INFLUENZA. CONSIDER THE BURDEN TO YOUR PATIENTS OVER 65[4]

In older age, immune responses can decline (immunosenescence)[5]

During the 2023-2024 flu season (cumulative from August 27, 2023 to March 30, 2024):[4†‡]

From a total of 4,077 influenza-associated hospitalizations:

- Adults aged 65+ accounted for 47% of the reported cases
- 92% were associated with influenza A (3,751/4,077) and 8% with influenza B (326/4,077)

From a total of 231 influenza-associated deaths:

- Adults aged 65+ accounted for 71% of the reported cases

† Influenza-associated hospitalizations are reported by Alberta, Manitoba, New Brunswick, Newfoundland and Labrador, Northwest Territories, Nova Scotia, Prince Edward Island and Yukon. Only hospitalizations that require intensive medical care are reported by Saskatchewan.
‡ FLUAD is not indicated to treat influenza or to reduce its complications such as hospitalization and death.

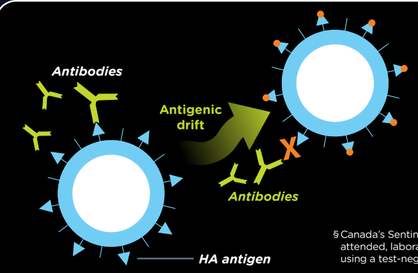
ANTIGENIC DRIFTED STRAINS[3,6]

What causes antigenic variation?

Small genetic changes in naturally circulating influenza viruses can accumulate over time and result in antigenically drifted strains compared to those that are in the vaccine.[3,6]

What does this do?

Antibodies produced by a particular influenza strain may not recognize or protect against an antigenically drifted or mismatched strain variant.[3]



The epidemic observed in the 2014/2015 influenza season in Canada was attributed to the antigenic mismatch (drift) with the circulating strain.[7§]

Adapted from the FLUAD® Product Monograph and NACI[3,6]

§ Canada's Sentinel Physician Surveillance Network (SPSN) assessed medically attended, laboratory-confirmed influenza A (H3N2) infection in January 2015 using a test-negative case-control design (n=861).

FREQUENTLY ASKED QUESTIONS

Is FLUAD® indicated for adults 65 years of age and older? — **Yes. FLUAD®, an adjuvanted vaccine, is indicated specifically for adults 65 years of age and older.[3]**

How long has FLUAD® been available in Canada? — **FLUAD® has been available in Canada since 2011.[15*]**

What is the experience of FLUAD® worldwide? — **Over 170 million doses of FLUAD® have been distributed worldwide.[1*]**

What was the safety profile of FLUAD®? — **FLUAD® was generally well tolerated.**

The most frequently reported local adverse events were injection-site pain (26%; N=3,712), injection-site temperature (18%; N=2,265) and erythema (14%; N=3,712), while systemic ones were myalgia (7%; N=3,712), headache (6%; N=3,712), fatigue (6%; N=1,493) and malaise (6%; N=3,712).[3]

The majority of solicited local reactions were reported as mild or moderate in intensity and generally resolved within 2–3 days with 3% or less of subjects reporting a severe local reaction.[3]

* Clinical significance is unknown.

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Product Monograph available on request.
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CAN-FLUD-24-0012E

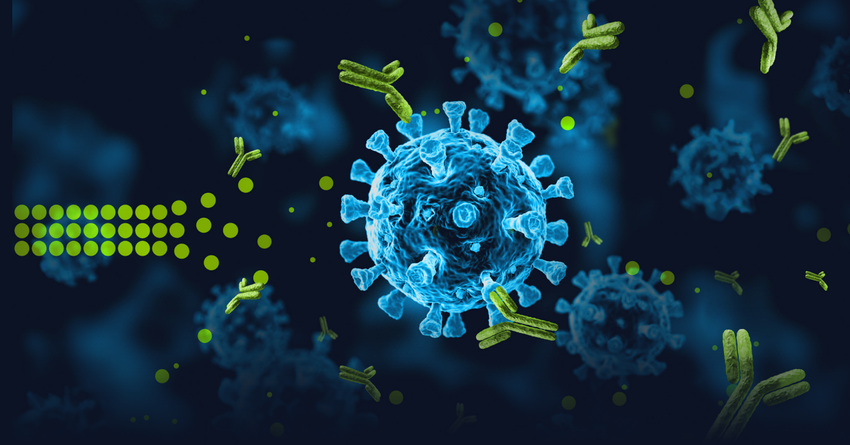
REVIEWED BY PAAB

FLUAD® Influenza Vaccine (surface antigen, inactivated, adjuvanted with MF59®)

Over 170 million doses distributed worldwide![1*]

FLUAD®

Influenza Vaccine (surface antigen, inactivated, adjuvanted with MF59®)



FLUAD® is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and B contained in the vaccine in adults 65 years of age and older.[3]

NACI recommendation

NACI recommends adjuvanted inactivated influenza vaccine as an option for adults 65+[2]

NACI recommends that adjuvanted inactivated influenza vaccine, high-dose inactivated influenza vaccine or recombinant influenza vaccine should be offered over other influenza vaccines for adults 65 years of age and older. If a preferred product is not available, any of the available age-appropriate influenza vaccines should be used. (Strong NACI recommendation).[2]

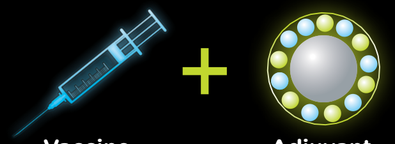
See the complete NACI Supplemental guidance on influenza **vaccination in adults 65 years of age and older** for more information.

* Clinical significance is unknown.

For **Real-World Evidence,** see inside.

CONSIDER FLUAD®

THE ONLY SEASONAL FLU VACCINE WITH THE MF59C.1 ADJUVANT FOR ADULTS AGED 65+[3,8*]



An adjuvant is added to a vaccine to:[5†]

- Enhance the immune response
- Extend the duration of B-cell and T-cell activation

†Clinical significance is unknown.

Contraindications:

- Individuals with a known hypersensitivity to the active substances, to any of the excipients and to eggs, chicken proteins, kanamycin and neomycin sulphate, hydrocortisone, formaldehyde, and cetyltrimethylammonium bromide (CTAB), or in anyone who has had a life-threatening reaction to previous influenza vaccination

Relevant warnings and precautions:

- Do not administer by any other route than intramuscularly
- Patients with endogenous or iatrogenic immunosuppression
- Patients who have had Guillain-Barré syndrome within 6 weeks of receipt of prior influenza vaccine
- Availability of appropriate medical treatment and supervision in case of an anaphylactic event following administration of the vaccine
- Patients with febrile illness or acute infections
- Patients with bleeding disorders
- Monitoring and laboratory tests
- False positive results in serology tests
- Skin

For more information:

Please consult the Product Monograph at https://health-products.canada.ca/dpd-bdpp/index-eng.jsp 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 by calling us at 1-855-358-8966.

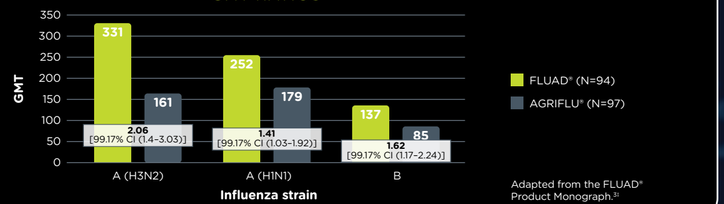
*Comparative clinical significance is unknown.

References: 1. Data on file. December 2023. **2.** Government of Canada. National Advisory Committee on Immunization (NACI). Supplemental guidance on influenza vaccination in adults 65 years of age and older. **3.** Seqirus Canada Inc., FLUAD® Product Monograph. **4.** Fluwatch March 24 to March 30 2024 (Week 13). Available at: https://www.canada.ca/en/public-health/services/publications/diseases-conditions/fluwatch/2023-2024/week-13-march-24-march-30-2024.html (accessed July 19, 2024). **5.** Government of Canada. Basic immunology and vaccinology: Canadian Immunization Guide. 2020. https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-14-basic-immunology-vaccinology.html (accessed July 19, 2024). **6.** An Advisory Committee Statement (ACS). National Advisory Committee on Immunization (NACI). Statement on Seasonal Influenza Vaccine for 2024-2025. **7.** Skowronski DM, *et al.* Interim estimates of 2014/15 vaccine effectiveness against influenza A (H3N2) from Canada's Sentinel Physician Surveillance Network, January 2015. *Eurosurveillance* 2015;20(4):21022. **8.** Data on file. March 2024. **9.** McGovern I, *et al.* Relative vaccine effectiveness of MF59®-adjuvanted vs high-dose trivalent inactivated influenza vaccines for prevention of test-confirmed influenza hospitalizations during the 2017–2020 influenza seasons. *International Journal of Infectious Diseases.* 2024;00231-5. **10.** WHO. Recommended composition of influenza virus vaccines for use in the 2017-2018 northern hemisphere influenza season. **11.** WHO. Recommended composition of influenza virus vaccines for use in the 2018-2019 northern hemisphere influenza season. **12.** WHO. Recommended composition of influenza virus vaccines for use in the 2019-2020 northern hemisphere influenza season (addendum). **13.** WHO. Recommended composition of influenza virus vaccines for use in the 2024-2025 northern hemisphere influenza season. **14.** Rockman S, *et al.* Cell-Based Manufacturing Technology Increases Antigenic Match of Influenza Vaccine and Results in Improved Effectiveness. *Vaccines* 2023;11(52):1-13. **15.** FLUAD® Compliance. Health Canada.

RANDOMIZED CLINICAL TRIALS: DEMONSTRATED IMMUNE RESPONSE DATA

GMT ratios versus homologous strains (strains included in the vaccine)[3‡]

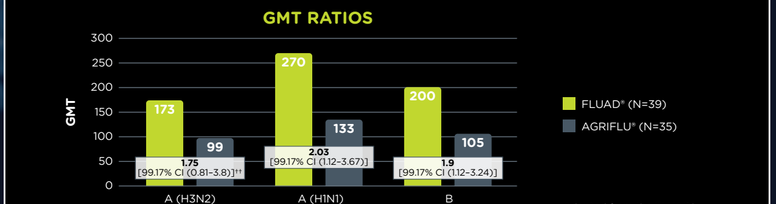
Demonstrated immune responses[§] data at Day 28 following vaccination with FLUAD® vs. a conventional non-adjuvanted influenza vaccine (AGRIFLU®) in adult patients 65 years of age and older (Study V7P5)[3¶]



Adapted from the FLUAD® Product Monograph.[3‡]

GMT ratios versus heterologous strains (strains not included in the vaccine)[3‡]

Demonstrated immune responses[§] data at Day 28 following vaccination with FLUAD® vs. a conventional non-adjuvanted influenza vaccine (AGRIFLU®) in adult patients 65 years of age and older (Study V7P3)[3]**



††Not statistically significant.

Adapted from the FLUAD® Product Monograph.[3‡]

Consider FLUAD®'s demonstrated immune response data.[3‡]**

CI=confidence interval; GMT=geometric mean titer; N=number of subjects in per-protocol population.
‡Comparative clinical significance is unknown.
§HI antibody titers to each virus strain in the vaccine.
¶Randomized, comparator-controlled, observer-blind clinical study in which the immunogenicity of FLUAD® (N=94) was compared with AGRIFLU® (N=97).
**Comparator-controlled clinical study in which the immunogenicity of FLUAD® (N=39) was compared with AGRIFLU® (N=35).

The data in this box is from a real-world evidence retrospective cohort study. It should be interpreted cautiously as it is not a randomized, controlled trial, or in the Product Monograph, and does not include a Canadian population.

Real-world evidence: Relative vaccine effectiveness of FLUAD® vs. Fluzone® High-Dose trivalent influenza vaccine[†‡]

Data regarding relative vaccine effectiveness for prevention of test-confirmed influenza emergency department visits and/or inpatient admissions and for inpatient admissions alone[9†]

Across 3 consecutive influenza seasons, real-world evidence (RWE) measuring relative vaccine effectiveness was gathered for FLUAD® and Fluzone® High-Dose trivalent influenza vaccine in patients 65 years and older:[9‡]

Seasons: 2017–2020	rVE, % (95% CI)
Inpatient admission or emergency department visit	
2017-2018[§]	1.6 (-31.4 to 26.2)
2018-2019[§¶]	1.6 (-22.7 to 21.1)
2019-2020[§]	-15.2 (-54 to 13.8)
Inpatient admission only	
2017-2018[§]	-1.0 (-43 to 28.7)
2018-2019[§¶]	3.3 (-27.4 to 26.5)
2019-2020[§]	-6.0 (-48.5 to 24.4)

rVE=relative vaccine effectiveness.
‡Fluzone® High-Dose quadrivalent has been used as of the 2021–2022 season.
§The WHO-recommended strain composition in the northern hemisphere for both vaccines was different for season 2017–2018 (A/Michigan/45/2015 [H1N1], A/Hong Kong/4801/2014 [H3N2] and B/Brisbane/60/2008 [B/Victoria]), season 2018–2019 (A/Michigan/45/2015 [H1N1], A/Singapore/INFIMH-16-0019/2016 [H3N2] and B/Colorado/06/2017 [B/Victoria]) and season 2019–2020 (A/Brisbane/02/2018 [H1N1], A/Kansas/14/2017 [H3N2] and B/Colorado/06/2017 [B/Victoria]). For the 2024–2025 season, the WHO-recommended strain composition of egg-based vaccines in the northern hemisphere is A/Victoria/4897/2022 (H1N1)pdm09-like virus, A/Thailand/8/2022 (H3N2)-like virus and B/Austria/1359417/2021 (B/Victoria lineage)-like virus.[10-13]
¶2018–2019 was considered a mismatched season due to antigenic drift of the A/H3N2 strain.[14]

Limitations for the data presented include the use of a smaller number of patients with valid influenza testing results (6,999–11,430) compared to the number of vaccine recipients in each season (1,054,359 to 1,743,557), which limited statistical power. Furthermore, potential sources of bias included: variability in patients' use of the US healthcare system; heterogeneity in the US healthcare system, regional variability in the distribution of FLUAD® (more prevalent in the South) and HD-TIV (more prevalent in the Midwest); and variability due to the broad definition for acute respiratory or febrile illness (ARFI). In addition, the accuracy of the test-negative approach could be impacted by the influenza tests' diagnostic accuracy.

CI=confidence interval; HD-TIV=high-dose trivalent inactivated influenza vaccine.
†Based on an observational study spanning three seasons using a dataset of electronic health records of subjects 65 years and older integrated with administrative claims data where available in the United States of America. Eligible subjects had a record of vaccination with FLUAD® or HD-TIV (2017–2018: n=11,430; 2018–2019: n=10,424; 2019–2020: n=6,999). Relative vaccine effectiveness by clinical setting (inpatient admission or emergency department visit vs. inpatient admission only) was estimated using test-confirmed influenza.