PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

RABEMED 10 (tablets)

RABEMED 20 (tablets)

Rabeprazole

Each Rabemed 10 tablet contains mannitol (46,00 mg)

Each Rabemed 20 tablet contains mannitol (92,00 mg)

Read all of this leaflet carefully before you start taking RABEMED

- 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.
- RABEMED 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 RABEMED is and what it is used for

2. What you need to know before you take RABEMED

3. How to take RABEMED

4. Possible side effects

5. How to store RABEMED

6. Contents of the pack and other information

1. What RABEMED is and what it is used for

RABEMED belong to a group of medicines called Proton Pump Inhibitors (PPIs). RABEMED acts by reducing the amount of acid made by the stomach.

RABEMED tablets are used for:

- Symptomatic relief and healing of intestine ulcer and stomach ulcer.
- Symptomatic treatment of gastro-oesophageal reflux disease (GORD). GORD is a condition in which the stomach contents (food or liquid) leak backwards from the stomach into the oesophagus (the tube from the mouth to the stomach).
- Maintenance treatment of healed GORD. Efficacy has not been demonstrated for periods exceeding 12 months.
- Zollinger-Ellison Syndrome, where the stomach produces large amounts of acid and other pathological hypersecretory conditions.
- *H. Pylori*-positive duodenal ulcers (ulcers caused by *H. Pylori*), as part of the eradication program with appropriate antibiotics.

2. What you need to know before you take RABEMED

Do not take RABEMED if you:

- are hypersensitive (allergic) to rabeprazole sodium, other medications in this class (substituted benzimidazoles) or any of the other ingredients of RABEMED (listed in section 6).
- are pregnant or breastfeeding.

Warnings and precautions:

Take special care with RABEMED:

- If you are allergic to other proton pump inhibitors.
- If you have a liver problem.
- If you are taking a medicine called atazanavir (used to treat HIV), as co-administration with RABEMED is not recommended.

- If you have reduced body stores or risk factors for reduced vitamin B12 and receive long term treatment with RABEMED. As with all acid reducing agents, RABEMED may lead to a reduced absorption of vitamin B12.
- If you have ever had a skin reaction after treatment with a medicine similar to RABEMED 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 RABEMED. Remember to also mention any other ill-effects like pain in your joints.
- If you are due to have a specific blood test (Chromogranin A).
- RABEMED can cause a type of kidney problem (acute tubulointerstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including RABEMED, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with RABEMED and can progress to kidney failure. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine.

If the above applies to you, consult your doctor before taking RABEMED tablets.

Do not give RABEMED to children.

Your doctor may perform or have performed an additional investigation called an endoscopy in order to diagnose your condition and/or exclude malignant disease. The possibility of stomach and oesophageal tumours should be excluded before the treatment is started.

If you take RABEMED tablets on a long term basis (longer than one year) your doctor will probably monitor you regularly. You should report any new or different symptoms whenever you see your doctor.

Taking a proton pump inhibitor like RABEMED tablets, especially over a period of more than one year, may slightly increase your risk of fracture of 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).

Talk to your doctor straight away if you experience severe (watery or bloody) or persistent diarrhoea with symptoms such as fever, abdominal pain or tenderness, as RABEMED has been associated with a small increase in infectious diarrhoea.

If you are on RABEMED 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. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Some abnormal blood values have been reported during treatment with RABEMED tablets. Usually, the values become normal when the treatment is discontinued.

Children and adolescents:

RABEMED is not recommended for use in children.

Other medicines and RABEMED:

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Medicines that may interact with RABEMED include:

- Ketoconazole or itraconazole (medicines used for fungal infections).
- Digoxin (medicine used for heart).
- Medicines used to treat HIV-infection, such as atazanavir.
- Methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer).

RABEMED with food and drink:

RABEMED may be taken with or without meals and should be swallowed whole with water.

Pregnancy, breastfeeding and fertility:

Do not take RABEMED if you are pregnant or breastfeeding 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 this medicine.

Driving and using machines:

You should not drive or operate machinery until you know how RABEMED affects you. RABEMED may cause dizziness or sleepiness.

3. How to take RABEMED

Always take RABEMED exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not stop taking RABEMED until you finished all your tablets even though you may start feeling better as your symptoms may return.

If symptom control has not been achieved after four weeks of treatment with the prescribed daily dose, further investigation is recommended.

Do not chew or crush tablets.

RABEMED may be taken with or without meals and should be swallowed whole with water.

Your doctor will prescribe the appropriate dose for you, depending on your condition and duration of treatment.

Method of administration:

If you are required to take RABEMED tablets once a day, you should take RABEMED tablets in the morning, before eating.

If you have the impression that the effect of RABEMED is too strong or too weak, talk to your doctor or pharmacist.

If you take more RABEMED than you should:

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

If you forget to take RABEMED:

Take a tablet as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed tablet at all. Do not take a double dose to make up for forgotten individual doses.

If you stop taking RABEMED:

Do not stop taking RABEMED until you finished all your tablets even though you may start feeling better as your symptoms may return.

4. Possible side effects

RABEMED can have side effects.

Not all side effects reported for RABEMED are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RABEMED, please consult your health care provider for advice.

If any of the following happen, stop taking RABEMED and tell or consult your doctor immediately or go to the casualty department at your nearest hospital:

- sudden wheezing, swelling of your lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction);
- chest pain;

- sign of infections, such as a sore throat or high temperature (fever);
- reddening of the skin with blisters or peeling and may be associated with a high fever and joint pains. There may also be ulcers in your mouth or throat (this could be erythema multiforme, Stevens-Johnson syndrome or toxic epidermal necrolysis);
- weakness;
- yellowing of the skin and eyes also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious reaction to RABEMED. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- infection;
- dizziness;
- headache;
- nausea (feeling sick);
- vomiting (being sick);
- diarrhoea;
- effects on your stomach or gut such as stomach pain;
- wind (flatulence);
- constipation;
- benign polyps (non-cancerous growths) in the stomach;
- difficulty sleeping;
- cough;
- sore throat (inflammation of the pharynx);
- runny nose;
- back pain;
- non-specific pain;

- flu-like symptoms;
- feeling abnormally weak and without energy.

Less frequent side effects:

- 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;
- loss of appetite and weight loss (anorexia);
- nervousness;
- depression;
- agitation;
- hallucinations;
- anxiety;
- night terrors (nightmares);
- poor concentration;
- feeling of tingling, prickling, pins and needles, burning sensation or numbness;
- sleepiness;
- visual disturbances;
- inflammation of the bronchial tubes in the lungs (bronchitis);
- inflammation of the sinuses (sinusitis);
- dryness of mouth;
- indigestion;
- belching;
- inflammation of the stomach;
- inflammation of the mouth;
- taste disturbance;
- inflammation of the liver;
- brain disturbance associated with liver failure (hepatic encephalopathy);

- rash;
- skin redness (erythema);
- lumpy rash (hives);
- hair loss;
- skin blisters;
- itching;
- sweating;
- joint pains, muscle pains, leg cramps;
- muscle weakness;
- fracture of the hip, wrist or spine;
- urinary tract infection;
- kidney inflammation (tubulointerstitial nephritis) which could progress to kidney failure;
- problems with getting or maintaining an erection (impotence);
- chills, fever;
- feeling weak, exhausted or generally unwell;
- spinning feeling (vertigo);
- ringing in the ears (tinnitus);
- increased liver enzymes, which is measured by blood tests;
- increased weight.

The frequency of the following side effects are unknown:

- low levels of sodium in the blood (seen in blood test);
- low levels of magnesium in the blood (seen in blood test);
- confusion;
- swelling of the feet and ankles;
- inflammation in the gut, leading to diarrhoea (macroscopic colitis);
- skin rash on areas exposed to sunlight (subacute cutaneous lupus erythematosus);
- enlarged breasts in men.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of RABEMED.

Suspected side effects can also be reported directly to the holder of certificate of registration via Patientsafety.sacg@novartis.com.

5. How to store RABEMED

Store at or below 25 °C.

Keep the blisters in the outer carton until required for use.

In order to protect from moisture, do not store in bathrooms.

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

Return all unused medicine to your pharmacist.

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

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What RABEMED contains:

The active substance is rabeprazole sodium 10 or 20 mg per tablet.

The other ingredients are calcium hydroxide, mannitol, low-substituted hydroxypropyl cellulose, sodium stearyl fumarate, hypromellose, talc, hypromellose phthalate, dibutyl sebacate, yellow ferric oxide (E172), red ferric oxide (E172), titanium dioxide (E171).

What RABEMED looks like and contents of the pack:

Rabemed 10: Pink, round, biconvex coated tablets.

Rabemed 20: Yellow, round, biconvex coated tablets.

Rabemed 10: Packed in Alcan blisters (Al/Al blister with a desiccant). The Al/Al blister with a desiccant consists of a coldform foil (soft, aluminium foil, matte, with a desiccant) and a lidding foil (hard aluminium foil). The lidding foil is primered and coated with LDPE, acting as the heatseal lacquer which seals to HDPE coating of the forming foil. 4 blisters are packed into an outer cardboard carton box as 28 tablets.

Rabemed 20: Packed in Alcan blisters (Al/Al blister with a desiccant). The Al/Al blister with a desiccant consists of a coldform foil (soft, aluminium foil, matte, with a desiccant) and a lidding foil (hard aluminium foil). The lidding foil is primered and coated with LDPE, acting as the heatseal lacquer which seals to HDPE coating of the forming foil. 2 or 4 blisters are packed into an outer cardboard carton box as 14 or 28 tablets. (Each blister contains 7 tablets).

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

This leaflet was last revised in

To be confirmed

Registration numbers

Rabemed 10: 44/11.4.3/0597

Rabemed 20: 44/11.4.3/0598

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07