PATIENT INFORMATION LEAFLET FOR

ESOMEPRAZOLE 10 GRANULES CIPLA

SCHEDULING STATUS S4

ESOMEPRAZOLE 10 GRANULES CIPLA

Esomeprazole magnesium dihydrate

Contains sugar: dextrose 2955,9 mg and sucrose 7,46 mg per sachet

Read all of this leaflet carefully before you start taking ESOMEPRAZOLE 10 GRANULES CIPLA

- 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.
- ESOMEPRAZOLE 10 GRANULES CIPLA 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 ESOMEPRAZOLE 10 GRANULES CIPLA is and what it is used for.
2. What you need to know before you are take ESOMEPRAZOLE 10 GRANULES CIPLA.
3. How to take ESOMEPRAZOLE 10 GRANULES CIPLA.
4. Possible side effects.
5. How to store ESOMEPRAZOLE 10 GRANULES CIPLA.
6. Contents of the pack and other information.

1. What ESOMEPRAZOLE 10 GRANULES CIPLA is and what it is used for

ESOMEPRAZOLE 10 GRANULES CIPLA (esomeprazole) belongs to a class of medicine known as proton pump inhibitors (medicines used to treat ulcers). They work by reducing the amount of acid produced by your stomach.

ESOMEPRAZOLE 10 GRANULES CIPLA is used for treating the following conditions:

- inflammation (swelling) and pain in the food pipe caused by a return flow of fluid from the stomach (erosive reflux oesophagitis).
- disease with symptoms e.g. heartburn and regurgitation, caused by a return flow of fluid from the stomach (symptomatic treatment of gastro-oesophageal reflux disease - GORD) and the prevention of this condition from happening again.

2. What you need to know before you take ESOMEPRAZOLE 10 GRANULES CIPLA

Do not take ESOMEPRAZOLE 10 GRANULES CIPLA:

- if you are hypersensitive (allergic) to esomeprazole, substituted benzimidazoles or any of the other ingredients of ESOMEPRAZOLE 10 GRANULES CIPLA (listed in **section 6**).
- if you are allergic to other “proton pump inhibitors” - medicines that work by reducing the amount of stomach acid.
- if you are taking medication for HIV treatment (atazanavir or nelfinavir).

Warnings and precautions

Tell your doctor or health care provider before taking or being given ESOMEPRAZOLE 10 GRANULES CIPLA:

- if you notice any of the following:

- if you feel that you are losing weight without trying to lose it.
- you begin to vomit blood or food.
- you pass black (blood-stained) stools. You should contact your doctor immediately.

- if you have severe liver problems. You should discuss this with your doctor, as he/she may wish to reduce the dose.
- if you have severe kidney problems. You should discuss this with your doctor.
- if you have severe, debilitating diarrhoea (known as *Clostridium Difficile*-associated diarrhoea), that does not improve. Symptoms may include watery stools, stomach pain and fever.
- if you are due to have a specific blood test (Chromogranin A).
- if you have ever had a skin reaction after treatment with a medicine similar to ESOMEPRAZOLE 10 GRANULES CIPLA that reduces stomach acid.

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 treatment with ESOMEPRAZOLE 10 GRANULES CIPLA. Remember to also mention any other ill-effects like pain in your joints.

Children and adolescents

ESOMEPRAZOLE 10 GRANULES CIPLA should not be used in children less than a year old since no data is available.

Other medicines and ESOMEPRAZOLE 10 GRANULES CIPLA

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

- The medicine's effects may be influenced if esomeprazole is taken at the same time as some medicines used to prevent fungal infections (itraconazole, ketoconazole, voriconazole), anxiety medication (diazepam), medicines used to prevent fitting (phenytoin), medicines used to prevent blood clotting (warfarin or clopidogrel), intermittent claudication (cilostazol), medicines used to speed up stomach emptying (cisapride), heart problems (digoxin), and also if you are using treatment for tuberculosis (rifampicin), St. John's Wort (*hypericum perforatum*) (used to treat depression), or certain type of antimalignancy medicines (such as erlotinib or another antimalignancy medicine from the same class).
- Esomeprazole should not be taken at the same time as some medicines for HIV, such as atazanavir, tipranavir and nelfinavir, as esomeprazole may reduce the blood levels of your antiretroviral medicine.
- If you are taking a high dose of methotrexate (a chemotherapy medicine in which high dose is used to treat cancer), esomeprazole may need to be temporarily withdrawn.
- Esomeprazole should not be taken at the same time as tacrolimus (organ transplantation medicine).
- Esomeprazole should not be taken at the same time as antibiotic medicine such as clarithromycin.

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 health care provider for advice before taking ESOMEPRAZOLE 10 GRANULES CIPLA.

Driving and using machines

It is not always possible to predict to what extent ESOMEPRAZOLE 10 GRANULES CIPLA 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 10 GRANULES CIPLA affects them.

ESOMEPRAZOLE 10 GRANULES CIPLA can cause dizziness and blurred vision, therefore it might impair your ability to drive and operate machinery. Caution is advised until you are fully aware of how ESOMEPRAZOLE 10 GRANULES CIPLA affects you.

ESOMEPRAZOLE 10 GRANULES CIPLA contains sugars (dextrose and sucrose)

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take ESOMEPRAZOLE 10 GRANULES CIPLA.

3. How to take ESOMEPRAZOLE 10 GRANULES CIPLA

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

Always take ESOMEPRAZOLE 10 GRANULES CIPLA exactly as your doctor or pharmacist has told you.

You should check with your doctor or pharmacist if you are not sure.

Your doctor will prescribe the correct dose and duration of treatment for your condition.

Method of administration

Empty the contents of the sachet into a container containing a tablespoon (15 mL) of water. Stir the contents and leave for a few minutes to thicken. Stir again and drink within 30 minutes. If any material remains after drinking, add more water, stir, and drink immediately.

Your doctor will tell you how long your treatment with ESOMEPRAZOLE 10 GRANULES CIPLA will last.

ESOMEPRAZOLE 10 GRANULES CIPLA should not be used in children younger than 1 year.

ESOMEPRAZOLE 10 GRANULES CIPLA can be used in the elderly.

If you have the impression that the effect of ESOMEPRAZOLE 10 GRANULES CIPLA is too strong or too weak, tell your doctor or pharmacist.

You will not be expected to give yourself ESOMEPRAZOLE 10 GRANULES CIPLA when you have a nasogastric or gastric tube in place. It will be given to you by a person who is qualified to do so.

If you take more ESOMEPRAZOLE 10 GRANULES CIPLA 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 ESOMEPRAZOLE 10 GRANULES CIPLA

Try take your medicine at the same time each day. If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, do not take the missed dose, and just take the next dose on time. Do not take a double dose to make up for forgotten individual doses.

Since a health care provider will administer ESOMEPRAZOLE 10 GRANULES CIPLA when you have a nasogastric or gastric tube in place, it is unlikely that the dose will be missed.

If you stop taking ESOMEPRAZOLE 10 GRANULES CIPLA

Not Applicable

4. Possible side effects

ESOMEPRAZOLE 10 GRANULES CIPLA can have side effects.

Not all side effects reported for ESOMEPRAZOLE 10 GRANULES CIPLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ESOMEPRAZOLE 10 GRANULES CIPLA, please consult your health care provider for advice.

If any of the following happens, stop taking ESOMEPRAZOLE 10 GRANULES CIPLA 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).
- 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 10 GRANULES CIPLA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache,
- stomach pain,
- diarrhoea,
- wind,
- feeling sick/being sick,
- constipation

Less frequent side effects:

- Skin reactions (rash, dermatitis, itching, hives) sensation of burning/prickling/numbness, difficulty sleeping,
- feeling sleepy,
- dizziness,
- vertigo,
- dry mouth and peripheral swelling,
- blurred vision,
- severe allergic reactions (swelling, anaphylactic reaction/shock),
- muscular pain,
- blood disorders (reduced number of cell in blood i.e. leukopenia and thrombocytopenia), depression,
- low blood sodium,
- nervousness,
- confusion,
- taste disorders,
- tightness in the chest,
- inflammation in the mouth,
- gastrointestinal fungal infection,
- gastrointestinal infection,

- inflammation of the liver (with or without jaundice),
- hair loss,
- sensitivity to sunlight,
- sore joints,
- feeling ill and increased sweating may occur.
- Severe skin disorders,
- other blood disorders (agranulocytosis and pancytopenia),
- aggression,
- hallucination,
- impaired liver function,
- decreased consciousness,
- muscular weakness,
- inflammation of the kidney,
- development of breasts in males.

  frequency: Unknown
- low blood magnesium (Hypomagnesaemia; severe hypomagnesaemia can correlate with hypocalca. Hypomagnesaemia may also be associated with hypokalaemia) and inflammation in the gut (leading to diarrhoea). Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, disorientation, convulsions, dizziness and ventricular arrhythmia can occur, but they may begin insidiously and be overlooked. If you get any of these symptoms, please tell your health care provider promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your health care provider may decide to perform regular blood tests to monitor your levels of magnesium.

The following side effect may also occur with esomeprazole. This would only be seen when a blood test is taken: increase in the amount of liver enzymes.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website or to Cipla Medpro (Pty) Ltd. by e-mail:drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ESOMEPRAZOLE 10 GRANULES CIPLA.

5. How to store ESOMEPRAZOLE 10 GRANULES CIPLA

- Store at or below 25 °C.
- To be used within 30 minutes after reconstitution.
- Store all medicines out of reach of children.
- Store in the original container.
- Do not use after the expiry date stated on the container.
- 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 ESOMEPRAZOLE 10 GRANULES CIPLA contains

The active substance is esomeprazole magnesium dihydrate 10 mg granules for oral suspension.

The other ingredients are anhydrous citric acid, crospovidone (Kollidon CL-M), dextrose anhydrous, ferric oxide (yellow), hydroxy propyl cellulose (Klucel LF), hydroxy propyl methyl cellulose E-15 (HPMC E-15), magnesium stearate, methacrylic acid and ethyl acrylate

copolymer dispersion (Eudragit L30 D 55), PlasACRYL® HTP-20 (glyceryl monostearate, polysorbate 80 and triethyl citrate), polysorbate 80, sugar spheres (starch, sucrose and water), talc and xanthan gum.

What ESOMEPRAZOLE 10 GRANULES CIPLA looks like and contents of the pack

Powder: fine yellow powder consisting of white to pale brownish esomeprazole granules and pale yellow inactive granules**.**

After reconstitution: opaque, pale yellow coloured, viscous liquid with suspended particle.

ESOMEPRAZOLE 10 GRANULES CIPLA are packaged in 4-ply laminate of PET/Aluminium foil sachets that are packed into outer cartons, in packs of 28's and 30's.

Not all pack sizes may be marketed.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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