

PROPOSED CLEAN PATIENT INFORMATION LEAFLET
RBC PHARMACEUTICALS (PTY) LTD.
PANTAKIND-40 (Pantoprazole sodium, Delayed release tablets)

SCHEDULING STATUS:

S4

PANTAKIND-40 (40 mg enteric coated tablet)

Pantoprazole sodium

Sugar free

Read this full leaflet carefully before your medical practitioner administers PANTAKIND-40.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- PANTAKIND-40 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 PANTAKIND-40 is and what it is used for
2. What you need to know before your doctor administers PANTAKIND-40
3. How PANTAKIND-40 will be given to you
4. Possible side effects that you may experience
5. How to store PANTAKIND-40
6. Contents of the pack and other information

1. What PANTAKIND-40 is and what it is used for.

The active substance of PANTAKIND-40 is Pantoprazole sodium.

PANTAKIND-40 is used to treat ulcers in your stomach or intestine. It acts by preventing the excessive acid formation and rising of acid from your stomach into your oesophagus (food pipe), which causes a sensation of severe heartburn.

PANTAKIND-40 may also be given with antibiotics to treat ulcers in the intestine infected with bacteria called *Helicobacter pylori* as a co-prescription medicine.

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It is also used in the:

- treatment of Zollinger-Ellison Syndrome
- relief of symptoms like Heartburn, acid reflux and pain on swallowing
- treatment of mild gastroesophageal reflux disease

2. What you need to know before you are given PANTAKIND-40.

PANTAKIND-40 should not be given to you if you:

- If you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of PANTAKIND-40 (listed in section 6).
- If you are allergic to medicines containing other proton pump inhibitors.
- If your liver function is severely impaired.
- Safety in children has not been established.
- If you are taking HIV protease inhibitors such as atazanavir or nelfinavir (for the treatment of HIV-infection).

Warnings and precautions

Special care should be taken with PANTAKIND-40:

Tell your doctor or health care provider before being given the PANTAKIND-40:

- If you suffer from liver or kidney disease.
- If you think you have signs of stomach cancer. These include weight loss, dark stools, loss of appetite, feeling full or a sensation of a lump in your stomach.
- If you are taking any HIV protease inhibitor medicines like atazanavir etc.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive long-term treatment with PANTAKIND-40. As with all acid reducing agents, PANTAKIND-40 may lead to a reduced absorption of vitamin B12.
- If you take PANTAKIND-40 on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.
- If you have severe and/or persistent diarrhoea, because this medicine has been associated with a small

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increase in infectious diarrhoea.

- If you are on PANTAKIND-40 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.
- Taking a proton pump inhibitor like PANTAKIND-40, 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).
- 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 PANTAKIND-40. 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).

If any of the above statements apply to you, ask your doctor or pharmacist for advice before you take PANTAKIND-40.

Children and adolescents

PANTAKIND-40 is not recommended for use in children.

Other medicines and PANTAKIND-40

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

(This includes complimentary, over-the-counter traditional medicines).

Inform your doctor if you take:

- Medicines used to treat HIV-infection, such as atazanavir.
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks.
- Fluvoxamine (used to treat depression and other psychiatric diseases) – if you are taking fluvoxamine your doctor may reduce your PANTAKIND-40 dose.
- Medicines (used to treat infections).

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- Erlotinib, which is used to treat certain cancers, as PANTAKIND-40 may prevent this medicine from working properly.
- Tablets containing ketoconazole, itraconazole or posaconazole, used to treat fungal infections to the skin and nails. This is because PANTAKIND-40 may increase or decrease the effect of ketoconazole, itraconazole or posaconazole, by altering the amount that gets in your body.
- St John's wort (*Hypericum perforatum*) (used to treat mild depression).
- Methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your PANTAKIND-40 treatment because pantoprazole can increase levels of methotrexate in the blood.

Tell your doctor or your pharmacist if you are taking, or have recently taken, any other medicine – even those not prescribed.

Receiving PANTAKIND-40 with food and drink

PANTAKIND-40 is not known to be affected by food.

Pregnancy, breastfeeding and fertility

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 receiving PANTAKIND-40.

You should not take PANTAKIND-40 if you are pregnant or breastfeeding.

Driving and using machines

If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

PANTAKIND-40 contains colourants

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to receive PANTAKIND-40

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

Always take PANTAKIND-40 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one 40 mg tablet per day.

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Swallow the tablet whole, with a drink of water, 1 hour before a meal. Do not crush, break or chew the tablet.

If you have ulcers in your intestine, your doctor may advise you to take your tablets for between 2 to 4 weeks.

If you have ulcers in your stomach or acid regurgitation, your doctor may advise you to take your tablets for 4 to 8 weeks.

For adolescents of 12 years and older, your doctor may advise you to take your tablet for 4 to 8 weeks.

If your stomach is producing too much acid, you will usually be advised to take a starting dose of two 40 mg tablets per day.

Your doctor will adjust the dose to match the amount of acid your stomach produces.

For ulcers infected with the bacteria *Helicobacter pylori* you may have to take one PANTAKIND-40 mg tablet plus your antibiotic tablet/capsule, according to your doctor's prescription. Take these medicines at the same time and take the second dose before your evening meal.

Take the tablets until you have finished the course of treatment or until your doctor tells you to stop.

PANTAKIND-40 mg is not recommended for use in children.

If you have the impression that the effect of PANTAKIND-40 is too strong or too weak, talk to your doctor or pharmacist.

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

If you are given more PANTAKIND-40 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 receive PANTAKIND-40:

Do not take a double dose to make up for forgotten individual doses.

If you forget to take a tablet, take it 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 two tablets at once to make up for the one you have missed.

If you stop taking PANTAKIND-40:

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Do not stop taking PANTAKIND-40 just because you feel better. If you stop taking your tablets too soon, your symptoms may return.

4. Possible side effects:

PANTAKIND-40 can have side effects.

Not all side effects reported for PANTAKIND-40 are included in this leaflet. Should your general health worsen while receiving PANTAKIND-40, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop administration of PANTAKIND-40 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Severe anaphylactic reactions (sometimes seen as swollen tongue or throat, feeling faint, increased sweating or increased pulse rate).
- Swelling of your kidneys (sometimes seen as lower back discomfort, changes (either more or less) in the amount of urine you pass or traces of blood in your urine).
- Liver problems (often seen as yellowing of your skin or the whites of your eyes).
- Blistering of your skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals (Stevens-Johnson-Syndrome, Lyell-Syndrome, Erythema multiforme), sensitivity to sunlight and drug rash with eosinophilia and systemic symptoms (DRESS) which is a type of drug allergy which can occur as a reaction to a large variety of medications.

These are all very serious side effects. If you have them, you may have had a serious reaction to PANTAKIND-40. You may need urgent medical attention or hospitalisation.

Frequent side effects:

Headache, Benign polyps (non-cancerous growths) in the stomach

Less frequent side effects:

- A reduction in white cells in your blood (often seen by increased infections)
- A reduction in platelets in your blood (often seen as a tendency to bruise or bleed)
- Sharp drop in circulating granular white blood cells, associated with high fever (seen in blood test)
- Coexisting abnormal reduction in the number of red and white blood cells, as well as platelets (seen in

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blood test)

- Skin rash
- Itchiness
- Sleep disorders
- Disorientation
- Dizziness
- Distortion or complete lack of the sense of taste
- Blurred vision
- Diarrhoea
- Feeling sick
- Being sick
- Wind
- Constipation
- Dry mouth
- Stomach pain
- Increases in some of the chemicals in your liver
- Increase in bilirubin (seen in blood test)
- Swollen ankles, legs or arms
- Fracture in the hip, wrist or spine
- Joint pain
- Muscle pain
- Feeling weak, exhausted or generally unwell
- Fever
- swelling
- Weight changes
- Breast enlargement in males
- Increased fats in your blood

Frequency unknown side effects:

- Decreased level of sodium in blood (seen in blood test)

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- Decreased level of magnesium in blood (seen in blood test)
- Decreased level of potassium in blood (seen in blood test)
- Hallucination
- Confusion
- Feeling of tingling, prickling, pins and needles, burning sensation or numbness
- Inflammation in the large bowel, that causes persistent watery diarrhoea
- Liver damage, Liver failure
- Severe skin reactions

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or health care professional. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform ([who-umc.org](https://www.who-umc.org)) found on SAHPRA website. <https://www.sahpra.org.za/Publications/Index/8> By reporting side effects, you can help provide more information on the safety of PANTAKIND-40.

5. How to store PANTAKIND-40

Do Not Store above 30 °C.

Keep the container tightly closed.

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

Return all unused medicine to your pharmacist.

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

Keep all medicines out of reach and sight of children.

6. Contents of the pack and other information

What PANTAKIND-40 contains:

The active substance is pantoprazole sodium.

PANTAKIND-40: Each enteric coated tablet contains pantoprazole sodium equivalent to 40 mg of pantoprazole.

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The other ingredients are Calcium stearate, Crospovidone, Hypromellose, Mannitol, Polyethylene glycol, Purified Water, Silicon dioxide, Sodium carbonate anhydrous, Sucrose, Talc, Methacrylic acid - Ethyl acrylate copolymer (1:1), Triethyl citrate, Isopropyl alcohol, Opadry brown 00B565003 (HPMC 2910/Hypromellose, MACROGOL/PEG, Talc, Iron Oxide Red and Ferrosoferric Oxide NF/ Black Iron Oxide), Opacode black (Ink) (Shellac Glaze, Isopropyl Alcohol, Black Iron Oxide, n-Butyl Alcohol, Propylene Glycol and Ammonium Hydroxide).

What PANTAKIND-40 looks like and contents of the pack:

Light brown to brown, round, biconvex tablets imprinted with 'L9' on one side and plain on the other side.

10 tablets are packed in Blister. 3 such blisters are packed in a carton.

REGISTRATION NUMBER

57/11.4.3/0571

Holder of Certificate of Registration

RBC PHARMACEUTICALS (PTY) LTD.

23 Kiaat Street, ERF 926, Extension 7,

Noordwyk, Midrand, Gauteng,

South Africa, 1687

This leaflet was last revised on:

TBA

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration: RBC PHARMACEUTICALS (PTY) LTD. Tel: +27 10 224 0999

Other sources of information

Detailed information on this medicine is available on the RBC PHARMACEUTICALS (PTY) LTD web site:

<http://www.rbcpharma.com>