PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ESOMEPRAZOLE 20 UNICORN (20 mg film-coated tablets)

ESOMEPRAZOLE 40 UNICORN (40 mg film-coated tablets)

Esomeprazole

ESOMEPRAZOLE 20 UNICORN

Contains sugar: Sucrose 62,016 mg

ESOMEPRAZOLE 40 UNICORN

Contains sugar: Sucrose 124,032 mg

Read all of this leaflet carefully because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. What is ESOMEPRAZOLE UNICORN and what is used for

Esomeprazole belongs to a group of medicines called ’proton pump inhibitors’. They work by reducing the amount of acid that your stomach produces.

Esomeprazole is used to treat the following conditions:

- ‘Gastroesophageal reflux disease’ (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Ulcers in the stomach or upper part of the gut (intestine) that are infected with bacteria called ‘Helicobacter pylori’. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Esomeprazole can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

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

Do not take ESOMEPRAZOLE UNICORN:

- If you are allergic to esomeprazole or any of the other ingredients of ESOMEPRAZOLE UNICORN (See section 6)
- If you are allergic to other “proton pump inhibitors”
- If you are taking medication for HIV treatment (atazanavir or nelfinavir).

Warnings and precautions

Tell your doctor or healthcare provider before taking ESOMEPRAZOLE UNICORN**:**

- if you have been experiencing indigestion
- if you have been on continuous medication for longer than a year
- if you develop kidney problems such as blood in the urine
- if you have been taking a medication that contains clopidogrel (used in the treatment of blood clots)
- if you are due to have a specific blood test (Chromogranin A)
- if you have had previous intestinal conditions
- if you develop severe diarrhoea that has watery stools, abdominal pain and fever
- if you are taking ESOMEPRAZOLE UNICORN when necessary and your symptoms change
- if you have vitamin B_{12} deficiency
- if you develop tiredness dizziness, tremor and muscle problems (hypomagnesaemia)
- if you have been diagnosed with osteoporosis (brittle bones) or are at risk of breaking your bones
- if you develop 'butterfly rash' with sensitivity to sun light (subacute cutaneous lupus erythematosus).

If any of these applies to you, tell your doctor or nurse before you are given **ESOMEPRAZOLE UNICORN.**

Children

ESOMEPRAZOLE UNICORN should not be used in children younger than 1 year.

Other medicines and ESOMEPRAZOLE UNICORN

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

It is particularly important that you mention the following:

- Itraconazole, ketoconazole voriconazole used in the treatment of fungal infections

- Diazepam used in the treatment of anxiety
- Medicines used to prevent fitting (phenytoin)
- Medicines used to prevent blood clotting (warfarin or clopidogrel)
- Medicine used to help the symptoms of intermittent claudication (cilostazol)
- Medicines used to speed up stomach emptying (cisapride)
- Digoxin used in the treatment of heart problems
- Rifampicin used for the treatment of Tuberculosis
- St. John's Wort - used to treat depression, or certain type of antimalignancy medicines (such as erlotinib or another antimalignancy medicine from the same class.
- ESOMEPRAZOLE UNICORN should not be taken at the same time as some medicines for HIV, such as atazanavir and nelfinavir, as ESOMEPRAZOLE UNICORN may reduce the blood levels of your antiretroviral medicine.
- Tipranavir used to treat HIV
- Clarithromycin, an antibiotic
- If you are taking a high dose of methotrexate (a chemotherapy medicine in which high dose is used to treat cancer), ESOMEPRAZOLE UNICORN may need to be temporarily withdrawn.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine. You should not take ESOMEPRAZOLE UNICORN if you are pregnant or breastfeeding your baby.

Driving and using machines

ESOMEPRAZOLE UNICORN may cause dizziness and blurred vision, thereby affecting the ability to drive or use machinery.

It is not always possible to predict to what extent ESOMEPRAZOLE UNICORN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ESOMEPRAZOLE UNICORN affects them

ESOMEPRAZOLE UNICORN contains sugar in the form of sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take ESOMEPRAZOLE UNICORN

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

Always take ESOMEPRAZOLE UNICORN exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended doses are given below:

Adults & Adolescents (12 – 18 years):

- *Gastro-oesophageal Reflux Disease (GORD):*
    - To treat an inflamed food pipe caused by gastroesophageal reflux disease (GORD): 40 mg once daily for 4 weeks
    - Long-term management of patients with healed inflammation: 20 mg once daily
    - To treat symptoms of gastroesophageal reflux disease (GORD), without an inflamed food pipe: 20 mg once daily for 4 weeks. Once symptoms have resolved, 20 mg once daily, when needed.

- *Patients requiring continued NSAID (Non-Steroidal Anti-Inflammatory Drugs) therapy*
    - To prevent stomach ulcers if you are taking NSAIDs: 20 mg or 40 mg once daily.

- *Eradication of Helicobacter pylori and healing of Helicobacter pylori associated ulcers:*
    - 20 mg ESOMEPRAZOLE UNICORN with 1 g amoxicillin and 500 mg clarithromycin, all twice daily for 7 days.

- *To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome)*
    - The recommended initial dosage is 40 mg twice daily. The dosage should then be individually adjusted, and treatment continued as long as clinically indicated.

Swallow the tablets whole with liquid. Do not chew or crush the tablets.

Your doctor will tell you how long your treatment with ESOMEPRAZOLE UNICORN will last.
Do not stop treatment early because. If you have the impression that the effect of ESOMEPRAZOLE UNICORN is too strong or too weak, tell your doctor or pharmacist.

If you take more ESOMEPRAZOLE UNICORN 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 ESOMEPRAZOLE UNICORN

Do not take a double dose to make up for forgotten individual doses.
If it is almost time for your next dose, do not take the missed dose, and just take the next dose on time.

4. Possible side effects

ESOMEPRAZOLE UNICORN can have side effects.

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

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

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction)
- Rash or itching in the form of Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be ‘Stevens-Johnson syndrome’ or ‘toxic epidermal necrolysis’
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems. These are all very serious side effects.

If you have them, you may have had a serious reaction to ESOMEPRAZOLE 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:

- Tightening of chest accompanied with severe coughing (bronchospasm)
- Loss or decreased vision
- Abdominal swelling (may be an indication of liver failure)
- Excessive sweating
- Blood in the urine (Nephritis)

- Significant reduction in the amount of urine with shortness of breath (This could be a sign of kidney failure).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Stomach pain
- Diarrhoea
- Nausea/Vomiting
- Constipation
- Headache.

Less Frequent side effects:

- Muscle weakness/pain
- Fever
- Development of breast tissue in males
- Joint pain
- Hair loss
- Dry mouth
- Inflammation of the mouth and lips
- Dizziness
- Blurred vision
- Tingling sensation
- Loss of balance
- Taste disturbance

- Sleepiness
- Inability to sleep
- Confusion
- Depression
- Agitation
- Hallucination
- Low white blood cell count.

Side effects of which the frequency is unknown:

- Decreased levels of calcium
- Decreased levels of magnesium
- “Butterfly rash” that lasts hours – days.

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 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 ESOMEPRAZOLE UNICORN.

Adverse reactions must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za.

How to store ESOMEPRAZOLE UNICORN

Store all medicines out of reach of children.

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

Store at or below 25°C.

Protect from light and moisture.

Keep the blister strips in the outer carton until required for use.

Return all unused medicine to your pharmacist.

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

5. Contents of the pack and other information

What ESOMEPRAZOLE UNICORN contains

The active substance is esomeprazole magnesium trihydrate.

Other ingredients are crospovidone, glycerol monostearate, hydroxypropylcellulose, hypromellose phthalate, iron oxide red, magnesium oxide light, macrogol 400, macrogol 6000, methacrylic acid ethyl acrylate copolymer, microcrystalline cellulose, polysorbate 80, povidone, pregelatinised starch, silica colloidal hydrated, confectioner's sugar (containing sugar and starch), sugar spheres (containing sugar and starch) and talc.

ESOMEPRAZOLE 20 UNICORN contains Opadry Pink 03B84893 containing hypromellose, iron oxide red, iron oxide yellow, macrogol, titanium dioxide.
ESOMEPRAZOLE 40 UNICORN contains Opadry Pink 03B54193 containing hypromellose, iron oxide red, macrogol, titanium dioxide.

What ESOMEPRAZOLE UNICORN looks like and contents of the pack

ESOMEPRAZOLE 20 UNICORN: A light pink coloured, oblong, biconvex, film coated gastro-resistant tablet, with "20" debossed on one side and "CE" on the other side.
ESOMEPRAZOLE 40 UNICORN: A pink coloured, oblong, biconvex, film coated

gastro-resistant tablet, with “40” debossed on one side and “CE” on the other side.

Aluminium/aluminium blister strips (PVC/OPA/Al/PVC blister with paper/PET/Al lidding foil) packed in an outer carton.

Pack size:

ESOMEPRAZOLE 20 UNICORN (14 tablets - 2 blister strips of 7 tablets each)

ESOMEPRAZOLE 20 UNICORN (28 tablets - 4 blister strips of 7 tablets each)

ESOMEPRAZOLE 40 UNICORN (28 tablets - 4 blister strips of 7 tablets each)

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

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8001

South Africa

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