

## Part VI: Summary of the risk management plan

### Summary of risk management plan for Esomeprazole Day Zero (esomeprazole)

This is a summary of the risk management plan (RMP) for Esomeprazole Day Zero. The RMP details important risks of Esomeprazole Day Zero and how more information will be obtained about Esomeprazole Day Zero's risks and uncertainties (missing information).

Esomeprazole Day Zero's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Esomeprazole Day Zero should be used.

Important new concerns or changes to the current ones will be included in updates of Esomeprazole Day Zero's RMP.

#### I. The medicine and what it is used for

Esomeprazole Day Zero is authorised for the following indications:

##### Adults

- Gastro-oesophageal Reflux Disease (GORD)
- In combination with appropriate antibacterial therapeutic regimens for the eradication of *Helicobacter pylori*
- In patients requiring continued NSAID therapy
- Prolonged treatment after i.v. induced prevention of rebleeding of peptic ulcers.
- Treatment of Zollinger Ellison Syndrome

##### Adolescents from the age of 12 years for:

- Gastro-oesophageal Reflux Disease (GORD)
- In combination with antibiotics in treatment of duodenal ulcer caused by *Helicobacter pylori*

See SmPC for the full indications.

The product contains esomeprazole as magnesium dihydrate as the active substance and it is given by oral route of administration.

#### II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Esomeprazole Day Zero, together with measures to minimise such risks and the proposed studies for learning more about Esomeprazole Day Zero's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;

- The medicine’s legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary.

These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Esomeprazole Day Zero is not yet available, it is listed under ‘missing information’ below..

### **II.A List of important risks and missing information**

Important risks of Esomeprazole Day Zero are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Esomeprazole Day Zero. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

<b>List of important risks and missing information</b>	
Important identified risks	Agranulocytosis Hypersensitivity reactions Hypomagnesaemia Depression Hepatic reactions Severe cutaneous adverse reactions Interstitial nephritis Fracture of the hip, wrist or spine Gastrointestinal infections Interaction with warfarin or other coumarine derivatives Interaction with phenytoin Interaction with atazanavir Interaction with nelfinavir Interaction with digoxin Interaction with methotrexate Interaction with tacrolimus Interaction with clopidogrel
Important potential risks	Convulsion/seizure Pneumonia
Missing information	Use in pregnant and lactating women Use in patients with renal impairment

### **II.B Summary of important risks**

The safety information in the proposed Product Information is aligned to the reference medicinal product.

### **II.C Post-authorisation development plan**

#### **II.C.1 Studies which are conditions of the marketing authorisation**

There are no studies which are conditions of the marketing authorisation or specific obligation of Esomeprazol Day Zero.

#### **II.C.2 Other studies in post-authorisation development plan**

There are no studies required for Esomeprazol Day Zero.