PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Gaviscon Double Action.

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

Gaviscon Double Action SmPC and its package leaflet give essential information to healthcare professionals and patients on how Gaviscon Double Action should be used.

I. The medicine and what it is used for

Gaviscon Double Action is authorised for treatment of symptoms resulting from the reflux of acid, bile and pepsin into the oesophagus such as acid regurgitation, heartburn and indigestion, for example following meals or during pregnancy. It contains sodium alginate, sodium hydrogen carbonate and calcium carbonate as the active substances and it is given orally.

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

Important risks of Gaviscon Double Action, together with measures to minimise such risks and the proposed studies for learning more about Gaviscon Double Action 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.

II.A List of important risks and missing information

Important risks of Gaviscon Double Action 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 Gaviscon Double Action. 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);

Identified Risks	None.
Potential Risks	None.
Missing Information	None.

Products marketed by RB have well-established safety profiles and can, therefore, be safely taken. The safety profile of Gaviscon Double Action is positive. RB rigorously performs routine pharmacovigilance activities and regularly evaluates its safety information based on adverse event data, literature and advice from regulatory authorities.

II.B Summary of important risks
Not applicable.

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 Gaviscon Double Action.

II.C.2 Other studies in post-authorisation development plan
There are no studies required for Gaviscon Double Action.