PATIENT INFORMATION LEAFLET for

LANSOPRAZOLE UNICORN

SCHEDULING STATUS:

S4

LANSOPRAZOLE UNICORN 15, capsules

LANSOPRAZOLE UNICORN 30, capsules

LANSOPRAZOLE UNICORN 15: Each capsule contains 15 mg lansoprazole.

Contains sugar. Sugar spheres: 70,00 mg and Sucrose: 16,55 mg

LANSOPRAZOLE UNICORN 30: Each capsule contains 30 mg lansoprazole.

Contains sugar. Sugar spheres: 140,00 mg and Sucrose: 33,10 mg

Please read all of this leaflet carefully before you start taking LANSOPRAZOLE UNICORN capsules

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **LANSOPRAZOLE 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 LANSOPRAZOLE UNICORN is and what it is used for

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

3. How to take LANSOPRAZOLE UNICORN

4. Possible side effects

5. How to store LANSOPRAZOLE UNICORN

6. Contents of the pack and other information

1. WHAT LANSOPRAZOLE UNICORN is and what it is used for

The active substance is lansoprazole. This medicine is known as a “proton pump inhibitor”, which reduces the production of acid in your stomach.

LANSOPRAZOLE UNICORN is indicated for

Helicobacter pylori- positive duodenal (small intestine) ulcers in conjunction with appropriate antibiotics as part of an eradication programme.

LANSOPRAZOLE UNICORN 30 is used in the short-term treatment of gastric (stomach) and duodenal (small intestine) ulcers and inflammation of oesophagus due to reflux of stomach acid.

LANSOPRAZOLE UNICORN 15 is used in the short-term management of mild functional dyspepsia (indigestion) and to prevent reflux of the stomach acid into the oesophagus.

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

Do not take LANSOPRAZOLE UNICORN:

- If you are hypersensitive (allergic) to lansoprazole or any of the other ingredients of **LANSOPRAZOLE UNICORN** (see **WHAT LANSOPRAZOLE UNICORN CONTAINS**).
- If you are pregnant or breastfeeding your infant.
- If you have liver impairment.
- If you are taking atazanavir or nelfinavir (used to treat HIV).

Take special care with LANSOPRAZOLE UNICORN:

- It is not known whether **LANSOPRAZOLE UNICORN** is safe and effective in children.
- Taking **LANSOPRAZOLE UNICORN** may improve the symptoms of cancerous ulcers which can delay diagnosis. Therefore, if you experience unintentional weight loss, recurrent vomiting, difficulty or discomfort when swallowing, vomiting blood, or dark stool with blood or if you suspect a stomach ulcer, tell your doctor.
- **LANSOPRAZOLE UNICORN** may affect the kidneys (interstitial nephritis). Inform your doctor if you experience any blood in your urine, pain while urinating or lower back pain.
- **LANSOPRAZOLE UNICORN** may be associated with an increased risk of *Clostridium difficile*-associated diarrhoea (CDAD) (you may develop diarrhoea that does not improve). Contact your doctor or healthcare professional as soon as possible.
- If you have low vitamin B12 levels or have risk factors for low vitamin B12 levels and you are using **LANSOPRAZOLE UNICORN** long period of time. **LANSOPRAZOLE UNICORN** reduces the amount of acid in your stomach. Stomach acid is needed to absorb vitamin B12 properly.
- **LANSOPRAZOLE UNICORN** may also affect the absorption of vitamin C and calcium.
- If you develop a rash on your skin (especially in areas exposed to the sun) or experience pain in you joints, tell your doctor as soon as you can. Your doctor may need to stop your treatment with **LANSOPRAZOLE UNICORN.**
- If you have been told you have low magnesium levels in your blood. Low levels of magnesium may cause tiredness; muscle cramps, spasms or tremors; confusion,

convulsions, dizziness and irregular heartbeat. This may be worsened while taking **LANSOPRAZOLE UNICORN**. If you are expected to be on long term treatment or are taking **LANSOPRAZOLE UNICORN** with digoxin or medicines which may cause low level of magnesium (e.g. water tablets), tell your doctor as **LANSOPRAZOLE UNICORN** can further reduce your magnesium levels.

- **LANSOPRAZOLE UNICORN** may increase your risk of hip, wrist and spine fracture. If you are at risk of osteoporosis, your doctor may advise you to take vitamin D and calcium. (See **POSSIBLE SIDE EFFECTS**.)
- If you experience severe diarrhoea, and it does not improve while using **LANSOPRAZOLE UNICORN**, you should see your doctor.
- Your doctor may conduct a test known as endoscopy before prescribing **LANSOPRAZOLE UNICORN**.
- If you experience symptoms such as diarrhoea, stomach cramping or stomach pain, please contact your doctor, as **LANSOPRAZOLE UNICORN** may lead to an increased risk of bacterial infections (*Salmonella, Campylobacter, Shigella* and *Clostridium difficile*) in your gastrointestinal tract.
- If you are due to have a specific blood test (Chromogranin A), talk to your doctor or pharmacist before taking **LANSOPRAZOLE UNICORN**.
- If you have liver problems.
- If you are using a medicine methotrexate (used for the treatment of auto-immune diseases).
- If you have been diagnosed with porphyria (a disorder where your body cannot break down certain foods or medicines).

Other medicines and LANSOPRAZOLE UNICORN:

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

includes complementary or traditional medicines.)

The following medicines may interact with **LANSOPRAZOLE UNICORN:**

- Ampicillin (antibiotic)
- Itraconazole, ketoconazole, osaconazole, voriconazole (to treat fungal infections)
- Iron supplements
- Digoxin (to treat heart problems)
- Dasatinib and erlotinib (used to treat cancer)
- Atazanavir and nelfinavir(to treat HIV)
- Theophylline (to treat a tight chest)
- Tacrolimus (to prevent transplant rejection)
- Fluvoxamine (used to treat depression)
- Rifampicin (to treat TB)
- St John's wort (to treat anxiety)
- Warfarin and clopidogrel (to prevent blood clots)
- Sucralfate (to treat ulcers)
- Antacids
- Methotrexate (to treat cancer).

LANSOPRAZOLE UNICORN with food or drink:

If you take **LANSOPRAZOLE UNICORN** within 30 minutes of food intake, it may result in lower lansoprazole plasma levels. Therefore, you should take **LANSOPRAZOLE UNICORN** before meals, preferably in the morning.

Pregnancy and breastfeeding:

You should not take **LANSOPRAZOLE UNICORN** while you are pregnant or

breastfeeding your baby.

If you are pregnant or breastfeeding your baby, p[Ꝑ]lease consult your doctor, pharmacist or other health care professional for advice before taking **LANSOPRAZOLE UNICORN**.

Driving and using machinery:

LANSOPRAZOLE UNICORN may impair your concentration and lead to drowsiness. If you simultaneously use alcohol or other central nervous system depressants, the drowsiness may be aggravated. Do not take charge of vehicles or machinery or perform potentially hazardous tasks where loss of concentration could lead to accidents.

Information about ingredients in LANSOPRAZOLE UNICORN:

LANSOPRAZOLE UNICORN contains a sugar called sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **LANSOPRAZOLE UNICORN.**

LANSOPRAZOLE UNICORN contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to use LANSOPRAZOLE UNICORN

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

Always take **LANSOPRAZOLE UNICORN** 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 treatment with **LANSOPRAZOLE UNICORN** will last.

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

Take **LANSOPRAZOLE UNICORN** before a meal, preferably in the morning.

LANSOPRAZOLE UNICORN capsules should be swallowed whole with a glass of water

and not crushed or chewed.

Do not stop treatment early because your condition may not be adequately treated and may worsen.

If you take more LANSOPRAZOLE UNICORN than you should:

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

Take this leaflet and the rest of the remaining **LANSOPRAZOLE UNICORN** with you so the doctor will know what you have taken.

If you forget to take LANSOPRAZOLE UNICORN:

If you missed a dose, take it as soon as you remember. However, if it is almost time for your next dose, continue to take the next capsule at the usual time. Do not take a double dose to make up for the forgotten individual doses

If you have trouble remembering when to take your medicine, ask your pharmacist for advice.

4. Possible side effects

LANSOPRAZOLE UNICORN can have side effects.

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

If any of the following happens, stop taking **LANSOPRAZOLE UNICORN** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- fever
- rash or itching
- 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 allergic reaction to **LANSOPRAZOLE UNICORN**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- **LANSOPRAZOLE UNICORN** may reduce the number of white cells in your blood, which may decrease your ability to fight infections. If you experience any infection with symptoms such as fever or a serious deterioration in your general health, or a fever with symptoms such as sore throat/mouth, or bladder problems, you should see your doctor immediately.
- chest pain, angina, changes in the way your heart beats, for example, if you notice it beating faster, slower, harder or irregular, difficulty in breathing, palpitations
- swelling, stroke, high or low blood pressure, migraine, fainting, shock (occurs when the body is not getting enough blood flow), an increase in blood vessels causing increased blood flow with redness of skin or warmth.
- a persistent, scaly red patch on the skin with irregular borders that sometimes crusts or bleeds (skin cancer)
- very serious skin reactions with reddening, blistering, severe inflammation and skin loss
- serious kidney problems: less urine than is normal for you, swelling of the legs, ankles

or feet, nausea or extreme tiredness, seizures or coma in severe cases.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- Headache, dizziness.
- Diarrhoea, nausea, vomiting, constipation, gas, dry mouth or throat, stomach pain, stomach polyps (cancer).
- An increase in liver enzymes.
- Skin rash, itching, hives (swelling of the skin).
- Feeling tired.

Less frequent

- Gout, feeling dehydrated, high and low blood glucose levels, swelling of the limbs, weight loss or gain.
- Feeling agitated, anxious, confused, depressed, hostile, aggravated, nervous; lack of interest, uncontrolled emotions, irrational anxiety/obsession, feeling disconnected, having abnormal thoughts, unable to sleep and other sleep disorders.
- Feeling drowsy, tremor, convulsions, muscle weakness/partial paralysis, numb feeling, tingling feeling of “pins and needles” in fingers and toes, feeling unbalanced, seeing double and feeling restless.
- Abnormal or blurred vision, itchy, water or red eyes, dry eyes, eye pain, sensitivity of eyes to the light, blurred vision and other problems with your vision including double vision
- Deafness, ear disorder, middle ear infection, ringing in ear
- Difficulty in breathing/ tight chest, increased coughing, shortness of breath, nose bleed

or coughing blood, hiccups, inflammation of the throat causing sore or scratchy throat or pain swallowing, inflammation of the lungs and breathing disorders, runny or blocked nose, sinus headache, abnormal noise when breathing, change in smelling sense.

- Inflammation of the tongue, mouth, lips, colon, stomach, small intestines, oesophagus, or pancreas; change in taste, bad breath, a blockage in your stomach/intestines, excess wind or gas, difficulty swallowing (narrowing or tightening of the oesophagus), discoloured faeces, disorders affecting the stomach and/or intestines, bleeding in the stomach, intestines or rectum; or gums, vomiting (sometimes with blood), increase in appetite, increase in saliva, blood in stool, mouth ulcer, thrush in the mouth, pain in the anus, feeling thirsty, tongue disorder, painful ulcers in the mouth, loss in taste, change in taste, thrush in the throat.
- Gall stones, inflammation of the liver, liver injury causing build-up of bilirubin causing yellowing of the skin and eyes.
- Hair loss and disorders, acne, inflammation of the skin, dry skin, rashes including both flat and raised skin lesions, problems with nails, sweating, tiny round, brown-purple spots due to bleeding under the skin, a rash of purple spots due to small blood vessels leaking blood into the skin, joints, intestines or organs; serious allergic reactions.
- Pain in joints and muscles, fracture of the hip, wrist or spine; joint disorders, leg cramping, inflammation of the joints, back pain, feeling chills, neck pain, stiff neck and weakness in muscles.
- Pain or discomfort on urination, kidney stones, back pain (kidney pain), excessive or abnormally large production of urine, frequent urination or the need to constantly urinate, urinary infection
- Breast enlargement or tenderness in both men and women, milky discharge from your nipples, pain in the pelvis, decrease or increase in sexual drive, abnormal periods

(heavy, lighter, longer or more painful), tender or painful breasts, whitish or yellowish discharge, penis disorder or inflamed vagina

- Fever, lack of energy, loss of appetite, swelling, pain, excessive sweating, impotence.
- Changes in test results (e.g. low sodium, cholesterol and triglyceride (fat) levels)

Frequency unknown:

- Changes in blood test results such as low levels of magnesium, calcium and potassium in your blood.
- Seeing objects that are not there (hallucinating).
- Muscle weakness or partial paralysis on the one side of your body that can affect your arms, legs and facial muscles.
- A decrease in eyesight, inflammation of your eyelid, clouding of the normally clear lens of the eye, a build-up of pressure in your eye.
- Inflammation of the bowel, growths forming in the stomach.
- Rash on your skin (especially in areas exposed to the sun) or experience pain in your joints.

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 or, 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.

Report all side effects to Unicorn Pharmaceuticals (Pty) Ltd to enquiries@unicornpharma.co.za

By reporting side effects, you can help provide more information on the safety of **LANSOPRAZOLE UNICORN.**

5. How to store LANSOPRAZOLE UNICORN

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN

Store in a dry place below 25 ºC.

Keep the capsules in the original container until required for use.

Do not use the capsules after the expiry date printed on the container.

Return all unused medicine to your pharmacist.

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

6. Contents Of The Pack And Other Information

What LANSOPRAZOLE UNICORN contains

Active ingredients:

LANSOPRAZOLE UNICORN capsules comes in two strengths, containing 15 mg and 30 mg lansoprazole.

Inactive ingredients:

The other ingredients are disodium hydrogen phosphate dehydrate, gelatine capsules, maize starch, methacrylic acid – ethyl acrylate copolymer (1:1) 30 % dispersion, polyethylene glycol 6000, polysorbate 80, povidone K-30, sodium lauryl sulphate, sucrose, sugar spheres, talc, and titanium dioxide.

What LANSOPRAZOLE UNICORN looks like and contents of the pack

LANSOPRAZOLE UNICORN 15:

Capsules filled with white to light brown or slightly pink coloured pellets. The body of the hard gelatine capsule is white and the cap is red-brownish coloured.

LANSOPRAZOLE UNICORN 30:

Capsules filled with white to light brown or slightly pink coloured pellets. The body and cap of the hard gelatine capsules are white.

LANSOPRAZOLE UNICORN 15 capsules are available in white plastic bottles closed with a plastic tamper-evident cap containing 7, 14, 28 or 30 capsules.

LANSOPRAZOLE UNICORN 30 capsules are available in white plastic bottles closed with a plastic tamper-evident cap containing 14, 28 or 30 capsules.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

Corner Searle and Pontac Streets

Cape Town

7925

REGISTRATION NUMBER

LANSOPRAZOLE UNICORN 15: 40/11.4.3/0249

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