Summary of risk management plan for Omeprazole Oral Suspension

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

The Omeprazole Oral Suspension summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Omeprazole should be used.

Important new concerns or changes to the current ones will be included in updates to the Omeprazole Oral Suspension RMP.

I. The medicine and what it is used for

Omeprazole Oral Suspension is authorised for the treatment of ulcers, reflux esophagitis (in adults and children), gastro-esophageal reflux disease (in adults and children) and, in combination with antibiotics, in the treatment of duodenal ulcers caused by *H. pylori* (in adults and children) (see SmPC for full indication). It contains Omeprazole as the active substance and it is given as a suspension by the oral route.

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

Important risks of Omeprazole Oral Suspension, together with measures to minimise such risks and the proposed studies for learning more about Omeprazole Oral Suspension 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 packaging;

•The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;

•The prescription only legal status of the medicine.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including 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 Omeprazole Oral Suspension is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Omeprazole Oral Suspension 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 Omeprazole Oral Suspension. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but where 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) and is detailed in Table VI.2.1 below. Table VI.2.1

List of important risks and missing information	
Important identified risks	• Hypersensitivity
Important potential risks	• Hyperkalaemia • Gastrointestinal effects / infections related to acid inhibition • Severe cutaneous reactions including Subacute cutaneous lupus erythematosus (SCLE) • Tinnitus • DRESS • All serious conditions associated with "Fall" • myocardial infarctionRisk of masking symptoms of more serious conditions • Risk of masking symptoms if more serious conditions
Important missing information	• Long-term treatment with omeprazole in children (with GERD)

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product except for the Important Potential Risk, Hyperkalaemia, and the Missing Information, Longterm treatment with omeprazole in children (with GERD), which were identified previously:

Table VI.II.B.1

Important Potential Risk: Hyperkalaemia	
Evidence for linking the risk to the medicine	Evidence is based on knowledge of medicinal formulation (Ref SmPC) and known absorption of potassium via gastrointestinal route
Risk factor and risk groups	Chronic kidney disease Diabetes Congestive heart failure Medications that disrupt potassium balance, such as certain blood pressure lowering drugs
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4: Recommendation for taking Potassium content of medicine into consideration by patients with reduced kidney function or patients on a controlled potassium diet. PIL Section 4: Recommendation for taking Potassium content of medicine into consideration by patients with reduced kidney function or patients on a controlled potassium diet. Other routine risk minimisation measures beyond the Product Information: This is a prescription only medicinal product.
Additional pharmacovigilance activities	Not Applicable

Table VI.II.B.2

Missing Information: Long-term treatment with omeprazole in children (with GERD)

Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.2: *Reflux esophagitis*: The treatment time is 4-8 weeks. *Symptomatic treatment of heartburn and acid regurgitation in gastroesophageal reflux disease:* The treatment time is 2–4 weeks. If symptom control has not been achieved after 2–4 weeks the patient should be investigated further. PIL Section 2: **Children** Some children with chronic illnesses may require long-term treatment although it is not recommended. Do not give this medicine to children under 1 month of age. Other routine risk minimisation measures beyond the Product Information: This is a prescription only medicinal product.
Additional pharmacovigilance activities	Not Applicable

II.C Post-authorisation Development Plan

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

The following studies are conditions of the marketing authorisation:

None

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

Not applicable