## PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

### Summary of risk management plan for Pantoprazole

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

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

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

Pantoprazole is authorised for treatment of reflux oesophagitis, gastric and duodenal ulcer and Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions. It contains pantoprazole sodium/pantoprazole sodium sesquihydrate as the active substance and it is given by orally/intravenously.

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

Important risks of pantoprazole, together with measures to minimise such 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 public (e.g. with or without prescription) can help to minimises its risks.

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

In addition to these measures, information about adverse events is collected continuously and is regularly analysed, including in PSUR assessment, 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 pantoprazole is not yet available, it is listed under 'missing information' below.

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

Important risks of pantoprazole are those risks that need special risk management activities to further investigate or minimise them, so that the medicinal product can be safely administered to/taken by patients. 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 pantoprazole. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but the definite causal 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/use in special patient populations etc.)

*Table 7 Part VI: Summary of safety concerns*

| **List of important risks and missing information** | |
|---|---|
| Important identified risks | • Marked decrease in the number of white blood cells (Agranulocytosis/pancytopenia) |

| **List of important risks and missing information** | |
|---|---|
| | • Potentially life-threatening rashes resulting from exposure to a drug (Severe cutaneous reactions)<br>• Weaken in strength of liver (Hepatic impairment)<br>• Taking atazanavir together with pantoprazole (Co-administration with atazanavir)<br>• Low magnesium blood levels (Hypomagnesaemia)<br>• Alteration of the effects of a drug by reaction with blood thinning medicines (Interaction with coumarin anticoagulants)<br>• Alteration of the effects of a drug by reaction with medicines used to treat fungal infections and several types of cancer (Interaction with antifungals and erlotinib) |
| Important potential risks | • An accumulation of abnormal cells in the breast (Atypical hyperplasia)<br>• Breaking of the hip, wrist or spine bones (Increased risk of hip, wrist and spine fracture)<br>• Damaged skeletal muscle breaks down rapidly (Rhabdomyolysis)<br>• Infection of the air sacs of the lungs (Pneumonia)<br>• Infection due to the spore-forming bacterium, *Clostridium difficile* (*Clostridium difficile* infection) |
| Missing information | • Use in pregnant or breastfeeding patients (Use in pregnancy and lactation) |

## II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the approved Mylan's RMP.

## 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 pantoprazole.

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

There are no studies required for pantoprazole.