Over 160 million doses distributed worldwide![1]

FLUAD®

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

The only seasonal flu vaccine with the MF59C.1® adjuvant for adults aged 65+[3,4†‡]

FLUAD® is listed in the NACI guidelines.[2]
See the complete Statement on Seasonal Influenza Vaccine for more information.

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]

† Comparative clinical significance is unknown.
‡ FLUAD® is not indicated to treat influenza or its complications.

INFLUENZA. CONSIDER THE BURDEN TO YOUR PATIENTS OVER 65[5]*

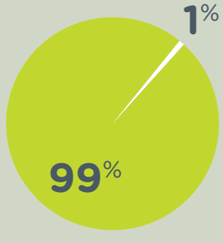
In older age, immune responses can decline (immunosenescence)[6]

The 65+ age group had the highest rate of laboratory-confirmed influenza detections with age information in the 2022-2023 flu season (across all age groups; cumulative to Week 17 – August 28, 2022 to April 29, 2023)*†

Of the overall reported 50,815 laboratory-confirmed influenza detections,[5]

- **25%** detections were from the 65+ age group[5†]
- Of the 12,824 detections of influenza in this age group, **99%** of cases were due to influenza A and **1%** to influenza B.[5]

PROPORTION OF DETECTIONS OF INFLUENZA IN THE 65+ AGE GROUP, BY SUBTYPE

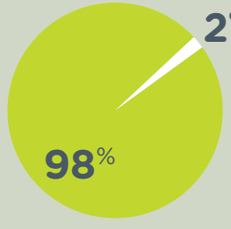


Adapted from Fluwatch[5]

Hospitalization rates in the overall population during the 2022-2023 flu season (cumulative to Week 17 – August 28, 2022 to April 29, 2023)[5*†]

- Of the 4,077 influenza-associated hospitalizations reported by participating provinces and territories, **98%** of cases were due to influenza A and **2%** to influenza B.[5]

PROPORTION OF HOSPITALIZATIONS DUE TO INFLUENZA ACROSS ALL AGES, BY SUBTYPE



Adapted from Fluwatch[5]

- The highest hospitalization rates were in the 65+ age group (133/100,000; cumulative to Week 17)[5]

FLUAD® is not indicated to reduce influenza-associated complications or mortality.

The 65+ age group reported the most ICUs and deaths in the 2022-2023 flu season (reported by participating provinces and territories; across all age groups; cumulative to Week 17 – August 28, 2022 to April 29, 2023)*†

Of the overall reported 348 admissions to intensive care units (ICU),[5]

- **32%** of ICUs were from the 65+ age group[5]
- Of the overall reported 268 influenza-associated deaths,[5] **76%** of deaths were from the 65+ age group[5]

FLUAD® is not indicated to reduce influenza-associated complications or mortality.

Consider immunizing your patients aged over 65 to help prevent the flu.[5]

*Based on Canadian data across from all groups and cumulative to Week 17 of the 2022-2023 season, which is defined as August 28, 2022 to April 29, 2023.
†Age groups studied were 0–4 years, 5–19 years, 20–44 years, 45–64 years, and those aged 65+.

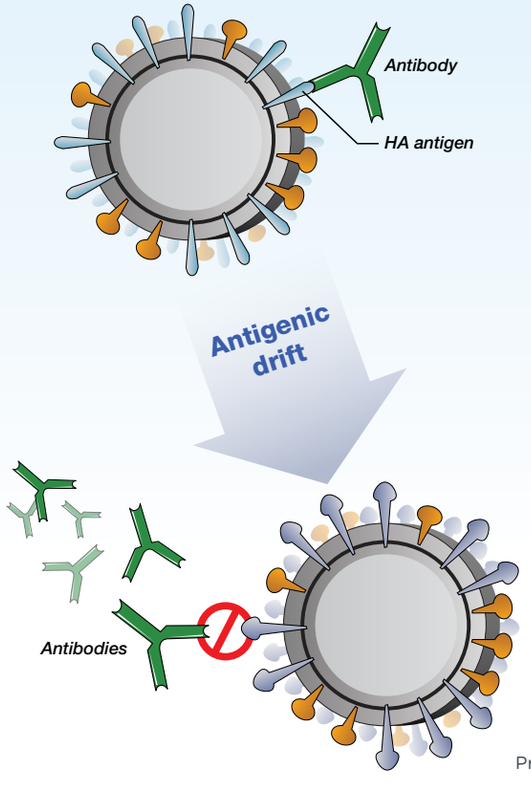
ANTIGENIC DRIFT

Antigenic drifted strains[2,4]

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.

What does this do?
Antibodies produced by a particular influenza strain may not recognize or protect against an antigenically drifted or mismatched strain variant.

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[2,4]

‡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).

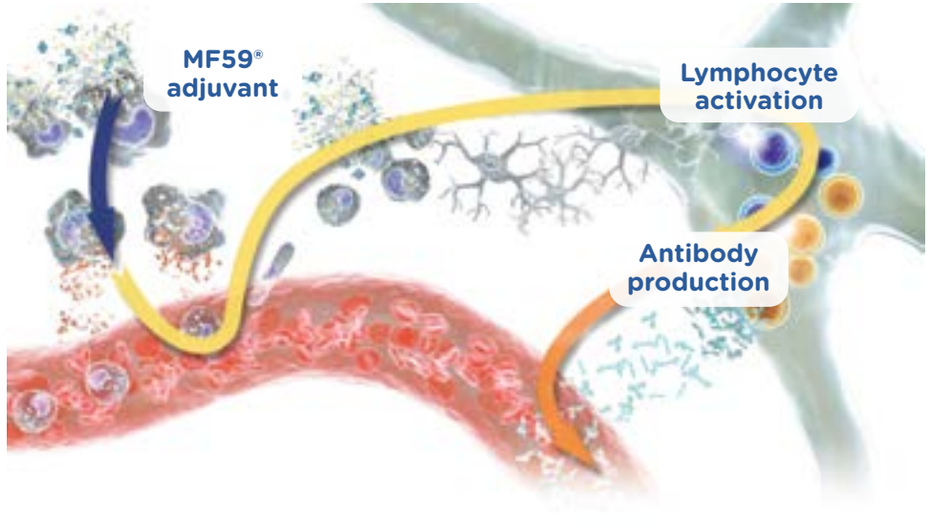
CONSIDER FLUAD® FOR YOUR PATIENTS OVER 65 YEARS OF AGE: THE ONLY SEASONAL FLU VACCINE WITH THE MF59® ADJUVANT[3,4*†]

Adjuvanted

FLUAD® contains **an adjuvant** called MF59® which is an oil-in-water emulsion composed of squalene as the oil phase, stabilized with the surfactants polysorbate 80 and sorbitan trioleate, in citrate buffer.[4†]

An adjuvant is a substance that is added to a vaccine to enhance the immune response.[4,6†]

The MF59® adjuvant can extend the duration of lymphocyte activation.[6†]



Adapted from the Canadian Immunization Guide[6†]

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.[4]

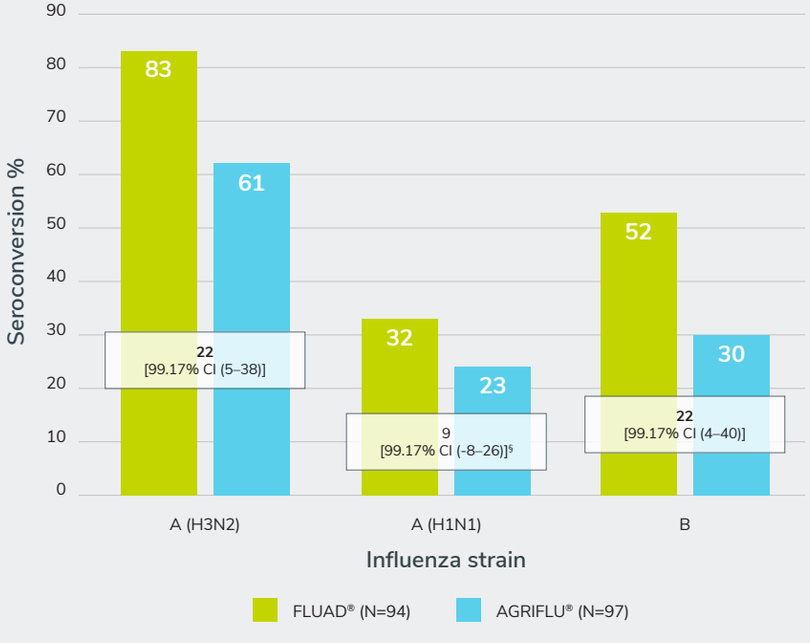
*Comparative clinical significance has not been established.
†Clinical significance has not been established.

PIVOTAL STUDY: DEMONSTRATED IMMUNE RESPONSE DATA

FLUAD® study evaluating seroconversion rates and GMTs in adults 65 years and older[4*]

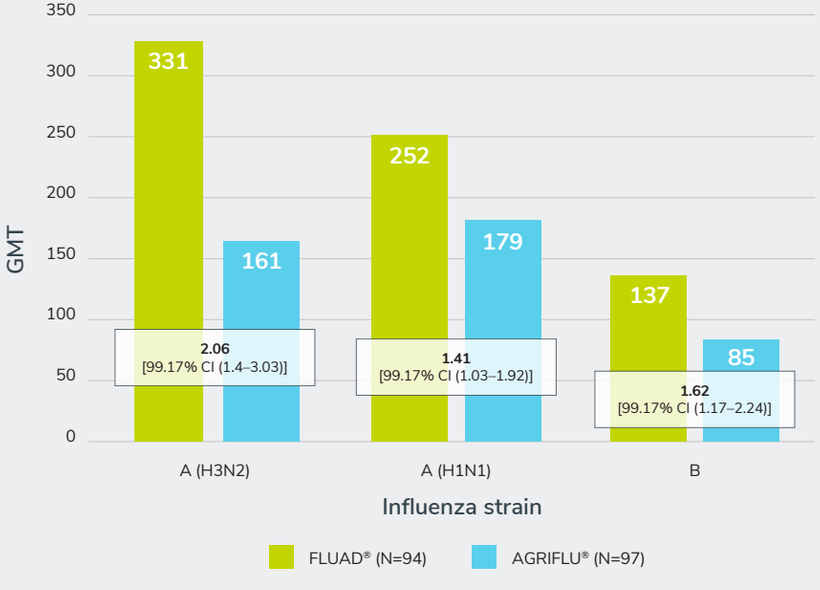
Demonstrated immune responses[†] at Day 28 following vaccination with FLUAD® vs. a conventional non-adjuvanted influenza vaccine (AGRIFLU®) in adult patients 65 years of age and older (Study V7P5)[4‡]

SEROCONVERSION RATE DIFFERENCES



Adapted from the FLUAD® Product Monograph[4*]

GMT RATIOS



Adapted from the FLUAD® Product Monograph[4*]

CI=confidence interval; GMT=geometric mean titre; 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).
§Not statistically significant.

PHARMACODYNAMICS OF SELECT INFLUENZA VACCINES AVAILABLE IN CANADA FOR USE IN PEOPLE 65 YEARS AND OLDER‡

FLUAD® (CSL Seqirus)	**Fluzone® High-Dose Quadrivalent** (Sanofi Pasteur)
Influenza Vaccine, Surface Antigen, Inactivated, Adjuvanted with MF59C.1	High-Dose Quadrivalent Influenza Virus Vaccine - Types A and B (Split Virion)
The antibody response to FLUAD® is increased when compared to the response to vaccines without adjuvant, and is most pronounced for A/H3N2 and B influenza antigens. Seroprotection is generally obtained within 2 to 3 weeks after vaccination. This increased response is seen particularly in elderly subjects with low pre-immunization titre and/or with underlying diseases (diabetes, cardiovascular and respiratory diseases) who are at increased risk of complications of influenza infection. A similar immunogenicity profile has been noted after a second and third immunization with FLUAD®. Consistent higher antibody titers after immunization with FLUAD® have also been observed against homologous and heterologous strains. The difference in antibody responses with FLUAD® administered in the elderly population was statistically significant for some strains and/or some endpoints compared with the comparator.	Seroprotection is generally obtained within 4 weeks. Adults 65 years and older generally have a heightened susceptibility to influenza-related complications due to natural and progressive weakening of the immune system over time known as immunosenescence. Immunosenescence can also render seniors less responsive to standard dose influenza vaccine. In clinical trials of adults 65 years of age and older, immunization with FLUZONE® High-Dose (Trivalent) induced a higher immune response to the A-strains contained in the vaccine than did immunization with a standard-dose influenza vaccine. Immune responses to FLUZONE® High-Dose Quadrivalent were shown to be non-inferior to those obtained with FLUZONE® High-Dose (Trivalent) in adults 65 years of age and older and statistically higher for the B strain not contained in FLUZONE® High-Dose.

Adapted from the respective Product Monographs[4,8§]

‡ Comparative clinical significance has not been established.
§ Data from separate Product Monographs; comparative clinical significance has not been proven.

DEMONSTRATED SAFETY PROFILE IN ADULTS AGED 65 YEARS AND OLDER[4]

The safety profile of FLUAD® is based on data from 39 clinical trials in 12,889 adult subjects 65 years of age and older.

Safety data after first vaccination for subjects 65 years of age and older were pooled from 31 trials.

Most frequently reported, solicited adverse reactions (≥5% and greater than comparator) – pooled studies[4]*		
Adverse reaction	**FLUAD® (N=3,713)**	**Comparator (N=1,656)**
Local adverse reactions		
Pain at injection site	26%	14%
Temperature at injection site†	18%	11%
Induration	11%	9%
Systemic adverse reactions		
Headache	6%	5%
Malaise	6%	5%
Myalgia	7%	3%

Adapted from the FLUAD® Product Monograph[4]

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.[4]

* Safety data after first vaccination for subjects 65 years of age and older pooled from 31 trials.
† Temperature at injection site "hot".

FLUAD® CHARACTERISTICS[4]*

- FLUAD® does not contain thimerosal or any other preservative
- The syringe plunger does not contain latex and FLUAD® is considered safe for use in persons with latex allergies

Dosing and administration[4]

FLUAD® is administered as one 0.5 mL intramuscular dose, preferably in the region of the deltoid muscle of the upper arm.

The vaccine should not be injected in the gluteal region or areas where there may be a major nerve trunk.

- Gently shake the contents of each syringe to aid inspection for the presence of particulate matter. After shaking, the vaccine should be a milky-white suspension.
- If there are visible particles, allow the vaccine to come to room temperature and shake before use (FLUAD® can be kept at room temperature [20°-25°C] for up to 2 hours as a holding time before injection).
- Do not use the vaccine if particles remain, if it is discoloured, or if it has been frozen.
- Before immunization, the skin over the site to be injected should be cleansed with a suitable germicide.

FLUAD® should, under no circumstances, be administered by any other route than intramuscularly. FLUAD® should not be mixed with other vaccines in the same syringe. Separate injection limbs should be used if more than one vaccine is being administered during the same visit.

Please refer to the Canadian Immunization Guide, Public Health Agency of Canada, for general information regarding vaccine administration practices.

*Clinical significance has not been established.

Indication and clinical use:

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.

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.

References:
1. Data on file. **2.** Government of Canada. National Advisory Committee on Immunization (NACI). https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html (accessed July 20, 2023). **3.** Data on file. **4.** FLUAD® Product Monograph. Seqirus Canada Inc. **5.** PHAC. FluWatch. April 16 to April 29, 2023 (weeks 16-17). https://www.canada.ca/en/public-health/services/publications/diseases-conditions/fluwatch/2022-2023/weeks-16-17-april-16-april-29-2023.html (accessed May 12, 2023) **6.** 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 April 14, 2022). **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.** Sanofi Pasteur Limited. FLUZONE® High-Dose Quadrivalent Product Monograph. April 19, 2022.

FLUAD®

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

The only seasonal flu vaccine with the MF59® adjuvant.[3,4*]

Consider FLUAD® for your patients aged 65 years and older[4]

Extensive experience: Over 160 million doses of FLUAD® have been distributed worldwide.[1†]

Demonstrated immunogenicity data[4*‡§]

FLUAD® was associated with numerically higher HI antibody titers and greater percentages of subjects achieving seroconversion or significant increase in HI titres (based on GMTs and seroconversion rates) at Day 28 vs. a conventional non-adjuvanted influenza vaccine (AGRIFLU®).

FLUAD® is listed in the NACI guidelines.[2]
See the complete Statement on Seasonal Influenza Vaccine for more information.

* Comparative clinical significance is unknown.
† Clinical significance is unknown.
‡ Clinical significance and comparative clinical significance have not been established.
§ Randomized, comparator-controlled, observer-blind clinical study in which the immunogenicity of FLUAD® (N=94) was compared with AGRIFLU® (N=97).

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

CSL Seqirus

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