Swiss Summary of the Risk Management Plan (RMP)

Vaxneuvance®

Active Substance: Pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed)

RMP summary version 1.0 (March 2023)

Based on EU-RMP Version 1.0 (07-Oct-2021)

Marketing Authorisation Holder: MSD Merck Sharp & Dohme AG, Lucerne

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 Vaxneuvance 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 Vaxneuvance in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

MSD Merck Sharp & Dohme AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Vaxneuvance.

SUMMARY OF THE RISK MANAGEMENT PLAN BY PRODUCT

Summary of risk management plan for VAXNEUVANCE (Pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed))

This is a summary of the risk management plan (RMP) for VAXNEUVANCE. The RMP details important risks of VAXNEUVANCE, and how more information will be obtained about pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed)'s risks and uncertainties (missing information).

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

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

I. The Medicine and What It Is Used For

VAXNEUVANCE is authorised for active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in adults 18 years of age and older. (see SmPC for the full indication). It contains pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed) as the active substance and it is given by intramuscular injection.

Further information about the evaluation of VAXNEUVANCE’s benefits can be found in VAXNEUVANCE’s EPAR, including in its plain-language summary, available under the medicine’s webpage link to product’s EPAR summary landing page on the EMA webpage.

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

Important risks of VAXNEUVANCE, together with measures to minimise such risks and the proposed studies for learning more about VAXNEUVANCE'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*.

If important information that may affect the safe use of VAXNEUVANCE is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of VAXNEUVANCE are risks that need special risk management activities to further investigate or minimise 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 VAXNEUVANCE. 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	Use in adult hematopoietic stem cell transplant (HSCT) recipients

II.B Summary of Important Risks

Table II.B.1: Missing Information: Use in Adult HSCT recipients

Risk minimisation measures	Routine risk minimisation measures: Special warnings and precautions for use section of the product information Additional risk minimisation measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: Study V114-022: Safety and Immunogenicity of V114 in Recipients of Allo-HSCT

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 VAXNEUVANCE.

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

Study: V114-022

Short Title: Safety and Immunogenicity of V114 in Recipients of Allo-HSCT

Rationale:

Allogeneic hematopoietic stem cell transplant (allo-HSCT) recipients are at increased risk for pneumococcal infections and have a high risk for invasive pneumococcal disease (IPD). IPD is associated with high morbidity and mortality in allo-HSCT recipients, with rates of disease being 20- to 30-fold higher than the general population. Pneumococcal disease can occur early (<3 months post-transplantation), but the majority of IPD cases are reported ≥4 months post transplantation.

This clinical study enrolled allo-HSCT recipients who had not received a non-study pneumococcal vaccine after the transplant, but prior to enrollment. The study is designed to describe the safety, tolerability, and immunogenicity of 3 doses of V114 compared with 3 doses of Prevenar 13™ in allo-HSCT recipients (≥3 years of age). The data from this study will contribute to the overall safety database and immunogenicity profile of V114 in individuals ≥3 years of age and older.

Primary Study Objectives:

To evaluate the safety and tolerability of 3 doses of V114 and 3 doses of Prevenar 13™ with respect to the proportion of participants with adverse events (AEs) within each vaccination group.

To evaluate the serotype-specific immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) at 30 days following the 3rd dose of V114 and following the 3rd dose of Prevenar 13™ within each vaccination group.