Patient Information Leaflet (PIL)

SCHEDULING STATUS
Schedule 4

PARIET® 10 mg enteric-coated delayed release tablets

PARIET® 20 mg enteric-coated delayed release tablets

PARIET 10 mg: Each enteric-coated delayed release tablet contains 10 mg of rabeprazole sodium, equivalent to 9,42 mg rabeprazole (racemate).

PARIET 20 mg: Each enteric-coated delayed release tablet contains 20 mg of rabeprazole sodium, equivalent to 18,85 mg rabeprazole (racemate).

Contains sugar (mannitol).

PARIET 10 mg: Each tablet contains 26 mg mannitol.

PARIET 20 mg: Each tablet contains 40 mg mannitol.

Read all of this leaflet carefully before you start taking PARIET

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PARIET has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 use 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 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 hypersensitive (allergic) to rabeprazole sodium or any of the other ingredients of PARIET (listed in section 6)
- You are allergic to substituted benzimidazoles (de-worming medicines)
- You are pregnant or breastfeeding
- You are taking medicines such as atazanavir and nelfinavir for HIV infection.

- You have previously experienced acute tubulointerstitial nephritis (TIN) , a type of kidney problem, while on treatment with a PPI.

<u>Warnings and precautions</u>

Take special care with PARIET

Tell your doctor or pharmacist before taking PARIET if:

- you have been told you have a stomach tumour
- you have a history of liver disease
- you are taking digoxin or antifungal medicines (ketoconazole, itraconazole)
- you have reduced body stores or risk factors for reduced vitamin B 12 and receive long-term treatment with PARIET. PARIET may lead to a reduced absorption of vitamin B 12
- you have ever had a skin reaction after treatment with a medicine similar to PARIET that reduces stomach acid
- 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
- Blood problems have been seen in some patients but often gets better when PARIET is stopped
- 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
- You are due to have a specific blood test (Chromogranin A).

Using medicines like PARIET for a long period of time may cause a growth in your stomach (polyp). This can lead to intestinal blockage or bleeding. Talk to your doctor if you experience nausea or stomach pain while you are taking PARIET.

If you are not sure, consult your doctor or pharmacist before taking PARIET tablets.

Children

PARIET should not be used in children.

Treatment with PARIET may possibly increase the risk of stomach (gastrointestinal) infections such as *Clostridium difficile, Campylobacter* and *Salmonella.* 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 such as PARIET, especially over a period of more than one year, may increase your risk of fracture in your hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Talk with your doctor if you have a type of kidney problem (acute tubulointerstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including PARIET, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with PARIET. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine.

Other medicines and PARIET:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional 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 **–** used to treat cancer, severe arthritis or other serious conditions.
- Ciclosporin - used in the prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants. Using PARIET together with ciclosporin may cause a condition called hypomagnesaemia, or low blood magnesium.
- Digoxin – used to treat mild to moderate heart failure. In the short-term, PARIET may cause an increase in the blood levels of digoxin. You should seek immediate medical attention if you experience signs and symptoms that may indicate excessive effects of digoxin, such as nausea, vomiting, diarrhoea, loss of appetite, visual disturbances (blurred vision; light halos around objects; green or yellow vision), or an abnormally fast or slow or uneven heartbeat. You may need a dose adjustment or more frequent monitoring by your doctor to safely use both medications.

PARIET with food and drink

Take the medicine in the morning before eating.

Pregnancy and Breastfeeding:

You should not take PARIET tablets if you are pregnant. If you are taking PARIET you should not breastfeed your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking PARIET.

Driving and using machines

It is unlikely that PARIET would affect your ability to drive or operate machinery. However, occasionally PARIET can cause drowsiness. Therefore, do not drive or operate complex machinery until you are sure how PARIET affects you.

PARIET contains mannitol

If you have been told that you have an intolerance to some sugars, you should not take PARIET.

3. How to take PARIET

Do not share medicines prescribed for you with any other person.
Always take PARIET tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with PARIET tablets will last. Do not stop early because your symptoms may reappear. If you have the impression that the effect of PARIET tablets is too strong or too weak, tell your doctor or pharmacist.

Taking this medicine

- Only remove a tablet from the blister strip when it is time to take your medicine
- Swallow the tablets whole with a drink of water. DO NOT chew or crush the tablets

- Your doctor will decide what dose of PARIET you should take, depending on your condition, e.g. 10 – 20 mg for 4 – 8 weeks initially or longer
- If you take PARIET for a long time, your doctor will want to monitor you.

Children

PARIET should not be used in children.

If you have liver problems:

Tell 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:

Do not take more tablets each day than you are prescribed.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take PARIET:

If you forget to take a dose, just take it immediately when you remember, and then continue as usual. Do not take a double dose to make up for the forgotten individual doses. If you forget to take your medicine for more than 5 days, call your doctor before taking any more medicine.

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.

4. Possible side effects

PARIET can have side effects. Not all side effects reported for PARIET are included in this leaflet. Should your general health worsen or if you experience any untoward effects while

taking PARIET, please consult your doctor, pharmacist or other healthcare professional for advice.

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: swelling of your face, tongue and throat, difficulty in breathing or low blood pressure which may cause fainting or collapse*
- *Frequent infections, such as sore throat or high temperature (fever), or ulcers in your mouth or throat*
- *Bruising or bleeding easily*
- *Severe skin blistering, or soreness of ulcers in your mouth and throat.*

Other possible side effects:

Frequent:

- 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.

Less frequent:

- Feeling nervous or drowsy
- Chest infections (bronchitis)

- Painful and blocked sinuses (sinusitis)
- Dry mouth
- Indigestion or belching
- Skin rash or redness
- Muscle, leg or joint pain
- Fracture of the hip, wrist or spine
- Bladder infection (urinary tract infection)
- Chest pain
- Chills or fever
- Changes in how your liver is working (shown in blood tests)
- 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 development 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 had previously had liver problems may very rarely get encephalopathy (a brain disease)
- Rash, possibly with pain in the joints.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety App (Medsafety X SAHPRA) and eReporting platform(who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PARIET.

5. How to store PARIET

Store at or below 25 °C.

Protect from moisture. Do not store in the refrigerator.

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.

Store all medicine out of reach of children.

How to Dispose of PARIET

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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

10 mg: Pink, film-coated biconvex tablets, with or without “E241” printed in black on one side.

20 mg: Light yellow, film-coated biconvex tablets, with or without “E243” printed in red on one side.

Primary packaging: Unit dose blister strips (aluminium/aluminium blister) of 14 tablets.

Holder of Certificate of Registration



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Registration numbers

PARIET 10 mg: 33/11.4.3/0206

PARIET 20 mg: 32/11.4.3/0614

Access to the corresponding Professional Information:

Included in the carton, accompanying this patient information leaflet.