Part VI: Summary of the risk management plan

Summary of risk management plan for Pralacid (esomeprazole), gastro-resistant granules for oral suspension, sachet

This is a summary of the risk management plan (RMP) for Pralacid. The RMP details important risks of Pralacid, how these risks can be minimised, and how more information will be obtained about Pralacid's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Pralacid is primarily indicated for:

Paediatric population

Children 1-11 years old

Gastroesophageal Reflux Disease (GERD)

- treatment of endoscopically proven erosive reflux esophagitis
- symptomatic treatment of gastroesophageal reflux disease (GERD)

Children over 4 years of age
In combination with antibiotics in treatment of duodenal ulcer caused by *Helicobacter pylori*

Adults and adolescents from the age of 12 years

For indications in patients from the age of 12 years reference is made to gastro-resistant tablets containing esomeprazole.

(see SmPC for the full indication)

It contains esomeprazole as the active substance, and it is given orally.

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

Important risks of Pralacid, together with measures to minimise such risks and the proposed studies for learning more about Pralacid risks, are outlined below.

Measures to minimise the risks identified for medicinal products are:

- 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*.

II.A List of important risks and missing information

Important risks of Pralacid 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 Pralacid. 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).

Summary of safety concerns	
Important identified risks	• none
Important potential risks	• none
Missing information	• none

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 Pralacid.

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

There are no studies required for Pralacid.