Part VI: Summary of the risk management plan

Summary of risk management plan for Loperamide 2 mg oral lyophilisate (loperamide):

This is a summary of the risk management plan (RMP) for Loperamide 2 mg oral lyophilisate. The RMP details important risks of Loperamide 2 mg oral lyophilisate, how these risks can be minimised, and how more information will be obtained about Loperamide 2 mg oral lyophilisate's risks and uncertainties (missing information).

Loperamide 2 mg oral lyophilisate's summary of product characteristics (SmPC[1]) and its package leaflet[2] give essential information to healthcare professionals and patients on how Loperamide 2 mg oral lyophilisate should be used.

Important new concerns or changes to the current ones will be included in updates of Loperamide 2 mg oral lyophilisate's RMP.

I. The medicine and what it is used for

Loperamide 2 mg oral lyophilisate is one of a group of medicines called "anti-diarrhoeals" which are used to treat diarrhoea by slowing down an overactive bowel (see SmPC[1] for the full indication). This allows water and salts that are usually lost in diarrhoea to be absorbed by the body. It contains loperamide as the active substance and it is given by oral route.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Loperamide 2 mg oral lyophilisate, 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[2] and SmPC[1] 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.

If important information that may affect the safe use of Loperamide 2 mg oral lyophilisate is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Loperamide 2 mg oral lyophilisate are risks 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 the use of Loperamide 2 mg oral lyophilisate. 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).

Summary of safety concerns	
Important identified risks	• Severe skin reactions, including Stevens Johnson syndrome, Toxic epidermal necrolysis and Erythema multiforme • Ileus (including paralytic ileus) • Megacolon (including toxic megacolon)
Important potential risks	• QT prolongation and/or serious ventricular arrhythmias, including Torsades de Pointes associated with abuse and misuse of loperamide. • CNS toxicity due to relative overdose in patients with hepatic impairment • Prolonged use masking an underlying condition requiring medical attention
Missing information	• Use in pregnant or breastfeeding women

II.B Summary of important risks

The safety information for the other important safety concerns 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 which is a specific obligation of Loperamide 2 mg oral lyophilisate.

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

There are no studies required for Loperamide 2 mg oral lyophilisate.