

PARIET® 10 Tablets

Rabeprazole sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PARIET 10 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 or pharmacist has weighed the risks of you taking PARIET 10 against the benefits this medicine is expected to have for you.

If you have any concerns about using PARIET 10 ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What PARIET 10 is used for

The name of your medicine is PARIET 10. It contains the active ingredient rabeprazole sodium.

PARIET 10 is used for symptomatic relief of heartburn and stomach acid complaints due to gastro-oesophageal reflux caused by "washing back" of food and acid from the stomach into 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. Frequent heartburn is when you have heartburn for two or more days a week. Heartburn that occurs frequently is a typical symptom of gastro-oesophageal reflux disease (GORD).

PARIET 10 belongs to a group of medicines called proton pump inhibitors (PPIs). PARIET 10 works by decreasing the amount of acid the stomach makes to give relief from the symptoms. Your food will still be digested in the same way.

PARIET 10 will start to suppress acid within a few hours; however it will not give instant symptom relief. You may need to take PARIET 10 for a few days before experiencing the full effect.

There is no evidence that PARIET 10 is addictive.

PARIET 10 is only available from your pharmacist or doctor.

Before you take PARIET 10

When you must not take it:

Do not take PARIET 10 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 or hypersensitivity 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 PARIET 10 after the expiry date (EXP) printed on the

pack has passed or if the packaging is torn or shows signs of tampering.

PARIET 10 is not recommended for use in children under 18 years of age. Safety and effectiveness of PARIET 10 in children has not been established.

If you are not sure whether you should start taking PARIET 10, talk to your doctor or pharmacist.

Before you start to take it:

You must tell your pharmacist or doctor if:

- you are pregnant, plan to become pregnant, or are breast-feeding.
- you have now, or have had in the past, liver problems.

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.

Some medicines and PARIET 10 may interfere with each other.

These include:

- clopidogrel, an antiplatelet medicine.
- cyclosporin, 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.
- atazanavir, a medicine used to treat viral 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 PARIET 10 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine. Tell your doctor or pharmacist that you are taking PARIET 10 if you are about to start taking a new medicine.

How to take PARIET 10

Follow the 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 per day, to be taken at the same time each day.

Children

PARIET 10 is not recommended for use in children under 18 years of age. Safety and effectiveness of PARIET

10 in children has not been established.

How to take it:

- PARIET 10 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 PARIET 10 with food or on an empty stomach.

How long to take it:

Take one tablet daily for at least 7 days and up to 14 days. You should not take PARIET 10 for more than 14 days unless directed by a doctor. If symptoms persist or recur within 14 days of completing the course, consult a doctor. Further examination may be required.

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):

If you think that you, or anyone else, may have taken too much PARIET 10, immediately telephone your doctor or the Poisons Information Centre (telephone 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 PARIET 10

Things you must not do:

- Do not use PARIET 10 to treat any other complaints unless your doctor says so.
- Do not give this medicine to anyone else, even if they have the same symptoms as you.

Tell your doctor if you need to have a specific blood test (Chromogranin A) while you are taking PARIET 10.

It may affect the results of this test.

Side Effects

PARIET 10 is usually well tolerated; however tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PARIET 10.

PARIET 10 helps most people with heartburn, 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 or pharmacist if you notice any of the following and they worry you:

- headache
- dizziness
- diarrhoea
- nausea
- 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
- flu-like symptoms
- sleeplessness (insomnia)
- indigestion
- belching
- rash or itchy rash accompanied by skin eruptions or blisters
- 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 as soon as possible if you notice any of the following:

- painful and/or frequent urination (common symptoms of a urinary tract infection)
- inflammation of the mouth and lips
- vision or taste disturbance
- depression
- feeling dizzy, faint, lightheaded or weak (hypotension)
- shortness of breath
- signs of frequent infections such as fever, 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 PARIET 10 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

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

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

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

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

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

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).

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.

Low magnesium can lead to low calcium and/or low potassium levels in blood.

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 (i.e. 1 year or longer) may have an increased risk of fractures of the hip, wrist, or spine.

After using PARIET 10

Storage

PARIET 10 tablets are packaged in a double-sided aluminium blister strip.

Do not take PARIET 10 tablets out of the blister pack until it is time to take them. If you take them out of the blister pack they may not keep well.

Keep PARIET 10 tablets in a cool dry place where the temperature is below 25°C. Do not keep PARIET 10 in the refrigerator or freezer.

Do not store PARIET 10, 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 you stop taking PARIET 10 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 PARIET 10 tablets look like:

PARIET 10 tablets are pink and have "E241" in black ink on one side.

The tablets are supplied in blister packs of 7 and 14 tablets.

Ingredients

Each PARIET 10 tablet contains 10 mg rabeprazole sodium as the active ingredient.

Each tablet also contains the following other ingredients:

- mannitol, magnesium oxide, hyprolose, magnesium stearate, ethylcellulose, hypromellose

phthalate, diacetylated monoglycerides, purified talc, titanium dioxide and carnauba wax, red iron oxide and printed with gray ink (Edible Ink Gray F6).

The tablets do not contain lactose or gluten.

Sponsor

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