PART VI

Summary of Risk Management Plan for Rennie (Calcium carbonate and M agnesium carbonate)

Active substance(s) (INN or common name):	Calcium carbonate + Magnesium carbonate

Medicinal products to which this RMP refers:	1

Name of Marketing Authorisation Holder or Applicant:	Bayer Consumer Care

Data lock point for this module	27 AUG 2019

Version number of RMP when this module was last updated	2.2

Summary of Risk Management Plan for Rennie (Calcium carbonate and Magnesium carbonate)

This is a summary of the risk management plan (RMP) for Rennie. None of the presented risks (all considered *identified* risks) have been recognized as an important risk, due to a lack of impact on the favorable risk-benefit profile of Rennie and as these risks do not warrant further evaluation as a part of the pharmacovigilance plan or additional risk minimization activities.

Rennie's summary of product characteristics (SmPC) and its package leaflet provides relevant and adequate information to both healthcare professionals and patients, on how Rennie should be used.

I. The Medicine and what it is used for

Rennie is authorised for symptomatic relief of acid-related symptoms, e.g. heartburn, indigestion and dyspepsia. (see SmPC for the full indication). It contains calcium carbonate and magnesium carbonate as the active substance and it is administered orally, either chewed or sucked.

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

Important risks of Rennie, together with measures to minimise such risks and the proposed studies for learning more about Rennie'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 so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of Important Risks and Missing Information

Important risks of Rennie 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 Rennie. 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);

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of Important Risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

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.

II.C.2 Other Studies in Post-authorisation Development Plan

There are no studies required for Rennie.