### PARIET®10 Tablets

#### **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

# 1. Why am I using PARIET 10?

PARIET 10 contains the active ingredient rabeprazole sodium. PARIET 10 is used for symptomatic relief of heartburn and stomach acid complaints due to gastro-oesophageal reflux.

For more information, see Section <u>1. Why am I using</u> PARIET 10? in the full CMI.

# 2. What should I know before I use PARIET 10?

Do not use if you have ever had an allergic reaction to rabeprazole sodium or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use PARIET 10? in the full CMI.

# 3. What if I am taking other medicines?

Some medicines may interfere with PARIET 10 and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

# 4. How do I use PARIET 10?

- The usual dose is one tablet per day, to be taken at the same time each day, for at least 7 days and up to 14 days.
- PARIET 10 should be swallowed whole, with a glass of water or other liquid.

More instructions can be found in Section 4. How do I use PARIET 10? in the full CMI.

# 5. What should I know while using PARIET 10?

# Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using rabeprazole sodium.
- Tell your doctor if you need to have a

	specific blood test (Chromogranin A) while you are taking PARIET 10.
Things you should not do	<ul> <li>Do not give this medicine to anyone else, even if they have the same symptoms as you.</li> <li>Do not crush or chew the tablets.</li> <li>You should not take PARIET 10 for more than 14 days unless directed by a doctor.</li> </ul>
Driving or using machines	<ul> <li>Make sure you know how you react to PARIET 10 before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.</li> </ul>
Looking after your medicine	<ul> <li>Keep PARIET 10 tablets in a cool dry place where the temperature is below 25°C. Do not keep PARIET 10 in the refrigerator or freezer.</li> <li>Do not take PARIET 10 tablets out of the blister</li> </ul>

pack until it is time to take them.

For more information, see Section <u>5. What should I know while using PARIET 10?</u> in the full CMI.

# 6. Are there any side effects?

PARIET 10 is usually well tolerated but tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PARIET 10. The common side effects include headache, dizziness, diarrhoea, nausea, abdominal pain, wind, vomiting, constipation, runny or blocked nose, sore throat, cough, non-specific pain, back pain, muscle pain, rash, muscle weakness, physical weakness or lack of energy, flu-like syndrome, infection, insomnia, and chest pain. The serious side effects include allergic or hypersensitivity reactions; frequent infections; urinary tract infection, vision or taste disturbance, depression, feeling dizzy, faint, lightheaded or weak (hypotension), pain or indigestion, begin to vomit blood or food, pass black (blood-stained) stools, symptoms of bowel inflammation such as severe (watery or bloody) diarrhoea, fever, abdominal pain or tenderness.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

# **PARIET® 10 Tablets**

Active ingredient(s): rabeprazole sodium

#### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using PARIET 10. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PARIET 10.

#### Where to find information in this leaflet:

- 1. Why am I using PARIET 10?
- 2. What should I know before I use PARIET 10?
- 3. What if I am taking other medicines?
- 4. How do I use PARIET 10?
- 5. What should I know while using PARIET 10?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I using PARIET 10?

# **PARIET 10 contains the active ingredient**

rabeprazole sodium. PARIET 10 belongs to a group of medicines called proton pump inhibitors (PPIs). PARIET 10 works by decreasing the amount of acid the stomach makes to give relief from the symptoms. Your food will still be digested in the same way.

PARIET 10 is used for symptomatic relief of heartburn and stomach acid complaints due to gastro-oesophageal reflux caused by "washing back" of food and acid from the stomach into the food pipe, also known as the oesophagus.

Reflux can cause a burning sensation in the chest, rising up to the throat, also known as heartburn. Frequent heartburn is when you have heartburn for two or more days a week. Heartburn that occurs frequently is a typical symptom of gastro-oesophageal reflux disease (GORD).

PARIET 10 will start to suppress acid within a few hours; however it will not give instant symptom relief. You may need to take PARIET 10 for a few days before experiencing the full effect.

There is no evidence that PARIET 10 is addictive.

# 2. What should I know before I use PARIET 10?

# **Warnings**

#### Do not use PARIET 10 if:

 you are allergic to rabeprazole sodium, other PPIs (omeprazole, esomeprazole, lansoprazole, pantoprazole), or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

### Check with your doctor or pharmacist if you:

- have now, or have had in the past, liver problems
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

## Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

#### Children and adolescents

PARIET 10 is not recommended for use in children under 18 years of age. Safety and effectiveness of PARIET 10 in children has not been established.

# 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

# Some medicines may interfere with PARIET 10 and affect how it works.

- clopidogrel, an antiplatelet medicine.
- cyclosporin, a medicine used to treat several conditions including prevention of graft rejection following kidney, liver or heart transplantation; severe, active rheumatoid arthritis; severe skin diseases; kidney disease where other treatments have failed.
- methotrexate, a medicine used to treat some kinds of cancer. It is also used to treat psoriasis (skin disease) and rheumatoid arthritis.
- digoxin, a medicine used to treat heart problems.
- ketoconazole, a medicine used to treat fungal infections.
- atazanavir, a medicine used to treat viral infections.
- mycophenolate mofetil, a medicine used to prevent organ rejection following kidney, liver or heart transplants.
- clarithromycin, a medicine used to treat infections.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PARIET 10.

# 4. How do I use PARIET 10?

#### How much to take

- The usual dose is one tablet per day.
- Follow the instructions provided with the medicine.

Do not exceed the recommended dosage.

#### When to take PARIET 10

- PARIET 10 should be taken at the same time each day.
- Take one tablet daily for at least 7 days and up to 14 days. You should not take PARIET 10 for more than 14 days unless directed by a doctor. If symptoms persist or recur within 14 days of completing the course, consult a doctor. Further examination may be required.
- If you forget to take your tablet, take it as soon as you remember and then continue to take it as you would normally. However, if it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose you missed. If you are not sure what to do, check with your doctor or pharmacist. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

#### **How to take PARIET 10**

- PARIET 10 should be swallowed whole, with a glass of water or other liquid.
- Do NOT crush or chew the tablets. They have a special coating, which protects them from the acid in your stomach. If the coating is broken by chewing, the tablets may not work.

 It does not matter if you take PARIET 10 with food or on an empty stomach.

### If you use too much PARIET 10

If you think that you have used too much PARIET 10, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

# 5. What should I know while using PARIET 10?

### Things you should do

 Tell your doctor if you need to have a specific blood test (Chromogranin A) while you are taking PARIET 10. It may affect the results of this test.

Remind any doctor, dentist or pharmacist you visit that you are using PARIET 10.

# Things you should not do

- Do not use PARIET 10 to treat any other complaints unless your doctor says to.
- Do not give this medicine to anyone else, even if they have the same symptoms as you.

# **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how PARIET 10 affects you.

PARIET 10 may cause dizziness in some people.

# Looking after your medicine

- Do not take PARIET 10 tablets out of the blister pack until it is time to take them. PARIET 10 tablets are packaged in a double-sided aluminium blister strip.
   If you take them out of the blister pack they may not keep well.
- Keep PARIET 10 tablets in a cool dry place where the temperature is below 25°C. Do not keep PARIET 10 in the refrigerator or freezer.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

#### Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

# 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

#### Less serious side effects

Less serious side effects	What to do
Brain or nervous system related:	Speak to your doctor or pharmacist if you have
• headache	any of these less serious
<ul><li>sleeplessness (insomnia)</li></ul>	side effects and they worry you.
<ul><li>sleepiness (somnolence)</li></ul>	
• nervousness	

Less serious side effects	What to do
Stomach or bowel related:	
<ul> <li>nausea</li> <li>vomiting</li> <li>stomach pain</li> <li>belching or indigestion</li> <li>wind</li> <li>diarrhoea</li> <li>constipation</li> </ul>	
<ul> <li>Skin related:</li> <li>rash or itchy rash accompanied by skin eruptions or blisters</li> <li>Muscle or joint related:</li> </ul>	
<ul> <li>pain (including back or joint pain)</li> <li>leg cramps</li> <li>muscle weakness, physical weakness or lack of energy</li> <li>Breathing related:</li> <li>cough</li> <li>flu-like symptoms</li> <li>runny or blocked nose</li> </ul>	

Less serious side effects	What to do
<ul> <li>sore throat and discomfort when swallowing</li> </ul>	
Other:	
<ul> <li>dry mouth</li> <li>swelling of the arms or legs</li> <li>loss of appetite for food</li> </ul>	
<ul><li>(anorexia)</li><li>weight gain</li></ul>	
<ul><li>sweating</li></ul>	
Long-term use related (when PPIs might be used for long periods of time under rare circumstances supervised by the doctor):	
<ul> <li>Low magnesium         can occur in some         people who take a         PPI. Symptoms of low         magnesium can include         seizures, dizziness,         spasms, cramps or         muscle weakness:</li> <li>Low magnesium can</li> </ul>	
lead to low calcium and/	

Less serious side effects	What to do
or low potassium levels in blood.  PPIs may reduce the amount of acid in your stomach. Stomach acid is needed to absorb vitamin B-12 properly. Talk with your doctor or pharmacist about the possibility of vitamin B-12 deficiency if you have been taking a PPI for a long time (i.e. more than 3 years).  People who take PPI medicines at high doses for a long period of time (1 year or longer) may have an increased risk of fractures of the hip, wrist, or spine.  Withdrawal of long-term PPI therapy may lead to worsening of acid-related symptoms.	

# **Serious side effects**

Serious side effects	What to do
Allergic or hypersensitivity reactions:	Call your doctor straight away, or go straight to the Emergency
<ul> <li>rash, reddening, blisters, itching or hives on the skin</li> <li>shortness of breath, wheezing or difficulty breathing</li> <li>swelling of the face, lips, tongue or other parts of the body</li> <li>Infection related:</li> </ul>	Department at your nearest hospital if you notice any of these serious side effects.
• inflammation of the	
<ul> <li>mouth and lips</li> <li>signs of frequent infections such as fever, chills, sore throat or mouth ulcers</li> </ul>	
<ul> <li>common symptoms of a urinary tract infection such as painful and/or frequent urination</li> </ul>	
Brain or nervous system related:	

Serious side effects	What to do
<ul><li>vision or taste disturbance</li></ul>	
<ul><li>depression</li></ul>	
<ul> <li>feeling dizzy, faint, lightheaded or weak (hypotension)</li> </ul>	
Heart related:	
• chest pain	
Stomach or bowel related:	
<ul> <li>pass black (blood- stained) stools</li> </ul>	
<ul> <li>symptoms of Clostridium difficile colitis (bowel inflammation) such</li> </ul>	
as severe (watery or bloody) diarrhoea, fever, abdominal pain or tenderness	

# Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

# Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. By reporting side effects, you can help provide more information on the safety of this medicine.

# 7. Product details

This medicine is available over-the-counter without a doctor's prescription. PARIET 10 is only available from your pharmacist or doctor.

#### What PARIET 10 contains

Active ingredient (main ingredient)	rabeprazole sodium
Other ingredients	mannitol,
(inactive ingredients)	magnesium oxide,
	hyprolose,
	magnesium stearate,
	ethylcellulose,
	hypromellose phthalate,
	diacetylated monoglycerides,

purified talc,
titanium dioxide,
carnauba wax,
red iron oxide and printed
with gray ink (Edible Ink
Gray F6)

Do not take this medicine if you are allergic to any of these ingredients.

The tablets do not contain lactose or gluten.

#### What PARIET 10 looks like

PARIET 10 tablets are pink and have "E241" in black ink on one side.

Each PARIET 10 tablet contains 10 mg rabeprazole sodium (Aust R 170438).

The tablets are available in blister packs of 7 and 14 tablets.

Not all pack sizes may be marketed.

#### **Who distributes PARIET 10**

JANSSEN-CILAG Pty Ltd

1-5 Khartoum Rd

Macquarie Park NSW 2113 Australia

Telephone: Toll Free 1800 226 334

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