

Package leaflet: Information for the user

PARIET™* 10 mg and 20 mg gastro-resistant tablets Rabeprazole sodium

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

* Pariet is a trademark of Eisai Co Ltd, Tokyo, Japan

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.
- 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).

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 applies 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.

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.

If you take more Pariet than you should

If you take more Pariet than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Pariet

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual
- If you forget to take your medicine for more than 5 days, talk to your doctor before taking any more medicine
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose

If you stop taking Pariet

Relief of symptoms will normally occur before the ulcer has completely healed. **It is important that you do not stop taking the tablets until told to do so by your doctor.**

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects are usually mild and improve without you having to stop taking this medicine.

Stop taking Pariet and see a doctor straight away if you notice any of the following side effects - you may need urgent medical treatment:

- Allergic reactions – the signs may include: sudden swelling of your face, difficulty breathing or low blood pressure which may cause fainting or collapse
- Frequent infections, such as a sore throat or high temperature (fever), or ulcers in your mouth or throat
- Bruising or bleeding easily.

These side effects are rare (affect fewer than 1 in 1,000 people).

- Severe skin blistering, or soreness or ulcers in your mouth and throat.

These side effects are very rare (affect fewer than 1 in 10,000 people).

Other possible side effects:

Common (affect fewer than 1 in 10 people)

- Infections
- Difficulty sleeping
- Headache or feeling dizzy
- Cough, runny nose or sore throat (pharyngitis)
- Effects on your stomach or gut such as stomach pain, diarrhoea, wind (flatulence), feeling sick (nausea), being sick (vomiting) or constipation
- Aches or back pain
- Weakness or flu-like symptoms
- Benign polyps in the stomach.

Uncommon (affect fewer than 1 in 100 people)

- Feeling nervous or drowsy
- Chest infection (bronchitis)
- Painful and blocked sinuses (sinusitis)
- Dry mouth
- Indigestion or belching
- Skin rash or redness
- Muscle, leg or joint pain
- Fractures of the hip, wrist and spine

- Bladder infection (urinary tract infection)
- Chest pain
- Chills or fever
- Changes in how your liver is working (shown in blood tests).

Rare (affect fewer than 1 in 1,000 people)

- Loss of appetite (Anorexia)
- Depression
- Hypersensitivity (includes allergic reactions)
- Visual disturbance
- Sore mouth (stomatitis) or taste disturbance
- Upset stomach or stomach pain
- Liver problems including yellowing of your skin and whites of your eyes (jaundice)
- Itchy rash or blistering skin
- Sweating
- Kidney problems
- Weight gain
- Changes in white blood cells (shown in blood tests) which may result in frequent infection
- Reduction in blood platelets resulting in bleeding or bruising more easily than normal.

Other possible side effects (unknown frequency)

- Breast swelling in men
- Fluid retention
- Inflammation of the gut (leading to diarrhoea)
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma
- Patients who have previously had liver problems may very rarely get encephalopathy (a brain disease)
- Rash, possibly with pain in the joints.

If you are on Pariet for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Do not be concerned by this list of side effects. You may not get any of them.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: HPRRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PARIET

Keep out of the sight and reach of children.

Do not store this medicine above 25° C.

Do not refrigerate.

Do not use Pariet after the expiry date which is stated on the carton and blister foil. The expiry date refers to the last day of that month.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Pariet contains

Each Pariet 10 mg tablet contains 10 mg of the active substance rabeprazole sodium.

The other ingredients it contains:

mannitol, magnesium oxide, low-substituted hyprolose, hyprolose, magnesium stearate, ethylcellulose, hypromellose phthalate, diacetylated monoglycerides, talc, titanium dioxide (E171), red iron oxide (E172), Carnauba wax and ink (white shellac, black iron oxide (E172)), dehydrated ethyl alcohol, 1-butanol.

Each Pariet 20 mg tablet contains 20 mg of the active substance rabeprazole sodium.

The other ingredients it contains:

mannitol, magnesium oxide, low-substituted hyprolose, hyprolose, magnesium stearate, ethylcellulose, hypromellose phthalate, diacetylated monoglycerides, talc, titanium dioxide (E171), yellow iron oxide (E172), Carnauba wax and ink (white shellac, red iron oxide (E172)), glycerine fatty acid ester, dehydrated ethyl alcohol, 1-butanol.

What Pariet looks like and contents of the pack

Pariet 10 mg gastro-resistant tablet is a pink, film coated biconvex tablet with 'E241' printed on one side.

Pariet 20 mg gastro-resistant tablet is a yellow, film coated biconvex tablet with 'E243' printed on one side.

The tablets are packed in blister strips and come in pack sizes that contain: 1, 5, 7, 14, 15, 25, 28, 30, 50, 56, 75, 98, 112 or 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Janssen Sciences Ireland UC, Barnahely, Ringaskiddy, Co. Cork, P43 FA46, Ireland.

Manufacturer:

Janssen Pharmaceutica NV, Turnhoutseweg 30, 2340, Beerse, Belgium

or

Eisai GmbH, Edmund-Rumpler-Straße 3, 60549, Frankfurt am Main, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	Name of the medicinal product	Name of the Member State	Name of the medicinal product
Austria	Pariet	Italy	Pariet
Belgium	Pariet	Luxembourg	Pariet
Denmark	Pariet	Netherlands	Pariet
Finland	Pariet	Portugal	Pariet
France	Pariet	Spain	Pariet
Germany	Pariet	Sweden	Pariet

Greece
Ireland

Pariet
Pariet

United Kingdom Pariet

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