Swiss Summary of the Risk Management Plan (RMP)

PRIORIX-TETRA

Combined measles, mumps, rubella and varicella vaccine (live, attenuated)

Active substance: Measles virus (Schwarz strain) (live, attenuated), mumps virus (RIT 4385 strain) (live, attenuated), rubella virus (Wistar RA 27/3 strain) (live, attenuated), varicella virus (OKA strain) (live, attenuated)

RMP Summary: Version 2, December 2024

Based on EU RMP version 8.0, 31 December 2023

Marketing Authorisation Holder: GlaxoSmithKline AG, Münchenbuchsee

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 minimize them.

The RMP summary of Priorix-Tetra 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 Priorix-Tetra in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic.

GlaxoSmithKline AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Priorix-Tetra.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Priorix-Tetra (measles, mumps, rubella, and varicella vaccine)

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

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

Important new concerns or changes to the current ones will be included in updates of Priorix-Tetra's RMP.

I. The medicine and what it is used for

Priorix-Tetra is authorized for active immunization of individuals from the age of 11 months against measles, mumps, rubella, and varicella (see SmPC for the full indication). It contains live attenuated of measles, mumps, rubella, and varicella viruses as the active substance, and it is given by subcutaneous route in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Priorix-Tetra, together with measures to minimize such risks and the proposed studies for learning more about Priorix-Tetra '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 package leaflet 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 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 Priorix-Tetra 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 Priorix-Tetra. 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.

II.C Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Priorix-Tetra.

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

There are no studies required for Priorix-Tetra.