Swiss Summary of the Risk Management Plan (RMP)

ZOSTAVAX®

Active Substance: Shingles (herpes zoster) vaccine (live)

RMP Summary: version 1.0 (August 2023)

Based on EU-RMP: Version 11.0 (25-Apr-2023)

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 ZOSTAVAX 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 ZOSTAVAX 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 ZOSTAVAX.

SUMMARY OF THE RISK MANAGEMENT PLAN BY PRODUCT

Summary of risk management plan for ZOSTAVAX (shingles [herpes zoster] vaccine [live])

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

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

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

I. The Medicine and What It Is Used For

ZOSTAVAX is authorised for vaccination for prevention of herpes zoster ("zoster" or shingles) and herpes zoster-related post-herpetic neuralgia (PHN). ZOSTAVAX is indicated for immunization of individuals 50 years of age or older (see SmPC for the full indication). It contains varicella-zoster virus, Oka/Merck strain, (live, attenuated) as the active substance and it is given by subcutaneous (SC) or intramuscular (IM) injection, preferably in the deltoid region. The vaccine should be administered subcutaneously in patients with severe thrombocytopenia or any coagulation disorder.

Further information about the evaluation of ZOSTAVAX's benefits can be found in ZOSTAVAX'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/zostavax

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

Important risks of ZOSTAVAX, together with measures to minimise such risks and the proposed studies for learning more about ZOSTAVAX'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 ZOSTAVAX 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 ZOSTAVAX. 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	Disseminated Disease Caused by Oka/Merck Vaccine Virus Strain in Immunodeficient Individuals and Individuals on Immunosuppressive Therapy
Important potential risks	Potential Transmission of Oka/Merck Vaccine Virus Strain
Missing information	None
* Certain important identified or potential risks included in prior versions of the RMP have been removed based on the review of accumulating clinical data and closure of an observational study, along with the guidance in GVP module V (Rev 2).	

II.B Summary of Important Risks

Table II.B.1: Important Identified Risk: Disseminated Disease Caused by Oka/Merck Vaccine Virus Strain in Immunodeficient Individuals and Individuals on Immunosuppressive Therapy

Evidence for linking the risk to the medicine	Evidence Source(s) and Strength of Evidence: Protocols 016 ,017, and the postmarketing database.
Risk factors and risk groups	Risk Factors and Risk Groups: Immunosuppression caused by a primary medical condition or from an immunosuppressive therapy. Vaccination with ZOSTAVAX is contraindicated in immunodeficient individuals and individuals on immunosuppressive therapy.
Risk minimisation measures	Routine risk minimisation measures: SmPC Sections 4.3 (Contraindications) and 4.4 (Special warnings precautions for use). Package Leaflet: Information for the user Section 2 (What you need to know before you receive ZOSTAVAX)

Table II.B.2: Important Potential Risk: Potential Transmission of Oka/Merck Vaccine Virus Strain

Evidence for linking the risk to the medicine	Evidence Source(s) and Strength of Evidence: As for all live attenuated vaccines, there is potential for transmission of mutated live vaccine virus. Potential transmission of Oka/Merck vaccine virus strain has been closely monitored with ZOSTAVAX. There are no cases of confirmed secondary transmission of vaccine strain VZV with ZOSTAVAX.
Risk factors and risk groups	Subjects who are theoretically most at risk for secondary transmission of Oka/Merck vaccine-strain VZV are immunocompromised individuals; pregnant women without documented positive history of chickenpox or laboratory evidence of prior infection; and newborns of mothers without documented positive history of chickenpox or laboratory evidence of prior infection..
Risk minimisation measures	Routine risk minimisation measures: SmPC Section 4.4 (Special warnings and precautions for use).

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 ZOSTAVAX.

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

There are no studies required for ZOSTAVAX.