

### What is in this leaflet

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### What ESOMAC is used for

- ‘Gastroesophageal reflux disease’ (GERD). 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.
- Prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

### How ESOMAC works

ESOMAC 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.

### Before you use ESOMAC

#### -When you must not use it

- If you are allergic to esomeprazole or any of the other ingredients of this medicine.

- If you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole).
- If you are taking a medicine containing nelfinavir (used to treat HIV).

#### -Before you start to use it

Talk to your doctor or pharmacist before taking esomeprazole tablets:

- If you have severe liver problems.
- If you have severe kidney problems.

Esomeprazole may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you start taking esomeprazole 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).

Treatment with proton pump inhibitors may lead to slightly increased risk of gastrointestinal infections.

If you have been prescribed ESOMAC “on demand” you should contact your doctor if your symptoms continue or change in character.

Taking a proton pump inhibitor like ESOMAC, 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 before taking this medicine, if you are due to have a specific blood test (Chromogranin A).

#### -Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription. This is because ESOMAC can affect the way some medicines work and some medicines can have an effect on ESOMAC.

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

- Atazanavir (used to treat HIV infection).
- Clopidogrel (used to prevent blood clots).
- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).
- 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 ESOMAC.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking ESOMAC.
- 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).
- 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 esomeprazole treatment.
- Tacrolimus (organ transplantation).
- Rifampicin (used for treatment of tuberculosis).
- St. John’s wort (*Hypericum perforatum*) (used to treat depression).

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

### How to use ESOMAC

#### -How much to use

The usual doses are given below. Adults and children aged 12 or above:

# ESOMAC Gastro Resistant Tablets

Esomeprazole (20mg, 40mg)

## Consumer Medication Information Leaflet (RiMUP)

### To treat erosive reflux esophagus inflammation and prevent relapse:

The usual dose is 40 mg tablet once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your gullet (esophagus) has not yet healed.

### To treat gastroesophageal reflux disease (GERD) symptoms:

The usual dose once the gullet has healed is 20 mg tablet once a day. If your gullet is not inflamed, the usual dose is 20 mg tablet each day. Once the condition has been controlled, your doctor may tell you to take your medicine as and when you need it, of one 20 mg tablet 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 from coming back:

Adults: The usual dose is one 20 mg tablet twice a day for one week. Your doctor will also tell you to take with antibiotics for example amoxicillin and clarithromycin.

### To treat stomach ulcers caused by NSAIDs:

Adults: The usual dose is one 20 mg tablet once a day for 4 to 8 weeks.

### To prevent stomach ulcers if you are taking NSAIDs:

Adults: The usual dose is one 20 mg tablet once a day.

### Prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole:

The usual dose is 40 mg tablet once a day for 4 weeks.

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

Adults: The usual dose is 40 mg 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.

ESOMAC tablets are not recommended for children less than 12 years old.

### -When to use it

You can take your tablets at any time of the day. You can take your tablets with food or on an empty stomach.

Swallow your tablets whole with a glass of water. Do not chew or crush the tablets. This is because the tablets contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

If you have trouble swallowing the tablets:

- Put them into a glass of still (non-fizzy) water. Do not use any other liquids.
- Stir until the tablets break up (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes. Always stir the mixture just before drinking it.
- To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it.

If you cannot swallow at all, the tablet can be mixed with some nonfizzy water and put into a syringe. It can be then be given to you through a tube directly into your stomach.

### -How long to use it

Always take ESOMAC exactly as your doctor has told you. You should 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.

### -If you forget to use it

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### -If you use too much (overdose)

If you take more ESOMAC than prescribed by your doctor, talk to your doctor or pharmacist straight away.

## While you are using ESOMAC

### -Things you must do

- Take your medication daily as prescribed.
- If your doctor prescribed antibiotics for you together with ESOMAC, ensure that you complete the whole course of medication as advised.

### -Things you must not do

Do not take other medication together with ESOMAC without speaking to your doctor or pharmacist first.

### -Things to be careful of

## Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will decide whether you can take ESOMAC during this time. It is not known if ESOMAC passes into breast milk. Therefore, you should not take ESOMAC if you are breastfeeding.

## Driving and using machines

Esomeprazole is not likely to affect you being able to drive or use any tools or machines. However, side effects such as dizziness and blurred vision may uncommonly or rarely occur. If affected, you should not drive or use machines.

ESOMAC tablets contain sucrose, which is 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.

### Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

When you are taking this medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Please tell your doctor promptly if you get any of the symptoms below:

- Rash (especially in areas exposed to the sun), possibly with pain in the joints (Subacute Cutaneous Lupus Erythematosus, SCLE)
- Fever, extreme tiredness, pus / blood in urine.
- Involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate
- Fracture in the hip, wrist or spine
- Watery stool, stomach pain and fever that do not go away
- Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioural changes).

**If you notice any of the following serious side effects, stop taking ESOMAC and contact a doctor immediately.**

- Sudden wheezing (a continuous, coarse, whistling sound produced in the lungs during breathing), swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow (severe allergic reactions).
- 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.

Other side effects include:

#### Common

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

#### Uncommon

- Swelling of the feet and ankles.
- 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 esomeprazole is used in high doses and over long duration).
- Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis)

#### Rare

- Interstitial Nephritis: Kidney problems (interstitial nephritis)

#### Frequency not known

- Proton pump inhibitors may cause vitamin B12 deficiency
- Clostridium Difficile Diarrhea: Severe diarrhoea which may be caused by an infection (Clostridium difficile) in your intestines.
- Hypomagnesaemia: Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood.
- Subacute Cutaneous Lupus Erythematosus (SCLE)

Esomeprazole 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 about your medication at this time.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website [npra.gov.my](http://npra.gov.my) [Consumers ->Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### Storage and Disposal of ESOMAC

#### -Storage

Store below 30°C

#### -Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

### Product description

#### -What it looks like

ESOMAC-20: Pink coloured, capsule shaped, biconvex, film coated tablet debossed "20" plain on one side and plain on side

ESOMAC-40: Pink coloured, capsule shaped, biconvex, film coated tablet debossed "40" plain on one side and plain on side

Pack size: Blister of 3 x 10's tablets

#### -Ingredients

Active ingredient :

Esomeprazole magnesium dihydrate.

Inactive ingredients :

- PEG coated pellets (Sugar spheres, hypromellose E-15, purified water, purified talc, Eudragit L30 D-55, triethyl citrate, Macrogol 6000, dichloromethane)

# ESOMAC Gastro Resistant Tablets

Esomeprazole (20mg, 40mg)

Consumer Medication Information Leaflet (RiMUP)

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- |   |   |
|---|---|
| <ul style="list-style-type: none"><li>• Stearyl alcohol placebo<br/>(Microcrystalline cellulose (Avicel pH 102), crospovidone, hypermellose, stearyl alcohol, colloidal anhydrous silica)</li><li>• Crospovidone</li><li>• Microcelac 100</li><li>• Colloidal anhydrous silica,</li><li>• Magnesium stearate</li><li>• Film Coating<br/>ESOMAC-20 :<br/>Opadry pink 04F54165 (Hypermellose, Titanium Dioxide, Macrogol 6000, Red Iron Oxide), Isopropyl Alcohol, Purified water</li></ul> | <b>Serial number</b><br>NPRA(R2) 19/142 |
|---|---|

ESOMAC-40 :  
Opadry pink 04F54008 (Hypermellose, Titanium Dioxide, Macrogol 6000, Iron Oxide Red, Erythrosine Aluminium Lake, Iron Oxide Black), Isopropyl Alcohol, Purified water

## -MAL number

ESOMAC-20:  
MALXXXXXXXXX

ESOMAC-40:  
MALXXXXXXXXX

## **Manufacturer and Product Registration Holder**

### **Manufacturer**

Cipla Ltd  
L-139 to L-146  
Verna industrial estate  
Verna Goa, India

### **Product Registration Holder**

CIPLA MALAYSIA SDN BHD  
Suite 1101, Amcorp Tower,  
Amcorp Trade Centre,  
18 Persiaran Barat, 46050  
Petaling Jaya, Selangor, Malaysia

### **Date of revision**

16/01/2020