

Part VI: Summary of the Risk Management Plan

Summary of risk management plan for Norvir (ritonavir)

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

Norvir's summary of product characteristics (SmPCs) and its package leaflets (PLs) give essential information to health care professional (HCP) and patients on how Norvir should be used.

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

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

I The Medicine and What it Is Used For

Norvir is indicated for the treatment of HIV-1 infected adults and children older than 2 years of age in combination with other ARV agents. Norvir is also used as a PK enhancer with certain PIs in adults and children (see SmPC for the full indication). Norvir is the active substance and it is given by mouth.

Further information about the evaluation of Norvir benefits can be found in Norvir 's EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage (<https://www.ema.europa.eu/en/medicines/human/EPAR/norvir>).

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

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

Norvir does not currently have risks designated as "important identified risks" or "important potential risks."

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and health care 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 (e.g., with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report (PSUR) assessments so that immediate action can be taken as necessary. These measures constitute routine PV activities.

II.A List of Important Risks and Missing Information

Important risks of Norvir are risks that need special risk management activities to further investigate or minimize 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 correlation with the use of Norvir. 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., 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

This section is not applicable.

II.C Post-Authorization Development Plan

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

There are no studies which are conditions of the marketing authorisation or specific obligation of Norvir.

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

There are no studies required for Norvir.