

RABEPRAZOLE-DRLA Tablets

Rabeprazole sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about RABEPRAZOLE-DRLA 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-DRLA against the benefits this medicine is expected to have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What RABEPRAZOLE-DRLA is used for

The name of your medicine is RABEPRAZOLE-DRLA. It contains the active ingredient rabeprazole sodium.

Reflux Oesophagitis:

RABEPRAZOLE-DRLA is used to treat reflux oesophagitis or reflux disease. 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-DRLA is also used to help stop reflux oesophagitis from coming back or relapsing.

Peptic Ulcers:

RABEPRAZOLE-DRLA 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-DRLA 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.

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

How RABEPRAZOLE-DRLA works

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

RABEPRAZOLE-DRLA 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-DRLA for another reason. Ask your doctor if you have any questions about why RABEPRAZOLE-DRLA has been prescribed for you.

RABEPRAZOLE-DRLA is only available with a doctor's prescription.

Before you take RABEPRAZOLE-DRLA

When you must not take it:

Do not take RABEPRAZOLE-DRLA if you have an allergy to:

- 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-DRLA 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-DRLA 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-DRLA 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.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- digoxin, a medicine used to treat heart problems.
- ketoconazole, a medicine used to treat fungal infections.
- atazanavir, a medicine used (with other antiretrovirals) to treat HIV-1 infection.

These medicines may be affected by RABEPRAZOLE-DRLA or may affect how well RABEPRAZOLE-DRLA 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-DRLA.

Your doctor will advise you whether or not to take RABEPRAZOLE-DRLA or if you need to have your dose adjusted.

Taking RABEPRAZOLE-DRLA

How much to take:

Adults

The usual dose is one tablet at the same time each day. For treating *Helicobacter pylori* infections in combination with antibiotics (clarithromycin and amoxicillin), the dose is one tablet twice each day, morning and evening.

The dose of RABEPRAZOLE-DRLA 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.

Children

RABEPRAZOLE-DRLA should not be given to children.

How to take it:

- RABEPRAZOLE-DRLA 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-DRLA 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 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.

Poisons Information Centre telephone numbers:

- Australia: 13 11 26

While you are using RABEPRAZOLE-DRLA

Things you must do:

- Use RABEPRAZOLE-DRLA exactly as your doctor has prescribed.
- Always swallow RABEPRAZOLE-DRLA tablets whole.
- Tell your doctor if you become pregnant while you are taking RABEPRAZOLE-DRLA.

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

Things you must not do:

- Do not use RABEPRAZOLE-DRLA 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-DRLA to children.

Things that may help your condition

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist for more information about these measures.

- **Alcohol** - your doctor may advise you to limit your alcohol intake.
- **Aspirin and many other medicines used to treat arthritis/period pain/headaches** - these medicines may irritate the stomach and may make your condition worse. Your doctor or pharmacist may suggest other medicines you can take.
- **Caffeine** - your doctor may advise you to limit the number of drinks which contain caffeine, such as coffee, tea, cocoa and cola drinks, because they contain ingredients that may irritate your stomach.
- **Eating habits** - eat smaller, more frequent meals. Eat slowly and chew your food carefully. Try not to rush at meal times.
- **Smoking** - your doctor may advise you to stop smoking or at least cut down.
- **Weight** - your doctor may suggest losing some weight to help your condition.

Side Effects

RABEPRAZOLE-DRLA 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-DRLA.

RABEPRAZOLE-DRLA 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
- muscle weakness
- flatulence
- dry mouth
- breast enlargement in men
- itchy rash accompanied by skin eruption

These side effects are usually mild.

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

- bleeding or bruising more easily than normal
- 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-DRLA 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.

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-DRLA.

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.

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

After using RABEPRAZOLE-DRLA

Storage

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

Do not store RABEPRAZOLE-DRLA, 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-DRLA 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-DRLA looks like:

- **RABEPRAZOLE-DRLA 10 mg** tablets are pink, round, biconvex coated tablets and plain on both sides.
- **RABEPRAZOLE-DRLA 20 mg** tablets are light yellow, round, biconvex coated tablets and plain on both sides.

RABEPRAZOLE-DRLA 10 and 20 mg tablets are supplied in blister packs of 2, 7, 10, 28 and 30 tablets and bottles of 30 tablets.

Ingredients

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

Each tablet also contains the following other ingredients:

- Mannitol, light magnesium oxide, hydroxypropylcellulose, magnesium stearate, ethylcellulose, hypromellose phthalate, diacetylated monoglycerides, purified talc, titanium dioxide and carnauba wax.
- The 20 mg tablets also contain iron oxide yellow.
- The 10 mg tablets contain iron oxide red.
- The tablets do not contain lactose or gluten.

Sponsor

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