Patient information leaflet for

Esomeprazole Cipla

SCHEDULING STATUS

S4

Esomeprazole Cipla (20 and 40 mg film-coated tablets)

Esomeprazole

Contains sugar:

Esomeprazole 20 mg Cipla: Sugar spheres (sucrose, maize starch, liquid glucose) **equivalent to 47,5 mg and lactose monohydrate 67,5 mg per tablet.**

Esomeprazole 40 mg Cipla: Sugar spheres (sucrose, maize starch, liquid glucose) **equivalent to 95,0 mg and lactose monohydrate 100,125 mg per tablet.**

Read all of this leaflet carefully before you start taking Esomeprazole Cipla

- 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 (see section **4**).

What is in this leaflet:

1. What Esomeprazole Cipla is and what it is used for
2. What you need to know before you take Esomeprazole Cipla

3. How to take Esomeprazole Cipla
4. Possible side effects
5. How to store Esomeprazole Cipla
6. Contents of the pack and other information

1. What Esomeprazole Cipla is and what it 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 Cipla

Do not take Esomeprazole Cipla:

- if you are allergic to esomeprazole or any of the other ingredients of Esomeprazole Cipla (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 Cipla:

- 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 Cipla when necessary and your symptoms change.
- if you have vitamin B12 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 apply to you, tell your doctor or nurse before you are given Esomeprazole Cipla.

Children

Esomeprazole Cipla is not suitable for use in children 1 – 11 years old.

Esomeprazole Cipla should not be used in children younger than 1 year.

Other medicines and Esomeprazole Cipla

Always tell your healthcare provider if you are taking any other medicine.

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 fits (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 a certain type of antimalignancy medicines (such as erlotinib, or another antimalignancy medicine from the same class).

- Esomeprazole Cipla should not be taken at the same time as some medicines for HIV, such as atazanavir and nelfinavir, as Esomeprazole Cipla 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 a high dose is used to treat cancer), Esomeprazole Cipla 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 professional for advice before taking this medicine. You should not take Esomeprazole Cipla if you are pregnant or breastfeeding your baby.

Driving and using machines

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

Esomeprazole Cipla contains sugar in the form of sucrose, glucose and lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Esomeprazole Cipla. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take Esomeprazole Cipla. These

form of sugar may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take Esomeprazole Cipla

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

Always take Esomeprazole Cipla 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 and 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 drug) 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 Cipla 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.

If you take more Esomeprazole 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 Cipla

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 Cipla can have side effects.

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

If any of the following happens, stop taking Esomeprazole 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 difficulty 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 Cipla. 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 to 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 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 Cipla.

5. How to store Esomeprazole Cipla

Store all medicines out of reach of children.

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

Do not store above 30 °C.

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 Cipla contains

Esomeprazole 20 mg Cipla: 21,75 mg esomeprazole magnesium dihydrate equivalent to esomeprazole 20 mg.

Esomeprazole 40 mg Cipla: 43,50 mg esomeprazole magnesium dihydrate equivalent to esomeprazole 40 mg.

The other ingredients are colloidal anhydrous silica (Aerosil), crospovidone (Kollidon CL), crospovidone CL-SF, hypromellose (HPMC E-15) (E464), hypromellose (HPMC-3 cps), macrogol (polyethylene glycol 6000), magnesium stearate (vegetable grade), methacrylic acid-ethylacrylate copolymer (1:1) dispersion 30 percent (Eudragit L 30-D-55), microcelac 100 (lactose monohydrate and microcrystalline cellulose), microcrystalline cellulose (Avicel PH 102) (E460), purified talc (E553b), stearyl alcohol, sugar spheres (sucrose, maize starch, liquid glucose), triethyl citrate (E1505).

Film-coating

Isopropyl alcohol

Esomeprazole 20 mg Cipla: Opadry pink 04F54165:

HPMC 2910 / hypromellose 15 mPas (E464), titanium dioxide (E171), macrogol / PEG 6000 (E1521), iron oxide red (E172).

Esomeprazole 40 mg Cipla: Opadry pink 04F54008

HPMC 2910 / hypromellose (E464), titanium dioxide (E171), macrogol / PEG (E1521), iron oxide red (E172), erythrosine aluminium lake (E127), ferrosoferric oxide / Black iron oxide (E172).

What Esomeprazole Cipla looks like and contents of the pack

Esomeprazole 20 mg Cipla: Pink coloured, capsule shaped, biconvex, film-coated tablets debossed '20' on one side and plain on other side.

Esomeprazole 40 mg Cipla: Pink coloured, capsule shaped, biconvex, film-coated tablets debossed '40' on one side and plain on other side.

Esomeprazole Cipla is packed in aluminium foil/alu-alu laminated film blisters of 7 tablets in pack sizes of 14's and 28's.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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