

Rabeprazole sodium (10mg, 20mg)

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What *Pariet*® is used for

Pariet® is intended for:

- Short-term (4 to 8 weeks) treatment in the healing of erosive or ulcerative Gastroesophageal Reflux Disease (GERD). For those people who have not healed after 8 weeks of treatment, an additional 8-week course of *Pariet*® may be considered.
- For maintaining healing and reduction in relapse rates of heartburn symptoms in people with erosive or ulcerative Gastroesophageal Reflux Disease (GERD maintenance).
- Short-term (up to four weeks) treatment in the healing and symptomatic relief of duodenal ulcers.
- Long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome.
- Symptomatic treatment of moderate to very severe GERD.
- *Helicobacter pylori* infection eradication to reduce the risk of duodenal ulcer recurrence in adults when used in combination with amoxicillin and clarithromycin as a three-medicine regimen.

GERD is a long-term condition where acid from the stomach comes up in to the esophagus (tube connecting your mouth and stomach).

How *Pariet*® works

Pariet® acts by inhibiting enzyme activity and thereby slowing or preventing the production of gastric acid in the stomach.

Before you use *Pariet*®

- When you must not use it

Do not take *Pariet*® if you have known hypersensitivity to rabeprazole sodium, or to any ingredient used in the formulation.

Pregnancy and lactation

Do not take *Pariet*® if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take *Pariet*® if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Pariet® is not recommended for use in children

- Before you start use it

Consult your doctor before using *Pariet*® if you have

- Specific blood test (Chromogranin A)
- Liver function disorder

- Taking other medicines

Tell your doctor if you are taking:

- Digoxin (medicine to treat heart conditions)
- Phenytoin (to treat seizure)
- Antacid containing aluminum hydroxide gel/Magnesium hydroxide
- Methotrexate (immune system suppressant)

and any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

- How much to use

The usual adult dose for oral use is 10 mg of sodium rabeprazole once daily. However, the dosage may be increased up to 20 mg orally once daily depending on the severity of symptoms.

Adults/elderly:

Healing of Erosive or Ulcerative Gastro-Oesophageal Reflux Disease (GERD): The recommended oral dose for this condition is 10mg or 20mg twice daily for four to eight weeks. Dose of 20 mg twice daily should only be administered if you have severe mucous membrane injury.

Gastro-Oesophageal Reflux Disease Long-term Management (GERD Maintenance):

For long-term management, a maintenance dose of PARIET 20 mg or 10 mg once daily can be used depending upon your response. Dose of 10 mg twice daily may be taken if the treatment is ineffective.

Zollinger-Ellison Syndrome:

The recommended adult starting dose is 60 mg once a day. The dose may be increased to 120 mg/day based on individual needs. Single daily doses up to 100 mg/day may be used. 120 mg dose may require divided doses, 60 mg twice daily. Treatment should continue for as long as advised by your doctor.

Symptomatic treatment of moderate to very severe Gastroesophageal Reflux Disease (symptomatic GERD):

10mg once daily in people without inflammation of esophagus lining. If symptom control has not been achieved during four weeks, consult your doctor for further advice. Once symptoms have resolved, subsequent symptom control can be achieved using an on-demand regimen taking 10mg once daily when needed.

Helicobacter pylori eradication to reduce the risk of duodenal ulcer recurrence:

THREE DRUG REGIMEN ^a

PARIET	20 mg	Twice daily for 7 Days
Amoxicillin	1000 mg	Twice daily for 7 Days
Clarithromycin	500 mg	Twice daily for 7 Days

All three medications should be taken twice daily with the morning and evening meals.

^a It is important that you comply with the full 7-day regimen

Kidney and liver impairment: No dosage adjustment is necessary.

Pariet® can be administered at a dose of 20 mg once daily in the case of severe, recurrent and intractable conditions.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not

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understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

For indications requiring once daily treatment, *Pariet*® should be taken in the morning before eating.

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *Pariet*® for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Pariet® should be swallowed whole and not chewed or crushed.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give *Pariet*® to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

It is unlikely that *Pariet*® would cause an impairment of driving performance or compromise the ability to use machinery. If, however, alertness is impaired due to sleepiness, it is recommended that

driving and operating complex machinery be avoided.

Make sure to remove *Pariet*® from the package prior to use to avoid swallowing of the press-through package sheet.

Side effects

When you are taking this medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor. Please tell your doctor promptly if you get any of the symptoms below:

- Rash (especially in areas exposed to the sun), possibly with pain in the joints. (Subacute Cutaneous Lupus Erythematosus, SCLE)
- Extreme tiredness, pus/blood in urine
- Involuntary muscle contractions, disorientation, convulsions, increased heart rate
- Constipation
- Fracture in the hip, wrist or spine
- Watery stool, stomach pain and fever that do not go away
- Headache
- Liver function disorder
- Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerves problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioral changes)

a) Subacute Cutaneous Lupus Erythematosus (SCLE)
Frequency “not known”

b) Interstitial Nephritis
Kidney problems

c) Hypomagnesaemia
Frequency “not known”. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood

d) Fracture
Frequency “uncommon”. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis)

e) Clostridium Difficile Diarrhea

Severe diarrhea which may be caused by an infection (*Clostridium difficile*) in your intestines

f) Fundic Gland Polyps (Benign)

Frequency “Common”. Benign polyps in the stomach

g) Vitamin B12 Deficiency

Proton pump inhibitors may cause vitamin B12 deficiency

- Increased level of Chromogranin A (CgA), a tumour marker, that may interfere with investigations for neuroendocrine tumours. To avoid this interference, *PARIET* treatment should be stopped for at least 5 days before CgA measurements.
- Frequency ‘not known’: Inflammation in the large bowel, that causes persistent watery diarrhea

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my [Public → Reporting Side Effects to Medicines (ConSERF) or Vaccine (AEFI)].

Storage and Disposal of *Pariet*®

- Storage

Pariet® should be stored at room temperature not exceeding 30°C and protected from moisture after unsealing.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Pariet® is a light yellow, film-coated round tablet

- Ingredients

- Active ingredient

- Rabeprazole sodium

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Inactive ingredients

- Mannitol
- Magnesium oxide
- Low-substituted hydroxypropylcellulose
- Hydroxypropylcellulose
- Magnesium stearate
- Ethylcellulose
- Magnesium oxide
- Hydroxypropylmethylcellulose phthalate
- Diacetylated monoglycerides
- Talc
- Titanium dioxide
- Ferric oxide
- Carnauba wax

- MAL numbers:

Pariet® Tablet 10mg

MAL19992540ACRZ

Pariet® Tablet 20mg

MAL19992541ACRZ

Manufacturer

Bushu Pharmaceuticals Ltd. Misato plant
950, Hiroki, Ohaza, Misato-machi,
Kodama-gun, Saitama-ken, Japan

Product Registration Holder

Eisai (Malaysia) Sdn Bhd
Unit 701D, Level 7, Tower D, Uptown 5,
No. 5, Jalan SS21/39, Damansara
Uptown,
47400 Petaling Jaya,
Selangor, Malaysia

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