Supemtek®, Quadrivalent Recombinant Influenza Vaccine

MA no. 68003

Active substance:

Quadrivalent Recombinant Influenza Vaccine

Risk-Management Plan Summary
V 0.2, dated 22 December 2021

Marketing Authorization Holder

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ABBREVIATIONS

DLP: Data Lock Point
EPAR: European Public Assessment Report
RMP: Risk Management Plan
SmPC: Summary of Product Characteristics
GBS: Guillain-Barré Syndrome
SD-IIV: Standard Dose-Inactivated Influenza Vaccine
SD-IIV4: Standard Dose-Quadrivalent Inactivated Influenza Vaccine
RIV4: Quadrivalent Recombinant Influenza Vaccine
RIV3: Trivalent Recombinant Influenza Vaccine
RIV: Recombinant Influenza Vaccine
MAH: Marketing Authorization Holder
EMA: European Medicines Agency
PIL: Product Information Leaflet
CBER: Center for Biologics Evaluation and Research
VE: vaccine effectiveness
rVE: relative vaccine effectiveness

SANOFI PASTEUR

SUMMARY OF RISK MANAGEMENT PLAN FOR QUADRIVALENT RECOMBINANT INFLUENZA VACCINE

This is a summary of the risk management plan (RMP) for Quadrivalent Recombinant Influenza Vaccine (RIV4). There are no important risks or important missing information for RIV4 that are considered as safety concerns.

The Summary of Product Characteristics (SmPC) and package leaflet give essential information to healthcare professionals and patients on how RIV4 should be used.

This summary of the RMP for Quadrivalent Recombinant Influenza Vaccine (RIV4) should be read in the context of information provided in the RMP and the assessment report including its plain-language summary, all of which is part of the European Public Assessment Report (EPAR).

New important safety concerns or any information that impacts the benefit-risk analysis will be included in updates of RIV4 RMP.

1. THE MEDICINE AND WHAT IT IS USED FOR

According to Swiss label

SUPEMTEK is used for the active immunization of adults 18 years of age and older against influenza due to the two influenza A virus subtypes and two influenza B virus subtypes contained in the vaccine.

SUPEMTEK is to be used according to the official vaccination recommendations.

According to EU SmPC

RIV4 is indicated for active immunization in persons 18 years of age and older for the prevention of influenza disease. RIV4 is a recombinant influenza vaccine manufactured using a baculovirus expression vector system and recombinant DNA technology.

Further information about the evaluation of RIV4 benefits can be found in the EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

2. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

There are no safety concerns for the RIV4 and no risk minimization measures beyond proposed SmPC. Together, these measures constitute routine risk minimisation measures.

Anaphylaxis has been communicated in the draft SmPC, in section 4.3, “Contraindications”, section 4.4 “Special warnings and precautions for use”, section 4.8 “Undesirable effects”. In the draft SmPC following information is provided. “Hypersensitivity to a previous administration of RIV4 or a vaccine containing the same components or constituents is a contraindication. As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.” In the package leaflet following information is provided for the healthcare professionals. “Appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine”.

In addition to the measure of communication via draft SmPC, the information about adverse reactions is collected continuously and regularly analysed, and presented in the PBRER assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

2.1. LIST OF IMPORTANT RISKS AND MISSING INFORMATION

There are no important identified risks with RIV4 that require inclusion as a safety concern in the RMP.

There are no important potential risks with RIV4 that require inclusion as a safety concern in the RMP.

There is no important missing information with RIV4 that requires inclusion as a safety concern in the RMP.

Table 1 - List of important risks and missing information

Important identified risk	None
Important potential risk	None
Missing information	None

2.2. SUMMARY OF IMPORTANT RISKS

The safety information in the proposed SmPC is aligned to the reference medicinal product.

2.3. POST-AUTHORIZATION DEVELOPMENT PLAN

2.3.1.STUDIES WHICH ARE CONDITIONS OF THE MARKETING AUTHORIZATION

There are no studies that are conditions of the marketing authorisation for RIV4.

2.3.2.OTHER STUDIES IN POST-AUTHORIZATION DEVELOPMENT PLAN

Additional pharmacovigilance in the post-marketing setting includes participating in Development of Robust Innovative Vaccine Effectiveness (DRIVE), conducting VAP00003, a phase IV, multicenter, modified-cluster randomized study (VAP00003) to assess the effectiveness of RIV4 compared to standard-dose inactivated influenza vaccine in adults and VAP00007, Phase IV, descriptive, post-licensure, safety surveillance study which will include pregnant women from Study VAP00003.

The objective of the Phase IV study is to estimate the relative vaccine effectiveness (rVE) of RIV4 versus Standard Dose Inactivated Influenza Vaccine (SD-IIV4) in vaccinees aged 18–64 years against all PCR-confirmed influenza. It is also anticipated that this study will generate sufficient data regarding use of RIV4 in pregnancy to fulfill the commitment for the pregnancy registry to CBER. This study is being conducted in the United States using Kaiser Permanente database.

The post-authorisation development plan is summarized below.

Table 2 - Other studies in post-authorisation development plan

1. Development of Robust Innovative Vaccine Effectiveness (DRIVE)

Purpose of the study:

Objectives is to measure season IVE against medically attended laboratory-confirmed influenza, by vaccine brand, then by vaccine type (e.g. by antigen preparation strategy, number of virus strains, adjuvant,) then by overall influenza vaccination. To comply with the Guideline on Influenza vaccines - Non-clinical and Clinical Module (EMA/CHMP/VWP/457259/2014) ofJuly 2016, a supporting IMI (Innovative Medicines Initiative) program called on DRIVE. DRIVE aims to assess the feasibility of building a sustainable platform in Europe able to generate brand specific influenza vaccine effectiveness data in Europe.

2. VAP00003: Examining vaccine effectiveness (VE) of RIV4 relative to standard doseinactivated influenza vaccine among Kaiser Permanente Northern California members aged 18-64 years

Purpose of the study:

To estimate the rVE of RIV4 versus SD-IIV against all PCR-confirmed influenza in vaccinees aged 18–64 years, this study will compare the incidence of PCR- confirmed influenza and various hospitalization definitions among RIV4 vaccinees versus SD-IIV vaccinees. The primary comparison will be focused on adults aged 50–64 years at KPNC during the 2018–2019 and 2019–2020 influenza seasons. All adults aged 18–64 years will alsobe assessed for both influenza seasons.

3. VAP00007: Post-licensure, safety surveillance study of RIV4 vaccine in pregnantwomen and their offspring

Purpose of the study:

Study VAP00007 is an observational post-authorization safety study that is designed to collect data on pregnancies and pregnancy outcomes among women immunized with RIV4 or a comparator SD-IIV4 influenza vaccine during pregnancy. This cohort study will include pregnant women from Study VAP00003, entitled “Examining vaccine effectiveness (VE) of RIV4 relative to standard dose inactivated influenza vaccine among Kaiser Permanente Northern California members aged 18-64 years.” Study VAP00003 is a Phase IV, multi-center,modified-cluster randomized study of up to 1,600,000 Kaiser Permanente Northern California members who will receive either QRIV or SD-IIV4 between September 2018 and May 2020.

REFERENCES

None