PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for nevirapine

This is a summary of the risk management plan (RMP) for Nevirapine Mylan (nevirapine). The RMP details important risks of nevirapine, how these risks can be minimised, and how more information will be obtained about nevirapine risks and uncertainties (missing information).

Nevirapine 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.

I. The medicine and what it is used for

Nevirapine Mylan is authorised for the treatment of HIV-1 infected adults, adolescents, and children three years and above and able to swallow tablets. It contains nevirapine as the active substance and it is given by oral route of administration.

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

Important risks of nevirapine, together with measures to minimise such risks and the proposed studies for learning more about nevirapine's 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 nevirapine is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of nevirapine are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered to 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 nevirapine. 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 7 Part VI: Summary of safety concerns

List of important risks and missing information	
Important identified risks	• Skin rash (including severe or life-threatening skin reactions, e.g. Steven-Johnson syndrome, toxic epidermal necrolysis) • Severe and life-threatening hepatotoxicity (including fatal fulminant hepatitis) • Granulocytopenia particularly in pediatric population
Important potential risks	N/A
Missing information	• Use in pregnant women

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 nevirapine.

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

Antiretroviral Pregnancy Registry.

Purpose of study: To collect information on the risk of birth defects in patients exposed to nevirapine during pregnancy.