Swiss Summary of the Risk Management Plan (RMP)

Maviret®

(Glecaprevir / Pibrentasvir)

100 mg/40 mg

Film-coated tablets

Based on Core/EU RMP, Version 9.1 (January 2023)

AbbVie AG

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Disclaimer

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 Maviret 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 Maviret in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. AbbVie AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Maviret.

Summary of risk management plan for Glecaprevir/Pibrentasvir

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

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

This summary of the RMP for glecaprevir/pibrentasvir 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 glecaprevir/pibrentasvir's RMP.

I The Medicine and What it Is Used For

Glecaprevir/pibrentasvir is authorized for the treatment of chronic hepatitis C virus (HCV) infection in adults and children aged 3 years and older (see SmPC for the full indication). It contains glecaprevir/pibrentasvir as the active substance and it is given by mouth.

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

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004430/human_med_002151.jsp&mid=WC0b01ac058001d124.

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

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

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 healthcare 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) 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 glecaprevir/pibrentasvir is not yet available, it is listed under "missing information" below.

II.A List of Important Risks and Missing Information

Important risks of glecaprevir/pibrentasvir 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 link with the use of glecaprevir/pibrentasvir. 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	Safety in patients with moderate hepatic impairment (Child-Pugh B)

II.B Summary of Important Risks

Missing information: Safety in patients with moderate hepatic impairment (Child-Pugh B)	
Risk minimization measures	Routine risk minimization measures: • SmPC Section 4.2 - Posology and method of administration, hepatic impairment section, provides information that advises that the use of GLE/PIB is not recommended in patients with moderate hepatic impairment (Child Pugh B). • SmPC Section 4.4 - Special warnings and precautions for use, advises that the use of Maviret is not recommended in patients with moderate hepatic impairment (Child-Pugh B). • Restricted medical prescription. o Use of treatment should be initiated and supervised by specialists. Additional risk minimization measures: None.

II.C Post-Authorization Development Plan

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

There are no ongoing studies that are conditions of the marketing authorization.

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

There are no other ongoing studies that are part of a post-authorization development plan.