PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Lopinavir/Ritonavir Mylan

This is a summary of the risk management plan (RMP) for Lopinavir/Ritonavir Mylan. The RMP details important risks of lopinavir/ritonavir, how these risks can be minimised, and how more information will be obtained about lopinavir/ritonavir's risks and uncertainties (missing information).

Lopinavir/Ritonavir Mylan's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

This summary of the RMP for lopinavir/ritonavir should be read in the context of all the information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Lopinavir/Ritonavir Mylan's RMP.

I. The medicine and what it is used for

Lopinavir/Ritonavir Mylan is authorised for the treatment of human immunodeficiency virus (HIV-1) infected adults, adolescents and children above the age of 2 years and the choice of lopinavir/ritonavir to treat protease inhibitor experienced HIV-1 infected patients should be based on individual viral resistance testing and treatment history of patients. It contains lopinavir/ritonavir as the active substance, and it is given by oral route of administration.

Further information about the evaluation of Lopinavir/Ritonavir Mylan's benefits can be found in Lopinavir/Ritonavir Mylan's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

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

Important risks of Lopinavir/Ritonavir Mylan, 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 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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including PSUR assessment, 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 lopinavir/ritonavir Mylan is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Lopinavir/Ritonavir Mylan are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered by patients. 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 lopinavir/ritonavir Mylan. 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/use in special patient populations etc.);

Table Part VI: Summary of safety concerns

List of important risks and missing information	
Important identified risks	• Immune reconstitution inflammatory syndrome (IRIS) manifesting as autoimmune disorders (such as Graves' disease). • Lipid elevations.
Important potential risks	• QT prolongation with supratherapeutic doses. • PR prolongation at therapeutic dosing.
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 Lopinavir/Ritonavir Mylan.

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

There are no studies required for Lopinavir/Ritonavir Mylan.