Viramune (nevirapine), Retardtabletten – ZL-Nr.: 62077 Tabletten – ZL-Nr. 54393

Public Risk Management Plan (RMP) Summary

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The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them. The RMP summary of Viramune is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.
Please note that the reference document which is valid and relevant for the effective and safe use of VIRAMUNE in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic.

Boehringer Ingelheim (Schweiz) GmbH is fully responsible for the accuracy and correctness of the content of the published summary RMP of Viramune.

SUMMARY OF RISK MANAGEMENT PLAN FOR VIRAMUNE (nevirapine)

This is a summary of the Risk Management Plan (RMP) for Viramune. The RMP details important risks of Viramune and how more information will be obtained about Viramune's risks and uncertainties (missing information).

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

This summary of the RMP for Viramune 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 Viramune's RMP.

I. THE MEDICINE AND WHAT IT IS USED FOR

Viramune is authorised in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infected adults, adolescents, and children of any age (see Summary of Product Characteristics [SmPC] for the full indication). It contains nevirapine (NVP) as the active substance and it is given by immediate-release tablet (containing 200 mg of NVP), extended-release tablet (containing 400 mg of NVP), or by oral suspension (containing 50 mg/5 mL of NVP).

Further information about the evaluation of Viramune's benefits can be found in Viramune's EPAR, including in its plain-language summary, available on the European Medicines Agency (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 Viramune, together with measures to minimise such risks and the proposed studies for learning more about Viramune'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 Periodic Safety Update Report (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 VIRAMUNE 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 VIRAMUNE. 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).

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 Viramune.

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

There are no studies required for Viramune.

ABBREVIATIONS

EMA	European Medicines Agency
EPAR	European Public Assessment Report
NVP	Nevirapine
PSUR	Periodic Safety Update Report
RMP	Risk Management Plan
SmPC	Summary of Product Characteristics