZOLE MYLAN looks like:

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

RABEPRAZOLE MYLAN 20 mg tablets are 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

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

Each tablet also contains the following other ingredients:

- magnesium oxide light, mannitol, sodium starch glycollate, povidone (K30), magnesium stearate, ethylcellulose, diethyl phthalate, hypromellose phthalate, titanium dioxide, purified talc
- 10mg tablet also contains iron oxide red
- 20mg tablet contains iron oxide yellow

The tablets do not contain lactose or gluten.

Supplier

Alphapharm Pty Limited

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30-34 Hickson Road
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