Swiss Summary of the Risk Management Plan (RMP)

FLUARIX

Trivalent influenza vaccine (split virion, inactivated)

Active substance: Strains of Influenza virus (inactivated, split) of the types A/H1N1, A/H3N2 and B/Victoria according to the yearly WHO recommendations for the northern hemisphere.

RMP Summary: Version 1, October 2025

Based on EU RMP version 0.1, 12 June 2024

Marketing Authorisation Holder: GlaxoSmithKline AG

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 Fluarix 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 Fluarix 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 Fluarix.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Fluarix

This is a summary of the RMP for Fluarix. The RMP details important risks of Fluarix, how these risks can be minimized, and how more information will be obtained about Fluarix risks and uncertainties (missing information).

Fluarix's SmPC and its package leaflet give essential information to healthcare professionals and patients on how Fluarix should be used.

Important new concerns or changes to the current ones will be included in updates of Fluarix‘s RMP.

I. The medicine and what it is used for

FLU D-TIV is authorized for active immunisation of adults and children from individuals 6 months of age and older for prevention of influenza disease caused by influenza virus types A and B contained in the vaccine (see SmPC for the full indication). It contains Haemagglutinin of three strains of influenza virus, two A strains and one B strain. as the active substance and it is given by intramuscular route of administration.

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

Important risks of FLU D-TIV together with measures to minimize such risks and the proposed studies for learning more about FLU D-TIV'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 FLU D-TIV 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 FLU D-TIV. 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 FLU D-TIV.

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

There are no studies required for FLU D-TIV.