



Influenza Vaccine

Fluzone[®] High-Dose Quadrivalent

FOR ADULTS 65+

SANOFI PASTEUR 



Demonstrated Evidence for FLUZONE[®] High-Dose Quadrivalent.

FLUZONE[®] High-Dose Quadrivalent vaccine is indicated for active immunization against influenza caused by the specific strains of influenza virus contained in the vaccine in adults 65 years of age and older.¹

The efficacy experience with FLUZONE[®] High-Dose (trivalent formulation) is relevant to FLUZONE[®] High-Dose Quadrivalent since both vaccines are manufactured according to the same process and have overlapping compositions.

Superior efficacy demonstrated for FLUZONE[®] High-Dose (trivalent) compared to FLUZONE[®] (trivalent), a standard-dose influenza vaccine.¹

Primary endpoint^{1*†‡}

24.2%

(attack rate 1.43% vs. 1.89%)[§]

FLUZONE[®] High-Dose (trivalent) vs. FLUZONE[®] (trivalent)

More efficacious against lab-confirmed influenza illness caused by any viral type or subtype in adults 65+ (95% CI: 9.7–36.5)

CI=confidence interval.

*In a multicentre study over two influenza seasons (2011-2012 and 2012-2013), adults 65+ were randomized to receive either FLUZONE[®] High-Dose (trivalent) or FLUZONE[®] (trivalent). FLUZONE[®] High-Dose (trivalent) contained 60 µg of HA/strain/dose while FLUZONE[®] (trivalent) contained 15 µg of HA/strain/dose. Per-protocol analysis set for efficacy assessments included 15,892 FLUZONE[®] High-Dose (trivalent) and 15,911 FLUZONE[®] (trivalent) recipients. Primary endpoint was occurrence of laboratory-confirmed influenza, defined as a new onset (or exacerbation) of at least one of the following: sore throat, cough, sputum production, wheezing, or difficulty breathing; concurrent with at least one of the following systemic signs or symptoms: temperature >37.2°C, chills, tiredness, headaches or myalgia. In the first year, the influenza B vaccine component and the majority of influenza B cases were of the Victoria lineage; in the second year, the influenza B vaccine component and the majority of influenza B cases were of the Yamagata lineage.¹

†The pre-specified statistical superiority criterion for the primary endpoint (lower limit of the 2-sided 95% CI of the vaccine efficacy of FLUZONE[®] High-Dose (trivalent) relative to FLUZONE[®] (trivalent) >9.1%; p-value against H0:VE ≤9.1% = 0.022 one-sided) was met.¹

‡The standard dose FLUZONE[®] vaccine (trivalent) is not available in Canada.

§FLUZONE[®] High-Dose (trivalent formulation) (1.43% attack rate, N=227/15,892), versus standard-dose FLUZONE[®] (trivalent) vaccine (1.89% attack rate, N=300/15,911).¹

National advisory committee on immunization (NACI) recommendations for 65+ year-olds

Recommendation for individual-level decision-making²

IIV-HD should be used over IIV-SD, given the burden of influenza A (H3N2) disease and based on IIV3-HD in adults 65 years of age and older.

The National Advisory Committee on Immunization (NACI) considers adults 65+ to be at high risk of influenza-related complications or hospitalization and recommends that all seniors get an influenza vaccine annually.²

SAFETY INFORMATION:

Indications and clinical use:

FLUZONE® High-Dose Quadrivalent vaccine is indicated for active immunization against influenza caused by the specific strains of influenza virus contained in the vaccine in adults 65 years of age and older.¹ The National Advisory Committee on Immunization (NACI) provides additional guidance on the use of the influenza vaccine in Canada. Please refer to the published Statement on Seasonal Influenza Vaccine for the current season.

Contraindications:

Should not be administered to anyone with a known systemic hypersensitivity reaction after previous administration of any influenza vaccine or to any component of the vaccine (e.g. eggs or egg products).

Relevant warnings & precautions:

- FLUZONE® High-Dose Quadrivalent is not indicated for persons less than 65 years of age.
- Syncope can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent falling and injury and to manage syncope.
- As with any vaccine, immunization with FLUZONE® High-Dose Quadrivalent may not protect 100% of individuals. At this time, current influenza virus vaccines are not effective against all possible influenza strains. Protection is highest against those strains of virus from which the vaccine is prepared or against closely related strains.
- Do not administer by intravascular injection. Do not administer into the buttocks.
- Postpone vaccination in case of moderate/severe febrile illness or acute disease.
- FLUZONE® High-Dose Quadrivalent should not be administered to persons suffering from coagulation disorders or on anticoagulation therapy unless potential benefits outweigh administration risk. If the decision is made to administer any product by intramuscular injection to such persons, it should be given with caution, with steps taken to avoid hematoma formation risk following injection.
- Immunogenicity may be reduced by immunosuppressive therapy or in immunocompromised individuals. It is recommended to postpone vaccination until after the immunosuppressive therapy or resolution of the immunosuppressive condition, if feasible.
- If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of any previous influenza vaccination, the decision to give FLUZONE® High-Dose Quadrivalent should be based on careful consideration of potential benefits and risks.
- Local reactions at injection site such as pain, erythema, swelling, induration and bruising may occur.

For more information:

Visit <https://products.sanofi.ca/en/fluzone-qiv-hd-en.pdf> for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The product monograph is also available through our medical department. Call us at 1-888-621-1146.

IIV-HD= high-dose inactivated influenza vaccine; IIV-SD= standard-dose inactivated influenza vaccine; IIV3-HD=high-dose trivalent inactivated influenza vaccine.

REFERENCES:

1. Product Monograph: FLUZONE® High-Dose Quadrivalent. Sanofi Pasteur. April 14, 2021.
2. An Advisory Committee Statement (ACS)/National Advisory Committee on Immunization (NACI): Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2021-2022. Advance copy – Dec 2020.

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