Part VI: Summary of the risk management plan

This is a summary of the risk management plan (RMP) for **ABIGERD** (Esomeprazole Magnesium Dehydrate). The RMP details important risks of **ABIGERD** how these risks can be minimised, and how more information will be obtained about **ABIGERD** 's risks and uncertainties (missing information). **ABIGERD** 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how **ABIGERD** should be used.

I. The medicine and what it is used for

ABIGERD is indicated is used to treat the following conditions:

Adults and young people aged 12 years and above
- 'Gastro-oesophageal reflux disease' (GORD). 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.

Adults
- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). /.../ can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).
- Prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole.

Gastro-oesophageal Reflux Disease (GORD)
- treatment of erosive reflux oesophagitis
- long-term management of patients with healed oesophagitis to prevent relapse
- symptomatic treatment of gastro-oesophageal reflux disease (GORD)

In combination with antibiotics in treatment of duodenal ulcer caused by Helicobacter pylori

It contains Esomeprazole Magnesium Dehydrate as the active substance.

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

Important risks of **ABIGERD** together with measures to minimise such risks and the proposed studies for learning more about **ABIGERD** 's risks, re 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.

If important information that may affect the safe use of **ABIGERD** is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of **ABIGERD** 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 **ABIGERD**. 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);

List of important risks and missing information	
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 for **ABIGERD**

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

There are no studies required for **ABIGERD**.