

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:**

S4

ESSIUM IV (Powder for solution for injection and infusion)**Esomeprazole**

Sugar free

Read all of this leaflet carefully before you are given **ESSIUM IV**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet:

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

1. What ESSIUM IV is and what it is used for

ESSIUM IV contains a medicine called esomeprazole. This belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

ESSIUM IV is used to treat the following conditions:

- Treatment of erosive reflux oesophagitis
- Long-term management of patients with healed oesophagitis to prevent relapse and treatment of severe symptoms of reflux disease
- Maintenance of haemostasis and prevention of rebleeding of gastric or duodenal ulcers

2. What you need to know before you are given **ESSIUM IV**

ESSIUM IV should not be administered to you:

- If you are allergic to esomeprazole or any of the other ingredients of **ESSIUM IV** (listed in section 6).
- If you are allergic to substituted benzimidazoles.
- If you are taking a medicine containing nelfinavir or atazanavir (used to treat HIV infection).

If you are not sure, talk to your doctor or pharmacist before you are given **ESSIUM IV**.

Warnings and precautions

Tell your doctor or health care provider before being given **ESSIUM IV**:

Special care should be taken with **ESSIUM IV**:

- If you have severe liver problems.
- If you have severe kidney problems.
- If you have ever had a skin reaction after treatment with a medicine similar to **ESSIUM IV** that reduces stomach acid.
- If you are due to have a specific blood test (Chromogranin A).

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

- 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).

Taking a proton pump inhibitor like **ESSIUM IV**, 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 **ESSIUM IV**. Remember to also mention any other ill-effects like pain in your joints.

Other medicines and ESSIUM IV

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

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

- Ketoconazole, itraconazole or voriconazole (used to treat fungal infections).
- Atazanavir, nelfinavir or saquinavir (used to treat HIV-infection).
- Phenytoin (used to treat epilepsy (fits/seizures)).
- Warfarin (used in the prevention of blood clotting formation).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Citalopram, imipramine or clomipramine (used to treat depression).
- Cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply).
- Erlotinib (used to treat cancer).
- Digoxin (used for heart problems).
- 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 **ESSIUM IV** treatment.
- Clopidogrel (used to prevent blood clots).
- Tacrolimus (organ transplantation).
- St. John's wort (*Hypericum perforatum*) (used to treat depression).
- Rifampicin (used for treatment of tuberculosis).

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving **ESSIUM IV**.

You should not be given **ESSIUM IV** if you are pregnant or breastfeeding.

Driving and using machines

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

3. How to use **ESSIUM IV**

Your doctor will tell you how long your treatment with **ESSIUM IV** will last.

You will not be expected to give yourself **ESSIUM IV**. It will be given to you by a person who is qualified to do so.

Your doctor or healthcare professional will administer **ESSIUM IV** to you into a vein (intravenous) or with a drip (infusion) in the hospital for a specific condition.

Your doctor or healthcare professional will make sure you receive the correct dose. If you have severe liver problems, your doctor may give you a lower dose.

If you take more **ESSIUM IV than you should**

Since a health care provider will administer **ESSIUM IV**, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take **ESSIUM IV**

Since a health care provider will administer **ESSIUM IV**, it is unlikely that the dose will be missed.

4. Possible side effects

ESSIUM IV can have side effects.

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

If you notice any of the following serious side effects, 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).
- 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

ESSIUM IV. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent:

- Headache
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, flatulence
- Feeling sick (nausea) or being sick (vomiting)
- Benign polyps (non-cancerous tumours) in the stomach.
- Tenderness, warmth, or redness along the vein or at the injection site

Less frequent:

- Allergic reactions, such as fever, swelling and anaphylactic shock
- Swelling of the feet and ankles
- Disturbed sleep (insomnia), state of confusion, depression, aggression and hallucinations
- Dizziness, tingling feelings such as “pins and needles”, feeling sleepy
- Spinning feeling (vertigo)
- Dry mouth
- Coughing
- Taste disturbance
- Suddenly feeling wheezy or shortness of breath,
- Inflammation of the inside of the mouth,
- Blurred vision, eye disorders,
- Ringing in the ears,
- Joint and muscle pains,
- Muscle weakness,
- Increased sweating,
- Enlarged breasts in men,
- Inability to get an erection in men,
- Generally feeling unwell and lacking energy,

- Hair loss
- Loss of male sexual ability,
- Tiredness,
- Changes in blood count including agranulocytosis (lack of white blood cells)
- 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 ESSIUM IV is used in high doses and over long duration).

Frequency unknown:

- 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.
- Inflammation in the gut (leading to diarrhoea).
- Rash, possibly with pain in the joints.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Liver failure
- Heart disease including tightness or chest pains, slower or increased heart rate

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. 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 ESSIUM IV

5. How to store ESSIUM IV

Store at or below 30 °C.

Keep **ESSIUM IV** vial in outer carton, in order to protect from light.

Keep out of reach of children

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 12 hours at 25 °C.

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

Ask your pharmacist how to dispose of medicines you no longer use.

6. Contents of the pack and other information

What ESSIUM IV contains

- The active substance is Esomeprazole
- The other ingredients are:
 - Disodium edetate
 - Sodium hydroxide (for pH adjustment)

What ESSIUM IV looks like and contents of the pack

ESSIUM IV is white to pale yellow coloured lyophilized powder.

Type I colourless glass vial with a grey bromobutyl rubber stopper and a transparent flip-off cap, in a unit carton containing 1 or 5 or 10 vials.

Holder of Certificate of Registration

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