PART V: RISK MINIMISATION MEASURES (INCLUDING EVALUATION OF THE EFFECTIVENESS OF RISK MINIMISATION ACTIVITIES)

Risk Minimisation Plan

V.1 Routine Risk Minimisation Measures

Table V.1.1: Description of Routine Risk Minimisation Measures by Safety Concern

Safety Concern	Routine Risk Minimisation Activities
Disseminated Disease Caused by Oka/Merck Vaccine Virus Strain	**Routine risk communication:** Information related to disseminated disease caused by Oka/Merck vaccine virus strain is included in the Contraindications, Special Warnings and Precautions for use, and Undesirable Effects sections of the Product Information. Information pertaining to disseminated disease caused by Oka/Merck vaccine virus strain is included in the Patient Information.
Secondary transmission of Oka/Merck varicella vaccine virus strain in susceptible individuals leading to disseminated disease	**Routine risk communication:** Information related to secondary transmission in susceptible individuals leading to disseminated disease is included in the Special Warnings and Precautions for use section of the Product Information. Information pertaining to secondary transmission in susceptible individuals leading to disseminated disease is included in the Patient Information.
Congenital Varicella Syndrome Among Susceptible Women Exposed to Varicella Vaccine	**Routine risk communication:** Information related to congenital varicella syndrome in susceptible pregnant women is included in the Contraindications, Special Warnings and Precautions for use, and Fertility, Pregnancy and Lactation sections of the Product Information. Information pertaining to congenital varicella syndrome in susceptible pregnant women is included in the Patient Information. Information on contraindication during pregnancy is included in the Outer Packaging

V.2 Additional Risk Minimization Measures

Routine risk minimisation activities as described in Part V.1 are sufficient to manage the safety concerns of the medicinal product.

V.3 Summary of Risk Minimization Measures

Table V.3.1: Summary Table of Pharmacovigilance Activities and Risk Minimisation Activities by Safety Concern

Safety Concern	Risk minimisation Measures	Pharmacovigilance Activities
Important Identified Risks		
Disseminated disease caused by Oka/Merck vaccine virus strain	Routine risk minimisation measures: Contraindications section, Special Warnings and Precautions for use section and Undesirable Effects section of the Product Information	Routine pharmacovigilance activities Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: VZVIP
Secondary transmission of Oka/Merck varicella vaccine virus strain in susceptible individuals leading to disseminated disease	Routine risk minimisation measures: Special Warnings and Precautions for use section of the Product Information	Routine pharmacovigilance activities Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: VZVIP
Important Potential Risks		
Congenital Varicella Syndrome Among Susceptible Women Exposed to Varicella Vaccine	Routine risk minimisation measures: Contraindications section, Special Warnings and Precautions for use section and Fertility, Pregnancy and Lactation section of the Product Information	Routine pharmacovigilance activities

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN BY PRODUCT

Summary of risk management plan for VARIVAX™ (varicella virus vaccine live [Oka/Merck])

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

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

Important new concerns or changes to the current ones will be included in updates of VARIVAX™'s RMP.

I. The Medicine and What It Is Used For

VARIVAX™ is authorised for vaccination against varicella in individuals from 12 months of age (see SmPC for the full indication). It contains varicella virus vaccine live (Oka/Merck) as the active substance and it is given by intramuscular (IM) or subcutaneous (SC) injection.

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

Important risks of VARIVAX™, together with measures to minimise such risks and the proposed studies for learning more about VARIVAX™'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 VARIVAX™ 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 VARIVAX™. 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 • Secondary transmission of Oka/Merck varicella vaccine virus strain in susceptible individuals leading to disseminated disease
Important potential risks	• Congenital varicella syndrome among susceptible women exposed to varicella vaccine
Missing information	None

II.B Summary of Important Risks

Table II.B.1: Important Identified Risk: Disseminated disease caused by Oka/Merck vaccine virus strain

Evidence for linking the risk to the medicine	The evidence from the literature and from spontaneous post-marketing reports supports a causal relationship between vaccination with varicella virus vaccine live (Oka/Merck) and disseminated Oka/Merck VZV in immunocompromised or immunocompetent individuals.
Risk factors and risk groups	Immunocompromised patients are at greater risk of disseminated disease caused by vaccination with Oka/Merck varicella virus ; however, it has been documented that cases of disseminated disease can also occur in immunocompetent patients. Administration of VARIVAX™ is contraindicated in patients with primary or acquired immunodeficiency states.
Risk minimisation measures	Routine risk minimisation measures Contraindications section, Special Warnings and Precautions for use section and Undesirable Effects section of the Product Information