
**PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN - IMODIUM®
(Loperamide Hydrochloride [HCl])****Summary of Risk Management Plan for IMODIUM® (Loperamide Hydrochloride [HCl])**

This is a summary of the Risk Management Plan (RMP) for IMODIUM (also known as IMOSEC®). Over 40 years' market experience with loperamide products has demonstrated a favorable benefit-risk profile for the indications specified in this RMP and, therefore, there are no important risks or uncertainties (missing information) associated with this product. IMODIUM's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how IMODIUM should be used.

Important new concerns will be included in updates of IMODIUM's RMP.

I. The Medicine and What it is Used For

IMODIUM is authorized for the symptomatic control of acute and chronic diarrhea. In patients with an ileostomy it can be used to reduce the number and volume of stools and to harden their consistency (see SmPC for the full indication). It contains loperamide HCl as the active substance and it is given by orally by capsules (1 or 2 mg), tablets (2 mg), granules (0.5 mg/g [0.05%] or 1 mg/g [0.1%]), oral solution (2 mg/10 mL), oral liquid (2 mg/15 mL), and orodispersible fast dissolving tablets (2 mg).

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

Not applicable, as there are no important identified risks or important potential risks for IMODIUM.

II.A. List of Important Risks and Missing Information

There are no important identified risks, important potential risks, or missing information for IMODIUM.

II.B. Summary of Important Risks

There are no important identified risks, important potential risks, or missing information for IMODIUM.

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 IMODIUM.

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

There are no studies required for IMODIUM.

**PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN - IMODIUM® PLUS
(Loperamide Hydrochloride [HCl]/Simethicone)****Summary of Risk Management Plan for IMODIUM® PLUS (Loperamide Hydrochloride [HCl]/Simethicone)**

This is a summary of the Risk Management Plan (RMP) for IMODIUM PLUS. Over 40 years' market experience with loperamide products has demonstrated a favorable benefit-risk profile for the indications specified in this RMP and, therefore, there are no important risks or uncertainties (missing information) associated with this product.

IMODIUM PLUS's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how IMODIUM PLUS should be used.

Important new concerns will be included in updates of IMODIUM PLUS's RMP.

I. The Medicine and What it is Used For

IMODIUM PLUS is authorized for:

- The control of acute diarrhea of any cause and its commonly associated symptoms. These are often attributed to “trapped wind” and include abdominal discomfort, bloating, cramping and flatulence.

See country/territory-specific SmPCs for the full indications. It contains loperamide HCl in combination with simethicone (loperamide HCl/simethicone) as the active substance and it is given by oral caplets (2 mg loperamide HCl and simethicone).

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

Not applicable, as there are no important identified risks or important potential risks for IMODIUM PLUS.

II.A. List of Important Risks and Missing Information

There are no important identified risks, important potential risks, or missing information for IMODIUM PLUS.

II.B. Summary of Important Risks

There are no important identified risks, important potential risks, or missing information for IMODIUM PLUS.

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 IMODIUM PLUS.

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

There are no studies required for IMODIUM PLUS.

Status : Final

Version : 1.0

Document ID : J0436542