Efluelda®, quadrivalent Influenza Vaccine (Split Virion, Inactivated) High-Dose

MA no. 67704

Active substance

Influenza virus (split, inactivated) of the following strains
as recommended by WHO and Europe

Hemagglutinin-strain A (H1N1)
Hemagglutinin-strain A (H3N2)
Hemagglutinin-strain B (Victoria Lineage)
Hemagglutinin-strain B (Yamagata Lineage)
Referred in this document as QIV-HD

Risk-Management Plan Summary
V 1.1, dated 17 September 2021

Marketing Authorization Holder

Sanofi-Aventis (Suisse) SA
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ABBREVIATIONS

DLP: Data Lock Point
IM: Intramuscular
INN: International Nonproprietary Name
PL: Package Leaflet
QIV-HD: Quadrivalent Influenza Vaccine High-Dose
RMP: Risk Management Plan
SmPC: Summary of Product Characteristics
WHO: World Health Organization

SUMMARY OF RISK MANAGEMENT PLAN FOR QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED) HIGH-DOSE, SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE

This is a summary of the RMP for Quadrivalent influenza vaccine (split virion, inactivated), High-Dose, suspension for injection in pre-filled syringe (referred hereafter as QIV-HD). The RMP details important risks of QIV-HD, how these risks can be minimized, and how additional information will be obtained about the risks and uncertainties (missing information).

Quadrivalent influenza vaccine (split virion, inactivated), High-Dose (QIV-HD)'s summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how QIV-HD should be used.

1. THE MEDICINE AND WHAT IT IS USED FOR

According to Swiss label

EFLUELDA is used for active immunization of adults 65 years of age and older for prophylaxis of influenza caused by the two influenza A virus subtypes and the two influenza B virus subtypes included in the vaccine.

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

According to EU SmPC

Quadrivalent influenza vaccine (split virion, inactivated), High-Dose is indicated for active immunization in adults 60 years of age and older for the prevention of influenza disease (See SmPC for full indication). It contains Influenza virus (inactivated, split virion), as recommended by World Health Organization (WHO)/Europe each season, Hemagglutinin-strain A (H1N1), Hemagglutinin-strain A (H3N2), Hemagglutinin-strain B (Victoria lineage) and Hemagglutinin-strain B (Yamagata lineage), as the active substances and it is given by intramuscular (IM) route of administration.

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

Important risks of QIV-HD, together with measures to minimize such risks and the proposed studies for learning more about QIV-HD's risks, are outlined in the next sections.

Measures to minimize the risks identified for medicinal products can be:

• Specific information, such as warnings, precautions, and advice on correct use, in the PL 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 (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

2.1. LIST OF IMPORTANT RISKS AND MISSING INFORMATION

There are no important risks or missing information with QIV-HD for the inclusion as safety concerns that require specific risk minimization measures.

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

Not applicable

2.3. POST-AUTHORIZATION DEVELOPMENT PLAN

2.3.1. STUDIES WHICH ARE CONDITIONS OF THE MARKETING AUTHORIZATION

There are no studies which are conditions of the marketing authorization or specific obligation of QIV-HD.

2.3.2. OTHER STUDIES IN POST-AUTHORIZATION DEVELOPMENT PLAN

There are no studies required for QIV-HD.

REFERENCES

None