FOR INDIVIDUALS
65+

Fluzone® High-Dose Influenza Vaccine
Senior Influenza Protection

Demonstrated Evidence for Fluzone® High-Dose

Fluzone® High-Dose 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 RISKS OF INFLUENZA

Adults 65+ suffer disproportionately from influenza-related morbidity and mortality. They account for 15% of the population, but experience:

- **Total Deaths**: 3,500
  - Adults 65+: up to 91% (3,185)
- **Total Hospitalizations**: 12,200
  - Adults 65+: up to 70% (8,540)

* Estimated from Canadian adults aged 65 and older during the 2013–2018 influenza seasons.
† FLUZONE® High-Dose is not indicated to reduce morbidity and mortality or complications associated with influenza, such as deaths or hospitalizations.
Indirect effects: beyond respiratory/direct effects*

Trigger for: \(^3, 10-12\)

Exacerbation of: \(^3, 13, 14\)

For adults 65+ higher influenza-attributed mortality is associated with chronic conditions\(^{15}\)

5X GREATER with chronic heart disease

20X GREATER with BOTH chronic heart and lung conditions

12X GREATER with chronic lung disease

* FLUZONE® High-Dose is not indicated for reduction of potential complications of influenza such as acute myocardial infarction (AMI), ischemic heart disease (IHD), cerebrovascular disease (CVD), renal disorders, diabetes or respiratory direct effects.

† FLUZONE® High-Dose is not indicated to reduce influenza-attributed mortality associated with chronic conditions such as chronic heart and lung disease.
In the elderly, vaccine effectiveness is ~50% less than that in healthy adults and varies depending on the outcome measures and the study population.\textsuperscript{3}

- Immunosenescence is a heightened susceptibility to influenza-related complications in older adults due to the natural and progressive weakening of the immune system over time\textsuperscript{1}
- This renders seniors less responsive to standard-dose influenza vaccine\textsuperscript{1}

VACCINE EFFECTIVENESS IN 65+ YEAR-OLDS

A study showed that for the influenza seasons 1998–1999 through to 2004–2005, the range of standard-dose vaccine effectiveness was:\textsuperscript{1,17*}

- 62%–76%\textsuperscript{1}
- 26%–52%\textsuperscript{1}

* Standard-dose trivalent influenza vaccine with 15 μg HA per strain/0.5 mL dose.

FLUZONE® High-Dose vaccine is the only vaccine demonstrated, through a large randomized study, to be more efficacious than FLUZONE® standard-dose vaccine in preventing influenza in adults 65+. FLUZONE® High-Dose, trivalent, inactivated influenza vaccine contains 60 μg of hemagglutinin (HA), which is 4X as much HA as in FLUZONE®, a standard-dose influenza vaccine with 15 μg HA.

*Comparative clinical significance has not been established.

Over 112 MILLION DOSES of FLUZONE® High-Dose have been distributed in the U.S. since 2009.
FLUZONE® High-Dose vaccine demonstrated superior efficacy compared to FLUZONE®, a standard-dose influenza vaccine, against laboratory-confirmed influenza illness.\textsuperscript{1,16}† Study results from a randomized, multicentre, double-blind trial with 31,803 adults 65+.\textsuperscript{1,16}

**24.2%**

MORE EFFICACIOUS

against influenza caused by any virus type or subtype in adults 65+ (95% CI: 9.7; 36.5)\textsuperscript{1,16,§¶}

- The attack rates of laboratory-confirmed influenza-like illness (primary endpoints) were 1.43% in the FLUZONE® High-Dose arm and 1.89% for the FLUZONE® arm
- The absolute rates of laboratory-confirmed influenza were 0.5% for FLUZONE® High-Dose and 0.7% for FLUZONE® Trivalent\textsuperscript{16}

**35.4%**

MORE EFFICACIOUS

against influenza caused by strains similar to the vaccine components (secondary endpoint; 95% CI: 12.5 to 52.5)\textsuperscript{16,§¶}

- Comparative clinical significance has not been established.
- FLUZONE\textsuperscript{®}: a standard-dose trivalent influenza vaccine with 15 μg HA per strain/0.5 mL dose.\textsuperscript{16}
- The pre-specified statistical superiority criterion for the primary endpoint (lower limit of the 2-sided 95% CI of the vaccine efficacy of FLUZONE\textsuperscript{®} High-Dose relative to FLUZONE\textsuperscript{®} > 9.1%; p-value against H\textscript{0}:VE ≤ 9.1% = 0.022 one-sided) was met.
- In a multicentre study (FIM12) conducted in the United States and Canada, adults 65+ were randomized (1:1) to receive either FLUZONE\textsuperscript{®} High-Dose or FLUZONE\textsuperscript{®} Trivalent. The study was conducted over two influenza seasons (2011–2012 and 2012–2013). FLUZONE\textsuperscript{®} High-Dose contained 60 μg of HA per strain while FLUZONE\textsuperscript{®} Trivalent contained 15 μg of HA per strain. The per-protocol analysis set for efficacy assessments included 15,892 FLUZONE\textsuperscript{®} High-Dose recipients and 15,911 FLUZONE\textsuperscript{®} Trivalent recipients. The primary endpoint of the study was the occurrence of laboratory-confirmed influenza, defined as a new onset (or exacerbation) of at least one of the following respiratory symptoms: 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 of the study, the influenza B component of the vaccine and the majority of influenza B cases were of the Victoria lineage; in the second year, the influenza B component of the vaccine and the majority of influenza B cases were of the Yamagata lineage.
National Advisory Committee on Immunization (NACI) Recommendations for 65+ Year-olds

2020-2021 NACI STATEMENT (FOR INDIVIDUAL-LEVEL DECISION-MAKING):

When available, “high-dose trivalent inactivated vaccine” should be used over the standard-dose trivalent inactivated vaccine, given the burden of influenza A(H3N2) disease.”

“NACI does not make comparative individual-level recommendations on the use of IIV3-Adj or IIV4-SD over IIV3-SD or among IIV3-Adj, IIV3-HD, and IIV4-SD.”

Click here to read the full statement

IIV3-Adj: adjuvanted trivalent inactivated influenza vaccine; IIV4-SD: standard-dose quadrivalent inactivated influenza vaccine; IIV3-SD: standard-dose trivalent inactivated influenza vaccine; IIV3-HD: high-dose trivalent inactivated influenza vaccine.
**INDICATIONS AND CLINICAL USE:**

FLUZONE® High-Dose 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. Annual flu vaccination using the most current vaccine is recommended as immunity declines in the year following vaccination.

**CONTRAINDICATIONS:**

- Known severe allergic reaction to egg protein or any component of the vaccine or after previous administration of FLUZONE® High-Dose or a vaccine containing the same components or constituents.

**RELEVANT WARNINGS AND PRECAUTIONS:**

- FLUZONE® High-Dose is not indicated for persons less than 65 years of age.
- As with any vaccine, immunization with FLUZONE® High-Dose may not protect 100% of individuals. Protection is limited to those strains of virus from which the vaccine is prepared or against closely related strains.
- Do not administer FLUZONE® High-Dose by intravascular injection. Do not administer into the buttocks.
- Postpone vaccination in case of moderate/severe febrile illness or acute disease.

- Administer FLUZONE® High-Dose with caution in persons suffering from coagulation disorders or on anticoagulation therapy.
- Immunocompromised persons (whether from disease or treatment) may not elicit the expected immune response.
- Avoid vaccinating persons who are known to have experienced Guillain-Barré syndrome (GBS) within 6 weeks after a previous influenza vaccination.

**ADVERSE REACTIONS:**

In clinical trials, the most frequently reported adverse reactions were pain (35.6%), swelling (8.9%) and erythema (14.9%) at the injection site, myalgia (21.4%), malaise (18.0%), headache (16.8%). Most of the side effects resolved within 3 days.

**FOR MORE INFORMATION:**

Visit [products.sanofi.ca/en/fluzone-hd.pdf](http://products.sanofi.ca/en/fluzone-hd.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.
**References:**

4. PHAC. FluWatch. August 11 to 24, 2013.
7. PHAC. FluWatch. August 14 to 27, 2016.

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