

**HCR:** LHC Pharmaceuticals (Pty) Ltd

**Product Name:** EMANERA 20 mg and EMANERA 40 mg

**Dosage form and strength:** Gastro-resistant capsules, Esomeprazole 20 mg and 40 mg

**Date of Approval:** 22 October 2024

## APPROVED PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S4

### PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

**EMANERA 20 mg** gastro-resistant capsules, hard

**EMANERA 40 mg** gastro-resistant capsules, hard

The active substance is esomeprazole (as esomeprazole magnesium dihydrate).

Contains sugar:

Sucrose: 28.46 – 32.56 mg (20 mg gastro-resistant capsule)

Sucrose: 56.93 – 65.11 mg (40 mg gastro-resistant capsule)

### Read all of this leaflet carefully before you start taking EMANERA Capsules:

- 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
- **EMANERA** capsules 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 this leaflet

1. What **EMANERA** capsules is and what it is used for
2. What you need to know before you use EMANERA capsules
3. How to use **EMANERA** capsules
4. Possible side effects
5. How to store **EMANERA** capsules

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#### 6. Contents of the pack and other information

##### 1. What EMANERA capsules are and what they are used for

**EMANERA** capsules contains a medicine called esomeprazole magnesium dihydrate. This belongs to a group of medicines called "proton pump inhibitors". They work by reducing the amount of acid that your stomach produces.

**EMANERA** capsules is used to treat the following conditions: Adults

- Gastro-oesophageal 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). **EMANERA** capsules 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).
- Adolescents aged 12 years and above
- "Gastro-oesophageal 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.

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### **2. What you need to know before you take EMANERA capsules**

#### **Do not take EMANERA capsules if:**

- If you are hypersensitive (allergic) to esomeprazole or any of the other ingredients of **EMANERA** capsules (listed in section 6).
- You are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole).
- You are taking a medicine containing nelfinavir and atazanavir (used to treat HIV infection).

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking **EMANERA** capsules if:

- You have severe liver problems.
- You have severe kidney problems.
- You have vitamin B12 deficiency.
- You have ever had a skin reaction after treatment with a medicine similar to EMANERA capsules that reduces stomach acid.
- You are due to have a specific blood test (Chromogranin A).

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 **EMANERA** capsules. Remember to also mention any other ill-effects like pain in your joints.

**EMANERA** capsules may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you start taking EMANERA capsules or while you are taking it, talk to your doctor straight away:**

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- You lose a lot of weight for no reason and have problems swallowing.
- You get stomach pain or indigestion.
- You begin to vomit food or blood.
- You pass black stools (blood-stained faeces).

If you have been prescribed **EMANERA** capsules "on demand" you should contact your doctor if your symptoms continue or change in character.

Taking a proton pump inhibitor like **EMANERA** capsules, 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 on **EMANERA** 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, or 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.

#### **Other medicines and EMANERA capsules**

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

**EMANERA** capsules can affect the way some medicines work and some medicines can have an effect on **EMANERA** capsules.

Do not take **EMANERA** capsules if you are taking a medicine containing nelfinavir (used to treat HIV).

Tell your doctor or pharmacist if you are taking any of the following medicines:

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- Atazanavir (used to treat HIV infection).
- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).
- Digoxin (used to treat heart problems).
- Erlotinib (used to treat cancer).
- Citalopram, imipramine or clomipramine (used to treat depression).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking **EMANERA** capsules.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking **EMANERA** capsules.
- Cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply).
- Cisapride (used for indigestion and heartburn).
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your **EMANERA** capsules treatment.
- Clopidogrel (used to prevent blood clots (thrombi)).
- Tacrolimus (organ transplantation).
- Rifampicin (to treat tuberculosis).
- St John's Wort (*Hypericum perforatum*) (used to treat depression).

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as **EMANERA** capsules to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor if you are taking any other medicines.

### **Pregnancy, breastfeeding and fertility**

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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.

Safety during pregnancy and lactation has not been established.

#### **Driving and using machines:**

**EMANERA** capsules may cause dizziness and blurred vision (inability to see fine detail) thereby affecting your ability to drive or use machines. It is not always possible to predict to what extent **EMANERA** may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which **EMANERA** affects you.

#### **EMANERA capsules contains sucrose**

**EMANERA** capsules contains sugar spheres which contain sucrose, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

### **3. How to take EMANERA capsules**

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

Always take **EMANERA** capsules exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- If you are taking this medicine for a long time, your doctor will want to monitor you (particularly if you are taking it for more than a year).
- If your doctor has told you to take this medicine as and when you need it, tell your doctor if your symptoms change.

#### **Adults aged 18 and above**

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#### **To treat heartburn caused by gastro-oesophageal reflux disease (GORD):**

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one **EMANERA** 40 mg gastro-resistant capsule once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your gullet has not yet healed.
- The recommended dose once the gullet has healed is one **EMANERA** 20 mg gastro-resistant capsule once a day.
- If your gullet has not been damaged, the recommended dose is one **EMANERA** 20 mg gastro-resistant capsule each day. Once the condition has been controlled, your doctor may tell you to take your medicine as and when you need it, up to a maximum of one **EMANERA** 20 mg gastro-resistant capsule each day.
- If you have severe liver problems, your doctor may give you a lower dose.

#### **To treat ulcers caused by *Helicobacter pylori* infection and to stop them coming back:**

- The recommended dose is one **EMANERA** 20 mg gastro-resistant capsule twice a day for one week.
- Your doctor will also tell you to take antibiotics for example amoxicillin and clarithromycin.

#### **To treat stomach ulcers caused by NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):**

- The recommended dose is one **EMANERA** 20 mg gastro-resistant capsule once a day for 4 to 8 weeks.

#### **To prevent stomach ulcers if you are taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):**

- The recommended dose is one **EMANERA** 20 mg gastro-resistant capsule once a day.

#### **To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome):**

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- The recommended dose is one **EMANERA** 40 mg gastro-resistant capsule twice a day.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for. The maximum dose is 80 mg twice a day.

#### **Adolescents aged 12 or above**

##### **To treat heartburn caused by gastro-oesophageal reflux disease (GORD):**

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one **EMANERA** 40 mg gastro-resistant capsule once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your gullet has not yet healed.
- The recommended dose once the gullet has healed is one **EMANERA** 20 mg gastro-resistant capsule once a day.
- If your gullet has not been damaged, the recommended dose is one **EMANERA** 20 mg gastro-resistant capsule each day.
- If you have severe liver problems, your doctor may give you a lower dose

#### **Children under the age of 1 year**

**EMANERA** should not be used in children younger than 1 year since no data is available.

#### **Elderly**

Dose adjustment is not required in the elderly.

#### **If you take more EMANERA capsules than you should**

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

#### **If you forget to take EMANERA capsules**

If you forget to take a dose, just take your next scheduled dose at the correct time.

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

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### **4. Possible side effects**

**EMANERA** capsules can have side effects.

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

**If you notice any of the following serious side effects, stop taking EMANERA capsules and contact a 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).
- 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 effects are rare and may affect up to 1 in 1,000 people.

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

**Other side effects include:**

**Frequent:**

- Headache.
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).
- Benign polyps in the stomach.

**Less frequent:**

- Swelling of the feet and ankles.

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- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as "pins and needles", feeling sleepy.
- Spinning feeling (vertigo).
- Dry mouth.
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Fracture of the hip, wrist or spine (if **EMANERA** capsules is used in high doses and over long duration).
- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- An inflammation of the inside of the mouth.
- An infection called "thrush" which can affect the gut and is caused by a fungus.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Generally feeling unwell and lacking energy.
- Increased sweating.
- Changes in blood count (pancytopenia) including agranulocytosis (lack of white blood

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cells).

- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Muscle weakness.
- Severe kidney problems.
- Enlarged breasts in men.

#### **Frequency unknown:**

- If you are on **EMANERA** capsules 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.
- Inflammation in the gut (leading to diarrhoea).
- Rash, possibly with pain in the joints.

**EMANERA** capsules may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information

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about your medication at this time.

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

#### **Reporting of side effects:**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

#### **5. How to store EMANERA capsules**

Store all medicines out of reach of children.

Store at or below 30 °C, protected from moisture.

Store in the original package/container

Do not store in a bathroom

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

#### **6. Contents of the pack and other information**

##### **What EMANERA capsules contains**

- The active substance is esomeprazole. Each gastro-resistant capsule contains 20 mg or 40 mg esomeprazole (as esomeprazole magnesium dihydrate).
- The other ingredients are sugar spheres (sucrose and maize starch), povidone K30, sodium lauryl sulphate, polyvinyl alcohol, titanium dioxide (E171), macrogol 6000, macrogol 3000, talc (E553b), heavy magnesium carbonate, polysorbate 80 (E433) and methacrylic

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acid – ethyl acrylate copolymer (1:1) dispersion 30 per cent in pellets in the capsule, and gelatine (E441), titanium dioxide (E171) and red iron oxide (E172) in the capsule shell.

See section 2 "**EMANERA** capsules contains sucrose".

#### **What EMANERA capsules looks like and contents of the pack**

**EMANERA** 20 mg: The body and the cap are slightly pink in colour; the capsules contain white to almost white pellets. Capsule size: no. 3.

**EMANERA** 40 mg: The body and the cap are off-pink in colour; the capsules contain white to almost white pellets. Capsule size: no. 1.

The capsules are available in boxes of 7, 10, 14, 15, 28, 30, 50, 56, 60, 90, 98 and 100 capsules in blister packs, and boxes of 98 capsules and a desiccant capsule in HDPE containers. Do not eat the desiccant capsule provided in the container.

Not all pack sizes may be marketed.

#### **Holder of Certificate of Registration**

LHC Pharmaceuticals (Pty) Ltd

N4 Gate Way Industrial Park

553 Willow Park Manor

33 Ghaap Street

PRETORIA

#### **This leaflet was last revised in**

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**Registration Number (s)**

**EMANERA 20 – 55/11.4.3/0910**

**EMANERA 40 – 55/11.4.3/0911**

**Access to the corresponding Professional Information**

Corresponding PI can be accessed on the following link:

<http://www.lhcpharma.com/professional-information>