Summary of risk management plan for STOCRIN

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

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

This summary of the RMP for STOCRIN should be read in the context of all this 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 efavirenz´s RMP.

I. The Medicine and What it is Used for

STOCRIN is authorised for use in antiviral combination treatment of human immunodeficiency virus-1 (HIV-1) infected adults, adolescents and children 3 years of age and older. It contains efavirenz as the active substance and it is given by mouth.

Further information about the evaluation of STOCRIN ’s benefits can be found in STOCRIN´s EPAR, including in its plain-language summary, available on the EMA website, under the medicine’s webpage
https://www.ema.europa.eu/en/medicines/human/EPAR/Stocrin

II. Risks Associated With the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of STOCRIN, together with measures to minimise such risks and the proposed studies for learning more about STOCRIN '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 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, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of Important Risks and Missing Information

Important risks of STOCRIN are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 STOCRIN. 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);

Table II.A.1: List of Important Risks and Missing Information

List of Important Risks and Missing Information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of Important Risks

Not applicable. There are no important identified risks, important potential risks, or missing information.

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 STOCRIN.

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

Not applicable