

PACKAGE LEAFLET: INFORMATION FOR THE USER
PARIET® 20 mg gastro-resistant tablets
(rabeprazole sodium)

Your medicine is known as the above but will be referred to as Pariet throughout the remainder of this leaflet.

This medicine is available in another strength and this strength will be referred to throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Pariet is and what it is used for
2. What you need to know before you take Pariet
3. How to take Pariet
4. Possible side effects
5. How to store Pariet
6. Contents of the pack and other information

1. What Pariet is and what it is used for

Pariet tablets contain the active ingredient rabeprazole sodium. This belongs to a group of medicines called 'Proton Pump Inhibitors' (PPIs). They work by lowering the amount of acid that your stomach produces.

Pariet tablets are used to treat the following conditions:

- 'Gastro-oesophageal reflux disease' (GORD), which can include heartburn. GORD is caused when acid and food from your stomach escapes into your food pipe (oesophagus)
- Ulcers in your stomach or the upper part of your gut (intestine). If these ulcers are infected with bacteria called 'Helicobacter pylori' (H. Pylori), you will also be given antibiotics. Using Pariet tablets and antibiotics together gets rid of the infection and makes the ulcer heal. It also stops the infection and ulcer from coming back
- Zollinger-Ellison Syndrome where your stomach produces too much acid

2. What you need to know before you take Pariet

Do not take Pariet if

- You are allergic (hypersensitive) to rabeprazole sodium, or any of the other ingredients of this medicine (listed in Section 6).
- You are pregnant or think that you are pregnant
- You are breast feeding

Do not use Pariet if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Pariet

Warnings and precautions

Talk to your doctor or pharmacist before taking Pariet if:

- You are allergic to other proton pump inhibitor medicines or 'substituted benzimidazoles'.
- Blood and liver problems have been seen in some patients but often get better when Pariet is stopped.
- You have a stomach tumour.
- You have ever had liver problems.
- If you are taking atazanavir- for HIV infection.
- If you have reduced body stores or risk factors for reduced vitamin B₁₂ and receive long term treatment with rabeprazole sodium. As with all acid reducing agents, rabeprazole sodium may lead to a reduced absorption of vitamin B₁₂.
- This medicine may affect the way that your body absorbs Vitamin B₁₂, particularly if you need to take it for a long time. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of Vitamin B₁₂:
 - Extreme tiredness or lack of energy
 - Pins and needles
 - Sore or red tongue, mouth ulcers
 - Muscle weakness
 - Disturbed vision
 - Problems with memory, confusion, depression.
- If you have ever had a skin reaction after treatment with a medicine similar to Pariet that reduces stomach acid.
- If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Pariet. Remember to also mention any other ill-effects like pain in your joints.
- You are due to have a specific blood test (Chromogranin A).
- When taking rabeprazole, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Pariet.

Children

Pariet should not be used in children.

If you experience severe (watery or bloody) diarrhoea with symptoms such as fever, abdominal pain or tenderness, stop taking Pariet and see a doctor straight away.

Taking a proton pump inhibitor like Pariet, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine.

Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Other medicines and Pariet

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

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

- Ketoconazole or itraconazole – used to treat infections caused by a fungus. Pariet may lower the amount of this type of medicine in your blood. Your doctor may need to adjust your dose.
 - Atazanavir– used to treat HIV-infection. Pariet may lower the amount of this type of medicine in your blood and they should not be used together.
 - Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Pariet treatment.
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Pariet.

Pregnancy, breast feeding and fertility

- Do not use Pariet if you are pregnant or think you may be pregnant
- Do not use Pariet if you are breast-feeding or planning to breast-feed

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

You may feel sleepy while taking Pariet. If this happens, do not drive or use any tools or machines.

Pariet contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per gastro-resistant tablet, that is to say essentially 'sodium-free'.

3. How to take Pariet

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Only remove a tablet from the blister strip when it is time to take your medicine.
- Swallow your tablets whole with a drink of water. Do not chew or crush the tablets.
- Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition.
- If you are taking this medicine for a long time, your doctor will want to monitor you.

Adults and older people

For 'gastro-oesophageal reflux disease' (GORD)

Treatment of moderate to severe symptoms (symptomatic GORD)

- The usual dose is one Pariet 10 mg tablet once a day for up to 4 weeks
- Take the tablet in the morning before eating
- If your condition returns after 4 weeks treatment, your doctor may tell you to take one Pariet 10 mg tablet as and when you require it

Treatment of more severe symptoms (erosive or ulcerative GORD)

- The usual dose is one Pariet 20 mg tablet once a day for 4 to 8 weeks
- Take the tablet in the morning before eating

Long-term treatment of symptoms (GORD maintenance)

- The usual dose is one Pariet 10 mg or 20 mg tablet once a day for as long as your doctor has told you
- Take the tablet in the morning before eating
- Your doctor will want to see you at regular intervals to check your symptoms and dosage

For ulcers of the stomach (peptic ulcers)

- The usual dose is one Pariet 20 mg tablet once a day for 6 weeks
- Take the tablet in the morning before eating
- Your doctor may tell you to take Pariet for another 6 weeks if your condition does not improve

For ulcers of the intestine (duodenal ulcers)

- The usual dose is one Pariet 20 mg tablet once a day for 4 weeks
- Take the tablet in the morning before eating
- Your doctor may tell you to take Pariet for another 4 weeks if your condition does not improve

For ulcers caused by H. Pylori infection and to stop them coming back

- The usual dose is one Pariet 20 mg tablet twice a day for seven days
- Your doctor will also tell you to take antibiotics called amoxicillin and clarithromycin

For further information on the other medicines used for the H. Pylori treatment, see the individual product information leaflets.

Zollinger-Ellison Syndrome where excess acid is produced in the stomach

- The usual dose is three Pariet 20 mg tablets once a day to start with
- The dose may then be adjusted by your doctor depending on how you respond to the treatment

If you are on long-term treatment you will need to see your doctor at regular intervals for review of your tablets and symptoms.

Patients with liver problems. You should consult your doctor who will take special care when beginning treatment with Pariet and while you continue to be treated with Pariet.