Consider FLUZONE® HIGH-DOSE INFLUENZA VACCINE for your patients 65+

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.[1]

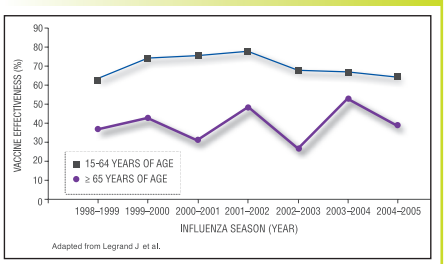
Influenza and vaccine effectiveness in 65+ year olds

Immunosenescence

The heightened susceptibility to influenza-related complications in older adults is due in large part to the natural and progressive weakening of the immune system over time—a phenomenon known as immunosenescence. Immunosenescence also renders seniors less responsive to standard-dose influenza vaccine.[1]

- In the elderly, vaccine effectiveness is **~50% less** than in healthy adults, and varies depending on the outcome measures and the study population.[2]
- A study showed that for the influenza seasons 1998–1999 through to 2004 2005, the range of standard-dose vaccine effectiveness was:[1†]
  - 62% to 76% in persons 15-64 years of age
  - 26% to 52% in persons ≥ 65 years of age

Effectiveness of standard-dose influenza vaccine[1,3†]



Adapted from Legrand J et al.

FLUZONE® High-Dose demonstrated superior protection compared to standard-dose FLUZONE® in a multicentre trial

FLUZONE® High-Dose trivalent, inactivated influenza vaccine was demonstrated to provide **superior efficacy** for the 65+ population against laboratory-confirmed influenza illness compared to FLUZONE®, a standard-dose influenza vaccine.[1,4‡§¶]

- **24.2% more efficacious** against laboratory-confirmed influenza illness caused by any virus type or subtype in adults 65 years of age and older (95% CI: 9.7; 36.5).[1,4]
  - FLUZONE® High-Dose: 227 (1.43%); FLUZONE® standard-dose: 300 (1.89%)
- **35.4% more efficacious** against laboratory confirmed influenza caused by strains similar to the vaccine components (secondary endpoint; 95% CI:12.5 to 52.5).[4]
  - FLUZONE® High-Dose: 73 (0.5%); FLUZONE® standard-dose: 113 (0.7%)

In its 2020-2021 influenza recommendations, the National Advisory Committee on Immunization (NACI) stated that for individual-level decision making, when available, IIV3-HD should be used over IIV3-SD in adults 65 years of age and older. There is insufficient evidence to make comparative individual-level recommendations on the use of IIV3-Adj or IIV4-SD over IIV3-SD or among IIV3-HD and IIV4-SD.[2]

IIV3-HD=high-dose trivalent inactivated influenza vaccine
IIV3-SD=standard-dose trivalent inactivated influenza vaccine
IIV3-Adj=adjuvanted trivalent inactivated influenza vaccine
IIV4-SD=standard-dose quadrivalent inactivated influenza vaccine

The impact of influenza on individuals 65+

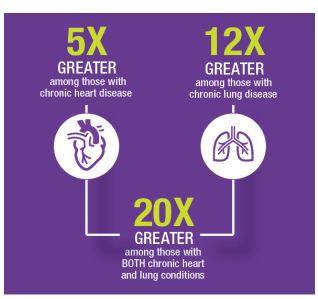
Hospitalizations and deaths

While Canadian adults age 65+ represented approximately 15% of the Canadian population, they accounted for up to:[5-11▲]

- **70%** of influenza-related hospitalizations
- **91%** of influenza-related deaths

Chronic conditions and mortality

Higher influenza-attributed mortality is associated with chronic conditions. For persons aged 65 years and over the risk for influenza-attributed death was:[12]



FLUZONE® High-Dose is not indicated to reduce morbidity and mortality, complications associated with influenza such as pneumonia, hospitalizations, deaths, decline in independence or functional status, or to reduce influenza-attributed mortality associated with chronic conditions such as chronic heart and lung disease

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:

Consult the product monograph at 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.

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

‡ 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 relative to FLUZONE® > 9.1%; p-value against H0:VE ≤ 9.1% = 0.022 one-sided) was met.

§ In a multicentre study (FIM12) conducted in the United States and Canada, adults 65 years of age and older were randomized (1:1) to receive either FLUZONE® High-Dose or FLUZONE® Trivalent. The study was conducted over two influenza seasons (2011-2012 and 2012-2013). FLUZONE® High-Dose contained 60 µg of HA per strain while FLUZONE® Trivalent contained 15 µg of HA per strain. The per-protocol analysis set for efficacy assessments included 15,892 FLUZONE® High-Dose recipients and 15,911 FLUZONE® 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.

▲ Public Health Agency of Canada, 2013-2018.

References:

1. FLUZONE® High-Dose vaccine. Product Monograph. Sanofi Pasteur Inc., April 28, 2020 . **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 2020-2021. **3.** Legrand J, *et al*. Real-time monitoring of the influenza vaccine field effectiveness. *Vaccine* 2006; 24:6605–6611. **4.** DiazGranados CA, *et al*. Efficacy of high-dose versus standard-dose influenza vaccine in older adults. *N Engl J Med*. 2014;371:635-645. **5.** Statistics Canada. (2019). Canada's population estimates: Age and sex, July 1, 2018. https://www150.statcan.gc.ca/n1/en/daily-quotidien/190125/dq190125a-eng.pdf?st=KJGD2vFk. Accessed June 25, 2019. **6.** Public Health Agency of Canada. (2013). FluWatch Report: August 11 to 24, 2013 (Weeks 33 & 34). http://publications.gc.ca/collections/collection_2013/aspc-phac/HP58-1-2013-34-eng.pdf. Accessed: June 25, 2019. **7.** Public Health Agency of Canada. (2014). FluWatch Report: 10 to 23 August, 2014 (weeks 33 & 34). http://publications.gc.ca/collections/collection_2014/aspc-phac/HP58-1-2014-34-eng.pdf. Accessed: June 25, 2019. **8.** Public Health Agency of Canada. (2015). FluWatch Report: August 16 to August 29, 2015 (weeks 33 and 34). http://publications.gc.ca/collections/collection_2015/aspc-phac/HP58-1-2015-34-eng.pdf. Accessed: June 25, 2019. **9.** Public Health Agency of Canada. (2016). FluWatch Report: August 14 to August 27, 2016 (Weeks 33-34). http://publications.gc.ca/collections/collection_2016/aspc-phac/HP58-1-2016-34-eng.pdf. Accessed: June 25, 2019. **10.** Public Health Agency of Canada. (2017). FluWatch report: August 20 to 26, 2017 (Week 34). https://www.canada.ca/content/dam/canada/public-health/services/publications/science-research-data/canadian-nosocomial-infection-summary/cnisp-aro-2011-2015%20report-final-en.pdf. Accessed: June 25, 2019. **11.** Public Health Agency of Canada. (2018b). FluWatch Report: July 22, to August 25, 2018 (Weeks 30-34). http://publications.gc.ca/collections/collection_2018/aspc-phac/HP58-1-2018-34-eng.pdf. Accessed: June 25, 2019. **12.** Schanzer DL, *et al*. Co-morbidities associated with influenza-attributed mortality, 1994–2000, Canada. *Vaccine* 2008;26:4697–4703.

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