

**Clean final patient information leaflet**

Submitted: 18 August 2015 ref: RA/2015/07/080cp

**Submission Type: Compliant response to CCC 04 June 2015**

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**CLEAN FINAL PATIENT INFORMATION LEAFLET**  
*(Clean version submitted 18 August 2015)*

**SCHEDULING STATUS**

Schedule 4

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

PARIET® 10 mg tablets

PARIET® 20 mg tablets

**Rabeprazole sodium**

**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 or your pharmacist.
- PARIET has been prescribed for you personally and you should not share it with other people. It may harm them, even if their symptoms are the same as yours.

**1.0 WHAT PARIET CONTAINS**

The active substance is rabeprazole sodium. Each yellow PARIET tablet contains 20 mg rabeprazole sodium; and each pink PARIET tablet contains 10 mg of rabeprazole sodium.

The other ingredients are: calcium carboxymethylcellulose, carnauba wax, diacetylated monoglycerides, ethylcellulose, ferric oxide, hydroxypropyl cellulose, hypromellose phthalate, low-substituted hydroxypropyl cellulose, magnesium oxide, magnesium stearate, mannitol, talc, titanium dioxide.

Ferric oxide red is used as an excipient in all 10 mg tablets and ferric oxide yellow is used as an excipient in all 20 mg tablets.

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## **2.0 WHAT PARIET 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

## **3.0 BEFORE YOU TAKE PARIET TABLETS**

**Do not take PARIET if:**

- You are hypersensitive (allergic) to rabeprazole sodium or any of the other ingredients of PARIET.
- You are allergic to substituted benzimidazoles (de-worming medicines)
- Pregnant or breastfeeding

### **Children**

PARIET should not be used in children.

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**Tell your doctor or pharmacist 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 are taking atazanavir for HIV infection.

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

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.

Treatment with PARIET may possibly increase the risk of stomach (gastrointestinal) infections such as *Clostridium difficile*, *Campylobacter* and *Salmonella*.

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).

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

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## **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.

## **Taking other medicines with PARIET:**

Always tell your healthcare professional if you are taking any other medicine. (This includes 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.

## **4.0 HOW TO TAKE PARIET**

Do not share medicines prescribed for you with any other person.

Always take PARIET 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 will last. Do not stop treatment early because you may get stomach ulcers. If you have the impression that the effect of PARIET is too strong or too weak for you, tell your doctor or pharmacist.

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**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 tell you how many tablets to take and how long to take them for. This will depend on your condition
- If you take PARIET for a long time, your doctor will want to monitor you
- Take the medicine in the morning before eating.

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.

**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 overdose, 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

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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.

**5.0 POSSIBLE SIDE EFFECTS**

PARIET can have side effects.

***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)*

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- *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*

**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*
- *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*

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- *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*
- *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).*

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.

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.

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

## **6.0 STORING AND DISPOSING OF PARIET**

Store all medicines out of reach of children.

Do not store above 25 °C. Do not refrigerate. Store in the original package. Do not store in bathrooms.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **7.0 PRESENTATION OF PARIET**

The tablets are packed in unit-dose aluminium foil blister strips of 14 tablets per strip.

Multiples of these blister strips are placed directly into a carton.

## **8.0 IDENTIFICATION OF PARIET**

10 mg: Pink, film-coated biconvex tablets

20 mg: Light yellow, film-coated biconvex tablets

## **9.0 REGISTRATION NUMBERS**

10 mg: 33/11.4.3/0206

20 mg: 32/11.4.3/0614

## **10.0 NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE**

**JANSSEN PHARMACEUTICA (PTY) LTD**  
PARIET® range : 10 mg and 20 mg tablets (rabeprazole)

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**11.0 DATE OF PUBLICATION**

Date of registration: 24 February 2000

Date of most recently revised patient information leaflet as approved by Council: 4 June  
2015