Summary of Risk Management Plan for Rennie Dual Action Chewable Tablets (Calcium carbonate 625mg Magnesium carbonate 73.5mg Alginic acid 150mg)

This is a summary of the risk management plan (RMP) for Rennie Dual Action Chewable Tablets (Calcium carbonate 625mg Magnesium carbonate 73.5mg Alginic acid 150mg). The RMP details important risks of Rennie Dual Action Chewable tablets, how these risks can be minimised, and how more information will be obtained about Rennie Dual Action Chewable tablets' risks and uncertainties (missing information).

Rennie Dual Action Chewable Tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how the product should be used.

I. The Medicine and what it is used for

Rennie Dual Action Chewable Tablet is authorised for symptomatic treatment of complaints resulting from gastro-oesophageal reflux and hyperacidity, such as regurgitation and heartburn (see SmPC for the full indication). It contains calcium carbonate, magnesium carbonate, alginic acid as the active substances and it is given by orally.

II. Risks Associated with the Medicine and Activities to Minimise or further Characterise the Risks

The risks of Rennie Dual Action Chewable Tablets (Calcium carbonate 625mg Magnesium carbonate 73.5mg Alginic acid 150mg), 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 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 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 this medicine. 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).

None of the presented risks (all estimated as identified) have been considered as important and having impact on the favorable risk-benefit balance of Rennie Dual Action Chewable Tablets or warranting further evaluation as part of the pharmacovigilance plan or additional risk minimization measures.

List of important risks and missing information

Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of Important Risks

Not applicable, as there were no important identified risk, important potential risk, or missing information.

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 Rennie Dual Action Chewable Tablets.

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

There are no studies required for Rennie Dual Action Chewable Tablets.