Over 150 million doses distributed worldwide!

FLUAD®

The only seasonal flu vaccine with the MF59® adjuvant for adults aged 65+[1,2†‡]

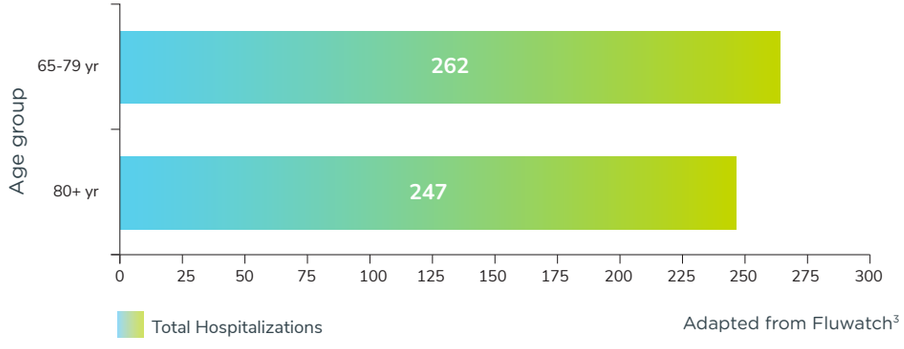
FLUAD® is an inactivated influenza virus vaccine indicated for active immunization against influenza in the elderly (65 years of age and older).

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

Influenza. Consider the burden to your patients over 65*

The 65+ age group had the highest hospitalization rates in the 2019-2020 flu season

CUMULATIVE NUMBERS OF ADULT HOSPITALIZATIONS (≥65 YEARS OF AGE) WITH INFLUENZA BY AGE GROUP REPORTED BY THE CANADIAN IMMUNIZATION RESEARCH NETWORK (CIRN) SERIOUS OUTCOMES SURVEILLANCE (SOS) NETWORK, CANADA, WEEKS 2019-45 TO 2020-19[3]



Cumulative numbers of adult hospitalizations

More than half of hospitalizations among persons infected with influenza A and B were 65 years of age and older.[3]
In the 2019-2020 flu season, among the 629 cases infected with influenza A and 170 cases infected with influenza B, more than half of hospitalizations were in adults 65 years of age and older, 66% and 52%, respectively.

Select laboratory-confirmed influenza detections in the elderly[3]

In the 2019-2020 season, the cases reported for adults 65 years of age and older were:[2]

Influenza A:

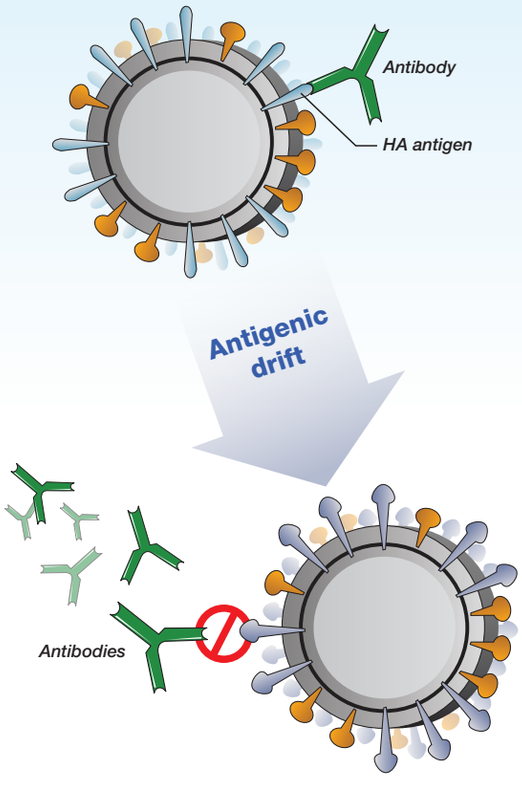
- 46% (largest proportion) of 2,057 cases of A/H3N2
- 28% of 3,740 cases of A/H1N1

A (H1N1) was the predominant subtype.

Influenza B:

- 7.7% of 18,194 cases

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



Adapted from the FLUAD Product Monograph and NACI[1,4]

Antigenic drifted strains[1,4]

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.[5‡]

‡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).

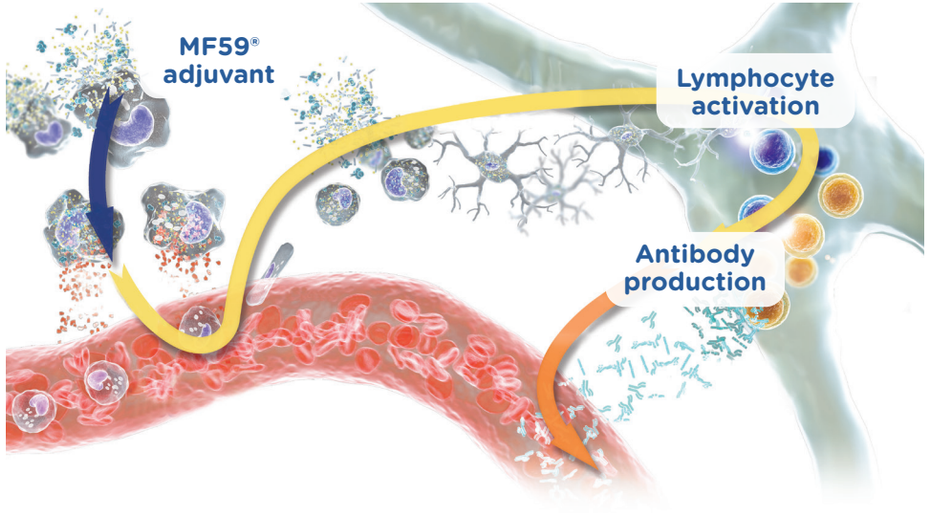
Consider FLUAD® for your patients over 65 years old. The only seasonal flu vaccine with the MF59® adjuvant[1,4*†]

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.[1†]

> An adjuvant is a substance that is added to a vaccine to enhance the immune response.[5†]

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

FLUAD® is an inactivated influenza virus vaccine indicated for active immunization against influenza in the elderly (65 years of age and older).[1]

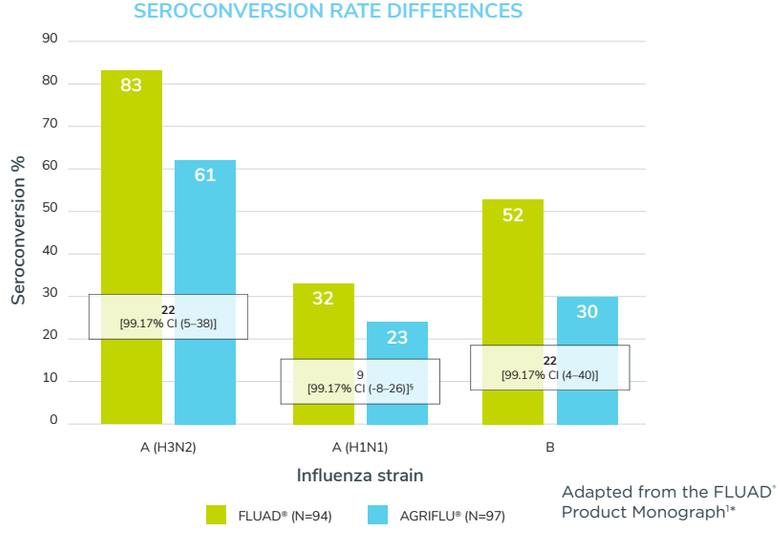


Adapted from the Canadian Immunization Guide[6†]

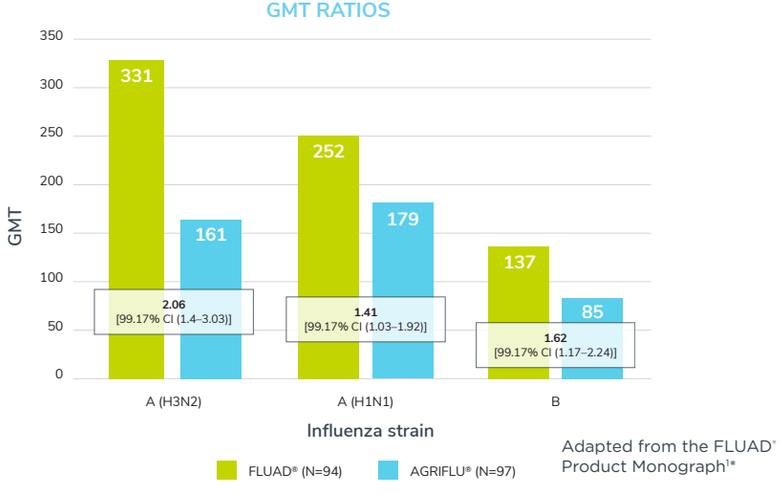
*Comparative clinical significance has not been established.
†Clinical significance has not been established.

FLUAD® study that evaluated seroconversion rates and GMTs in adults 65 years and older[1*]

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)[1‡]



Adapted from the FLUAD® Product Monograph[1*]



Adapted from the FLUAD® Product Monograph[1*]

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.

Demonstrated safety profile in elderly patients[1]

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[1]*		
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[1]

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.[1]

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

FLUAD® characterisitics[1]*

- 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[1]

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.

The only seasonal flu vaccine with the MF59® adjuvant[1,2†]

Consider FLUAD® for your patients 65 and older[1*]

Pharmacodynamic profile - 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.[1†]

FLUAD® study that evaluated seroconversion rates and GMTs in adults 65 years and older[1*‡]

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®).

Demonstrated safety and tolerability profile[1]

In pooled studies, the most frequently reported solicited adverse reactions (≥10%) were pain at the injection site (26%), temperature at the injection site (18%) and induration (11%) in adults 65 and older.*

* Comparative 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®)

NOTES

NOTES

FLUAD®

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

Indication and clinical use:

FLUAD® is an inactivated influenza virus vaccine indicated for active immunization against influenza in the elderly (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

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. Seqirus Canada Inc., FLUAD® Product Monograph. September 9, 2021. **2.** Data on file. **3.** PHAC. FluWatch. July 19 to August 22, 2020 (weeks 30-34). https://www.canada.ca/en/public-health/services/publications/diseases-conditions/fluwatch/2019-2020/weeks-30-34-july-19-august-22-2020.html (accessed Oct. 20, 2020) **4.** PHAC. 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. **5.** 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. **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).

FLUAD®

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

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REVIEWED BY PAAB