PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PANTOPRAZOLE UNICORN 20 (enteric-coated tablet)

PANTOPRAZOLE UNICORN 40 (enteric-coated tablet)

Pantoprazole

Sugar free

Read all of this leaflet carefully before you start taking PANTOPRAZOLE UNICORN

- 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.
- **PANTOPRAZOLE UNICORN** 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 **PANTOPRAZOLE UNICORN** is and what it is used for
2. What you need to know before you take **PANTOPRAZOLE UNICORN**
3. How to take **PANTOPRAZOLE UNICORN**
4. Possible side effects
5. How to store **PANTOPRAZOLE UNICORN**
6. Contents of the pack and other information

1. What PANTOPRAZOLE UNICORN is and what it is used for

PANTOPRAZOLE UNICORN 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.

PANTOPRAZOLE UNICORN may also be given with antibiotics to treat ulcers in the intestine infected with bacteria called *Helicobacter pylori*.

It is also used in the:

- treatment of Zollinger-Ellison Syndrome
- relief of symptoms like heartburn, acid reflux and pain on swallowing, and
- treatment of mild gastro-esophageal reflux disease

2. What you need to know before you take PANTOPRAZOLE UNICORN

Do not take PANTOPRAZOLE UNICORN:

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

Warnings and precautions

Take special care with PANTOPRAZOLE UNICORN:

- If you suffer from liver or kidney disease.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive long-term treatment with **PANTOPRAZOLE UNICORN**. As with all acid reducing agents, **PANTOPRAZOLE UNICORN** may lead to a reduced absorption of vitamin B12.
- 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 take **PANTOPRAZOLE UNICORN** 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 increase in infectious diarrhoea.

- 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 **PANTOPRAZOLE UNICORN**. Remember to also mention any other ill-effects like pain in your joints.
- If you are on **PANTOPRAZOLE UNICORN** 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 **PANTOPRAZOLE UNICORN**, 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 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 **PANTOPRAZOLE UNICORN**.

Children and adolescents

PANTOPRAZOLE UNICORN is not recommended for use in children, as it has not been proven to work in children below 12 years of age.

Other medicines and PANTOPRAZOLE UNICORN

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Inform your doctor if you take:

- Tablets containing ketoconazole, itraconazole or posaconazole, used to treat fungal infections to the skin and nails. This is because **PANTOPRAZOLE UNICORN** may increase or decrease the effect of ketoconazole, itraconazole or posaconazole, by altering the amount that gets in your body.



- Erlotinib, which is used to treat certain cancers, as **PANTOPRAZOLE UNICORN** may prevent this medicine from working properly.
- 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 **PANTOPRAZOLE UNICORN** dose.
- Rifampicin (used to treat infections).
- 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 **PANTOPRAZOLE UNICORN** 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.

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 healthcare provider for advice before taking **PANTOPRAZOLE UNICORN**.

You should not take **PANTOPRAZOLE UNICORN** 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.

PANTOPRAZOLE UNICORN contains colourants

The tablets also contain colourants, including Quinoline yellow aluminium lake (E104), which may generate allergic reactions.

3. How to take PANTOPRAZOLE UNICORN

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

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

The usual dose is one 20 mg or 40 mg tablet per day.

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 **PANTOPRAZOLE UNICORN** 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.

PANTOPRAZOLE UNICORN 20 mg or 40 mg is not recommended for use in children below 12 years.

If you have the impression that the effect of **PANTOPRAZOLE UNICORN** 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 take more PANTOPRAZOLE UNICORN 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 PANTOPRAZOLE UNICORN

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 PANTOPRAZOLE UNICORN

Do not stop taking **PANTOPRAZOLE UNICORN** just because you feel better. If you stop taking your tablets too soon, your symptoms may return.

4. Possible side effects

PANTOPRAZOLE UNICORN can have side effects.

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

If any of the following happens, stop taking **PANTOPRAZOLE UNICORN** 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 **PANTOPRAZOLE UNICORN**. You may need urgent medical attention or hospitalisation.

Frequent side effects:

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

Less frequent side effects:

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

The frequency of the following side effects are unknown:

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

If any of the side effects get serious, or if you notice any side effects not listed in the leaflet, tell you 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 **PANTOPRAZOLE UNICORN**.

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store PANTOPRAZOLE UNICORN

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store tightly closed at or below 25 °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).

6. Contents of the pack and other information

What PANTOPRAZOLE UNICORN contains

PANTOPRAZOLE UNICORN 20: Each enteric-coated tablet contains pantoprazole sodium sesquihydrate equivalent to 20 mg of pantoprazole.

PANTOPRAZOLE UNICORN 40: Each enteric-coated tablet contains pantoprazole sodium sesquihydrate equivalent to 40 mg of pantoprazole.

The other ingredients are calcium stearate, cellulose – microcrystalline, crospovidone, type A, ferric oxide yellow (E172), hydroxypropylcellulose (type EXF), hypromellose, macrogol 400, methacrylic acid - ethyl acrylate copolymer (1:1) dispersion, opadry yellow, polysorbate 80, ponceau 4R aluminium lake (E124), quinoline yellow aluminium lake (E104), silica – colloidal anhydrous, sodium carbonate - anhydrous, sodium lauryl sulfate, titanium dioxide E171, triethyl citrate.

What PANTOPRAZOLE UNICORN looks like and contents of the pack

PANTOPRAZOLE UNICORN 20: A yellow, oval, enteric-coated tablet; dimensions approximately 8,9 x 4,6 mm.

PANTOPRAZOLE UNICORN 40: A yellow, oval, enteric-coated tablet; dimensions approximately 11,7 x 6,0 mm.

White polyethylene containers with white polypropylene screw cap (tamper evident) with a desiccant insert, containing 14, 28, 30, 56, 100, 250, 300 or 500 tablets.

Aluminium foil and OPA/Al/PVC foil blister strips packed in cardboard cartons, containing 14, 28, 30 or 56 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Waterfall 5-lr

Magwa Crescent West

Waterfall City

Jukskei View

2090

Marketed by **UNICORN PHARMACEUTICALS (PTY) LTD**

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Access to the corresponding Professional Information

Not applicable.

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