Consumer Medicine Information

This leaflet provides important information about using ESOPREZE. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ESOPREZE.

Where to find information in this leaflet:

- 1. Why am I using [medicine name]?
- 2. What should I know before I use [medicine name]?
- 3. What if I am taking other medicines?
- 4. How do I use [medicine name]?
- 5. What should I know while using [medicine name]?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using ESOPREZE?

ESOPREZE contains the active ingredient esomeprazole magnesium trihydrate.

ESOPREZE is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place.

ESOPREZE is used to treat reflux oesophagitis. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus). ESOPREZE is also taken to help stop reflux oesophagitis coming back or relapsing.

EZOPREZE is taken to treat the symptoms of pain or discomfort in the stomach caused by NSAIDs, a type of medicine for pain or inflammation.
ESOPREZE is also taken to help heal and prevent ulcers caused by NSAIDs.

ESOPREZE together with antibiotics is taken to treat peptic ulcer. Most people who have a peptic (gastric and duodenal) ulcer also have a bacterium called Helicobacter pylori in their stomach.

When ESOPREZE and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

ESOPREZE is also used to treat a rare condition called Zollinger-Ellison syndrome. This is a condition where the stomach produces large amounts of acid,

much more than in ulcers or reflux disease. ESOPREZE is taken as follow up treatment for bleeding peptic ulcers.

2. What should I know before I use ESOPREZE?

Warnings

Do not use ESOPREZE if:

- You are allergic to esomeprazole, or any of the ingredients listed at the end of this leaflet.
- You are allergic to any medicines containing a proton-pump inhibitor.
- Always check the ingredients to make sure you can use this medicine.
- You are taking atazanavir or cilostazol

ESOPREZE is not approved for use in children younger than 1 year of age.

Check with your doctor if you:

- have any allergies to any other medicines or foods
- have any other medical conditions such as any problems with your liver, severe kidney problems
- have been diagnosed with osteoporosis
- have ever had a skin reaction after treatment with a medicine similar to ESOPREZE that reduces stomach acid
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not take ESOPREZE if you are pregnant or breastfeeding unless your doctor says so.

It is not known if it is safe for you to take ESOPREZE while you are pregnant. It may affect your baby.

It is not known if your baby can take in ESOPREZE from breast milk if you are breastfeeding.

3. What if I am taking other medicines?

Do not take ESOPREZE if you are taking the following medicines:

- atazanavir and nelfinavir medicines used to treat viral infections such as HIV
- cilostazol a medicine used to treat intermittent claudication

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ESOPREZE and affect how it works.

These include:

- ketoconazole, itraconazole and voriconazole - medicines used to treat fungal infections
- diazepam a medicine used to treat anxiety and some other conditions
- phenytoin a medicine used to treat epilepsy or fits
- citalopram, clomipramine and imipramine - medicines used to treat depression
- St John's wort a herbal remedy used to treat mood disorders

ESOPREZE