Part VI: Summary of the risk management plan

Summary of risk management plan for Peptonorm 1g tablets (Sucralfate)

This is a summary of the risk management plan (RMP) for Peptonorm 1g tablets. The RMP details important risks of Peptonorm, how these risks can be minimised, and how more information will be obtained about Peptonorm's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Peptonorm is indicated in adults and adolescents over 14 years old for the treatment of duodenal ulcer, ventricular ulcer, reflux esophagitis and the prophylaxis of gastrointestinal haemorrhage from stress ulceration in seriously ill patients (see SmPC for the full indication). It contains sucralfate as the active substance and it is given by oral route.

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

Important risks of Peptonorm, together with measures to minimise such risks and the proposed studies for learning more about Peptonorm'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, 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 Peptonorm is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

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

II.B Summary of important risks

No safety concerns have been identified for Peptonorm 1g tablets.

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 Peptonorm 1 g tablets.

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

There are no studies required for Peptonorm 1 g tablets.