

## PATIENT INFORMATION LEAFLET:

### RAYZIUM TABLETS:

{Esomeprazole 20/40mg per tablet}

*Read this leaflet carefully before you start taking this medicine.*

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.
- In order that this medicine works, it must be taken exactly as directed.
- Keep all medicines out of reach of children.
- If you want more information about this medicine ask your doctor or pharmacist.

#### In this leaflet:

1. What Rayzium is and what it is used for
2. Before you use Rayzium
3. How to use Rayzium
4. Possible side effects
5. How to store Rayzium.
6. Further information

#### 1. WHAT IS RAYZIUM AND WHAT IS IT USED FOR?

The name of the medicine is Rayzium.

Rayzium contains the active substance Esomeprazole which belongs to a group of medicines called proton pump inhibitors that work by reducing production of acids by the stomach.

Rayzium is used to treat Gastro esophageal reflux disease (GERD), ulcers in the stomach and hyperacidity.

#### 2. BEFORE YOU USE RAYZIUM:

*Do not use without medical advice:*

- If you have had an allergy to any of the ingredients in the past.
- If you are on any other drugs.
- You must talk to a doctor if you do not feel better or if you feel worse.
- If you are pregnant
- If you are breastfeeding.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Esomeprazole:

- If you have severe liver problems.
- If you have severe kidney problems.
- If you have a vitamin B12 deficiency or there is a risk of a vitamin B12 deficiency.
- If you have ever had a skin reaction after treatment with a medicine similar to Esomeprazole that reduces stomach acid.
- If you are due to have a specific blood test (Chromogranin A).

#### Take special care with Rayzium:

*If you are about to have any of the following, tell your doctor that you are taking 'Rayzium':*

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).

If any of the above applies to you, talk to your doctor or dentist before the procedure.

#### Taking other medicines

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

Do not take Esomeprazole if you are taking a medicine containing nelfinavir (used to treat HIV infection).

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). Your doctor may need to change your dose and/or to take other precautions.

#### Using Rayzium with food and drink

You can take 'Rayzium' with or without food.

You can take the tablets with food or on an empty stomach.

#### Pregnancy & breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

#### 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.

#### Important information about some of the ingredients of Rayzium

Rayzium contains Lactose which may cause allergic reactions.

#### 3. HOW TO USE RAYZIUM:

*Always take or give this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.*

The usual initial dose is Rayzium 20mg or 40mg once or twice daily. The dosage depends on the condition being treated.

Rayzium is not recommended for children under the age of 12 years.

#### If you take more 'Rayzium' than you should

Contact your doctor or go to the nearest hospital casualty department straight away. Remember to take with you any remaining tablets and the pack, so the doctor knows what you have taken.

**If you forget to take 'Rayzium':** If you miss a dose do not worry. Take your normal dose when it is next due. Do not take a double dose to make up for a forgotten tablet.

**If you stop taking 'Rayzium':** Do not stop taking your medicine, unless your doctor has advised you to do so.

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

#### 4. POSSIBLE SIDE EFFECTS:

Like all medicines, Rayzium can have side effects though not everyone gets them. Report this or any other side effects to your doctor or pharmacist.

These include headache, diarrhea, stomach pain, constipation, flatulence and rarely, taste changes. Report these or any other side effects to your doctor or pharmacist.

#### 5. HOW TO STORE RAYZIUM:

Do not use Rayzium after the expiry date stamped on the pack. The expiry date refers to the last day of the month.

Do not store above 30°C. Store sartilos in the original carton/container in a cool dry place protected from direct sunlight. Keep out of the sight and reach of children.

Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose off medicines no longer required. These measures will help protect the environment.

#### 6. FURTHER INFORMATION:

What Rayzium contains

The active substances is Esomeprazole.

#### This product contains lactose

This product should be used on the advice of a doctor or pharmacist.

Rayzium is available as follows:

Round, biconvex, off pink to brownish, enteric coated tablets, scored and embossed 'BD' on one side and plain on the other.

3 x10's & 14's Blister packs in unit boxes.

Further information on summary of product characteristics can be obtained from the regulatory affairs department of Biodeal Laboratories Ltd. [regulatoryaffairs@biodealkenya.com](mailto:regulatoryaffairs@biodealkenya.com).



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