PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for MOTILIUM (domperidone)

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

MOTILIUM's Summary of Product Characteristics (SmPC) and its Package Leaflet give essential information to healthcare professionals and patients on how MOTILIUM should be used.

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

I. The Medicine and What it is Used For

MOTILIUM is authorized for the relief of the symptoms of nausea and vomiting (see SmPC for the full indication). It contains domperidone as the active substance and it is given orally in the form of orodispersible tablets, film-coated tablets, or as an oral suspension.

II. Risks Associated with the Medicine and Activities to Minimize or Further Characterize the Risks

Important risks of MOTILIUM, together with measures to minimize such risks and the proposed studies for learning more about MOTILIUM's risks, are outlined below.

Measures to minimize 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 authorized 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 (eg, with or without prescription) can help to minimize its risks.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Report assessment, so that immediate action can be taken as necessary.

Together, these measures constitute routine risk minimization measures.

II.A. List of Important Risks and Missing Information

Important risks of MOTILIUM are risks that need special risk management activities to further investigate or minimize 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 MOTILIUM. 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 (eg, on the long-term use of the medicine); there is no missing information for MOTILIUM.

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 risks for MOTILIUM.

II.C. Postauthorization Development Plan

II.C.1. Studies Which are Conditions of the Marketing Authorization

There are no studies which are conditions of the marketing authorization or specific obligation of MOTILIUM.

II.C.2. Other Studies in Postauthorization Development Plan

There are no studies required for MOTILIUM.