PATIENT INFORMATION LEAFLET: ESOFLUX

SCHEDULING STATUS: **S4**

ESOFLUX 20 mg (Gastric-Resistant Tablets)
ESOFLUX 40 mg (Gastric-Resistant Tablets)
Esomeprazole
Contains sugar:

ESOFLUX 20 contains sugar (lactose monohydrate 31,88 mg and sucrose no more than 14,63 mg per tablet).
ESOFLUX 40 contains sugar (lactose monohydrate 63,75 mg and sucrose no more than 29,26 mg per tablet).

Read all of this leaflet carefully before you start taking ESOFLUX

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
ESOFLUX 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 ESOFLUX is and what it is used for

2. What you need to know before you take ESOFLUX

3. How to take ESOFLUX

4. Possible side effects

5. How to store ESOFLUX

6. Contents of the pack and other information

1. What ESOFLUX is and what it is used for

Esomeprazole as contained in ESOFLUX 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:

- ‘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). 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 ESOFLUX

Do not take ESOFLUX

- if you are allergic to esomeprazole or any of the other ingredients of ESOFLUX (listed in section 6).
- if you are allergic to other “proton pump inhibitors”.
- if you are taking medication for HIV treatment (nelfinavir or atazanavir).

Warnings and precautions

Talk to your pharmacist, doctor or other healthcare provider before taking ESOFLUX:

- if you have been experiencing indigestion.
- if you have been on continuous medication for longer than a year.
- 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 ESOFLUX 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 you develop any signs of kidney problems such as blood in the urine, increased or decreased urine output or swelling of any area of the body.

If any of these applies to you, tell your doctor, nurse or pharmacist before you are given ESOFLUX.

Children and adolescents

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

Other medicines and ESOFLUX

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

It is particularly important that you mention the following:

- Itraconazole, ketoconazole and 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 anti-malignancy medicines (such as erlotinib or another anti-malignancy medicine from the same class).
- ESOFLUX should not be taken at the same time as some medicines for HIV, such as atazanavir and nelfinavir, as ESOFLUX may reduce the blood levels of your antiretroviral medicine.
- Tipranavir used to treat HIV.
- Clarithromycin, an antibiotic.
- Tacrolimus used to treat organ transplant rejection.
- If you are taking a high dose of methotrexate (a chemotherapy medicine in which high dose is used to treat cancer), ESOFLUX may need to be temporarily withdrawn.

Taking ESOFLUX with food, drink and alcohol:
ESOFLUX tablets may be taken with or without food.

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

Driving and using machines

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

ESOFLUX contains sugar in the form of sucrose and lactose

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 ESOFLUX

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

Always take ESOFLUX exactly as your doctor or pharmacist 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 gastro-oesophageal reflux disease (GORD): 40 mg once daily for 4 weeks.
    - Long-term management of patients with healed inflammation: 20 mg once daily.
- *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 ESOFLUX 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 ESOFLUX 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 ESOFLUX
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

ESOFLUX can have side effects.

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

If any of the following happens, stop taking ESOFLUX 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 ESOFLUX. 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 of 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 frequency is unknown:

- Decreased levels of calcium
- Decreased levels of magnesium
- “Butterfly rash” that lasts from 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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Cipla Medpro (Pty) Ltd. by email:

drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free).

5. How to store ESOFLUX

Store all medicines out of reach of children.
Store at or below 25 °C in the original package.
Do not use after the expiry date stated on the carton.
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 ESOFLUX contains

The active substance is: esomeprazole magnesium

The other ingredients are:

Tablet Core:

copovidone,

crospovidone,

diethyl phthalate,

ethylcellulose,

light magnesium oxide,

macrogol,

magnesium stearate,

methacrylic acid–ethyl acrylate copolymer,

povidone,

silica (colloidal anhydrous),

silicified microcrystalline cellulose (consisting of microcrystalline cellulose and colloidal anhydrous silica),

starlac (consisting of lactose and maize starch),

Sugar spheres [consisting of corn (maize), starch and sucrose],

talc (purified)

Tablet Coating:

ferric oxide red, hypromellose, macrogol, talc (purified), titanium dioxide, silica (colloidal anhydrous) and opacode S-1-17823 black ink.

What ESOFLUX looks like and contents of the pack

ESOFLUX 20: Brick red coloured, round shape, biconvex, film-coated tablets, imprinted with "20" on one side with black ink and plain on the other side.

ESOFLUX 40: Brick red coloured, round shape, bevelled edge, biconvex, film-coated tablets, imprinted with "40" on one side with black ink and plain on the other side.

Each carton contains blister foil strips of 10 tablets each.

Pack sizes: 10's, 30's, 60's and 100's.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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