European Union Risk Management Plan (EU-RMP)
Simeticone

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

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Summary of Risk Management Plan for Simeticone

This is a summary of the risk management plan (RMP) for simeticone. The RMP details important risks of Imonogas 120 mg and 240 mg soft capsule, Mylicongas 40 mg chewable tablet, and Mylicon Bambini 66.6 mg/1 mL oral drops, how these risks can be minimised, and how more information will be obtained about the product's risks and uncertainties (missing information).

The Summary of Product Characteristics (SmPC) and Package Leaflet of Imonogas 120 mg and 240 mg soft capsule, Mylicongas 40 mg chewable tablet, and Mylicon Bambini 66.6 mg/1 mL oral drops give essential information to healthcare professionals and patients on how the product should be used.

Important new concerns or changes to the current ones will be included in the RMP updates for Imonogas 120 mg and 240 mg soft capsule, Mylicongas 40 mg chewable tablet, and Mylicon Bambini 66.6 mg/1 mL oral drops.

I. The Medicine and What it is Used For

Imonogas 120 mg and 240 mg soft capsule, Mylicongas 40 mg chewable tablet, and Mylicon Bambini 66.6 mg/1 mL oral drops are authorised for the symptomatic treatment of flatulence and gas associated with gastrointestinal disorders (see SmPC for the full indication). These products contain simeticone as the active substance and are given via oral route.

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

Important risks of Imonogas 120 mg and 240 mg soft capsule, Mylicongas 40 mg chewable tablet, and Mylicon Bambini 66.6 mg/1 mL oral drops, together with measures to minimise such risks and the proposed studies for learning more about 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 as to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (eg, 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.

If important information that may affect the safe use of Imonogas 120 mg and 240 mg soft capsule, Mylicongas 40 mg chewable tablet, and Mylicon Bambini 66.6 mg/1 mL oral drops is not yet available, it is listed under 'missing information' below.

II.A. List of Important Risks and Missing Information

Important risks of Imonogas 120 mg and 240 mg soft capsule, Mylicongas 40 mg chewable tablet, and Mylicon Bambini 66.6 mg/1 mL oral drops are those that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with product use. Potential risks are concerns for which an association with product use is possible based on available data but has not been established 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 (eg, 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

There are no important identified risks, important potential risks, and missing information for Imonogas 120 mg and 240 mg soft capsule, Mylicongas 40 mg chewable tablet, and Mylicon Bambini 66.6 mg/1 mL oral drops.

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 Imonogas 120 mg and 240 mg soft capsule, Mylicongas 40 mg chewable tablet, and Mylicon Bambini 66.6 mg/1 mL oral drops.

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

There are no studies required for Imonogas 120 mg and 240 mg soft capsule, Mylicongas 40 mg chewable tablet, and Mylicon Bambini 66.6 mg/1 mL oral drops.