FLUAD®
influenza vaccine, adjuvanted

PREFERENTIALLY RECOMMENDED BY ACIP FOR ADULTS 65+*[1]

THE ADJUVANT ADVANTAGE*

BACKED BY 20+ YEARS OF REAL-WORLD EVIDENCE[2-20]

FLUAD® has clinical trial data demonstrating a robust immune response, which is supported by real-world evidence (RWE) evaluated in over 71 million adults 65+.[2-21]

- FLUAD met immunogenicity non-inferiority criteria compared to a non-adjuvanted, standard-dose influenza vaccine[21]
- FLUAD has a demonstrated safety profile[21]
- The most common (≥10%) local and systemic reactions with FLUAD were myalgia, fatigue, headache, injection-site pain, and injection-site tenderness[21]

***Preferentially recommended by ACIP for adults 65+ over non-adjuvanted, standard-dose influenza vaccines.**

ACIP=Advisory Committee on Immunization Practices

FLUAD® (Influenza Vaccine, Adjuvanted)

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

FLUAD is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD is approved for use in adults 65 years of age and older.

This indication is approved under accelerated approval based on the immune response elicited by FLUAD. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Do not administer FLUAD to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or to a previous influenza vaccine.

Please see Important Safety Information throughout and the full US Prescribing Information for FLUAD.

For US Healthcare Professional Use Only

CSL Seqirus

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DESIGNED TO ADDRESS 2 KEY CHALLENGES

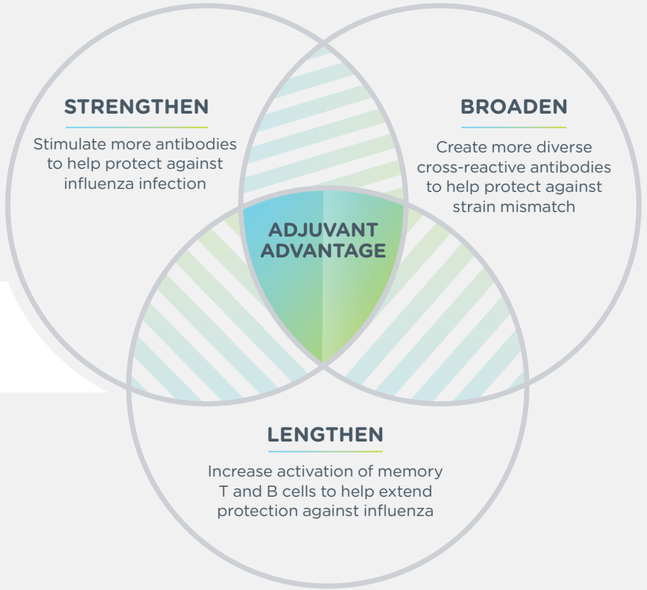
Weakened Immune System

Vaccine effectiveness may be reduced in adults 65+ due to a **weakened immune response to vaccines**[22,23]

Strain Mismatch

Strain mismatch, which occurred in 7 of 10 recent flu seasons, **may further reduce vaccine effectiveness***[24-34]

FLUAD® is adjuvanted to boost the immune response beyond standard-dose flu vaccines[35-37]



FLUAD: Adding MF59® Adjuvant does more than antigen alone.[35-37]
Click here to see how it works

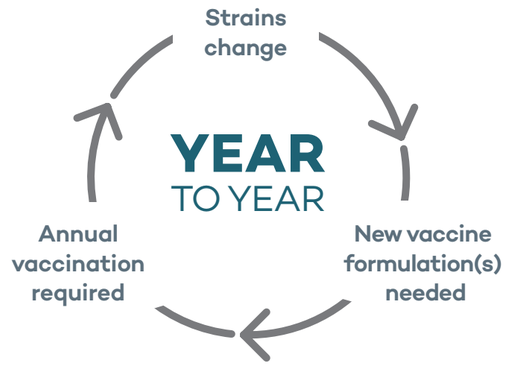
*2010-2011 through 2019-2020 US influenza seasons.

WARNINGS AND PRECAUTIONS

If Guillain-Barré Syndrome (GBS) has occurred within six weeks of previous influenza vaccination, the decision to give FLUAD should be based on careful consideration of the potential benefits and risks.

Please see Important Safety Information throughout and full US Prescribing Information for FLUAD.

BACKED BY REAL-WORLD EVIDENCE



Look to both clinical trial and RWE data when choosing an influenza vaccine

Given the variable nature of influenza, RCTs can only provide data from a snapshot in time. By offering ever-growing data of large, diverse patient populations outside clinical trials, RWE offers a complementary approach to RCTs to assess seasonal influenza vaccine effectiveness.[38-40]

ACIP recognizes the value of RWE

ACIP's preferential recommendation of FLUAD for adults 65+ was based on a multi-year, rigorous review of both RCT and RWE data.[1]

FLUAD vs standard-dose influenza vaccines

Clinically meaningful outcomes evaluated in an estimated **18.5 million adults** 65+ across 18 influenza seasons†[2-17]

FLUAD vs high-dose influenza vaccine

Clinically meaningful outcomes evaluated in an estimated **52.9 million adults** 65+ across 4 influenza seasons†[3-7,12-14,18-20]

†The outcomes reported in these publications contain information not included in the Prescribing Information. This is the full body of evidence as of January 2023. All of the RWE data is published in peer-reviewed journals.

WARNINGS AND PRECAUTIONS (continued)

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of FLUAD.

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FLUAD® influenza vaccine, adjuvanted

VS STANDARD-DOSE INFLUENZA VACCINE

ADJUVANT ADVANTAGE

FLU-RELATED HOSPITALIZATIONS/ER VISITS

Results	Favors TIV/QIV ← → Favors aTIV (-50, -25, 0, 25, 50, 75, 100)	Subjects	Season(s)
59% more effective than SD[a*†2] (rVE 59.2%; 95% CI 14.6, 80.5)		512	2 (2018-2020)
8% more effective than SD[b*†3] (rVE 8.2%; 95% CI 4.2, 12)		>4.1 million	1 (2019-2020)
8% more effective than SD[b*†4] (rVE 7.7%; 95% CI 3.9, 11.14)		>3.5 million	1 (2018-2019)
4% more effective than SD[b*†5] (rVE 3.9%; 95% CI 1.4, 6.3)		>3.2 million	1 (2017-2018)
9% more effective than SD[b*†6] (rVE 8.6%; 95% CI 1.2, 15.6)		446,600	1 (2017-2018)
10% more effective than SD[b*†7] (rVE 10%; 95% CI -15, 31)		159,964	2 (2016-2018)

ALL-CAUSE AND OTHER HOSPITALIZATIONS

Results	Favors TIV/QIV ← → Favors aTIV (-50, -25, 0, 25, 50, 75, 100)	Subjects	Season(s)
12% all-cause more effective than SD[c*†8] (rVE 12%; 95% CI 3, 20)		21,712	18 (2002-2019)
4% cardio-respiratory more effective than SD[d*†6] (rVE 4%; 95% CI 1.9, 6.2)		446,600	1 (2017-2018)
33% pneumonia more effective than SD[d*†9] (rVE 33%; 95% CI 25, 41)		479,397	6 (2011-2017)
39% pneumonia, cerebro/CV more effective than SD[c‡§10] (rVE 39%; 95% CI 4, 61)		43,000	15 (2001-2017)
25% influenza, pneumonia more effective than SD[e*‖¶11] (rVE 25%; 95% CI 2, 43)		107,661	3 (2006-2009)

ONE OR MORE FLU SEASONS IMPACTED BY ANTIGENIC MISMATCH (IE, ANTIGENIC DRIFT OR STRAIN SELECTION MISMATCH)

aTIV=adjuvanted trivalent influenza vaccine; CI=confidence interval; CV=cardiovascular; ER=emergency room; QIV=quadrivalent influenza vaccine; rVE=relative vaccine effectiveness; SD=standard-dose influenza vaccine; TIV=trivalent influenza vaccine

WARNINGS AND PRECAUTIONS (continued)

Syncope (fainting) may occur in association with administration of injectable vaccines including FLUAD. Procedures should be in place to avoid injury from fainting.

Please see Important Safety Information throughout and full US Prescribing Information for FLUAD.

FLU-RELATED MEDICAL ENCOUNTERS

Results	Favors TIV/QIV ← → Favors aTIV (-50, -25, 0, 25, 50, 75, 100)	Subjects	Season(s)
28% more effective than SD[b*‡12] (rVE 27.5%; 95% CI 24.4, 30.5)		>1.5 million	1 (2019-2020)
28% more effective than SD[b*‡13] (rVE 27.8%; 95% CI 25.7, 29.9)		>1.9 million	1 (2018-2019)
20% more effective than SD[b*‡14] (rVE 20.4%; 95% CI 16.2, 24.4)		>679,487; ≥1 comorbidity	1 (2018-2019)
18% more effective than SD[b*‡13] (rVE 18.2%; 95% CI 15.8, 20.5)		>1.4 million	1 (2017-2018)
7% more effective than SD[b*‡14] (rVE 7.1%; 95% CI 3.3, 10.2)		528,504; ≥1 comorbidity	1 (2017-2018)

FLU-RELATED OFFICE VISITS

Results	Favors TIV/QIV ← → Favors aTIV (-50, -25, 0, 25, 50, 75, 100)	Subjects	Season(s)
36% more effective than SD[b*†6] (rVE 36.3%; 95% CI 31, 41.2)		446,600	1 (2017-2018)
63% more effective than SD[f*¶15] (rVE 63%; 95% CI 4, 86)		227	1 (2011-2012)

LONG-TERM CARE SETTING

Results	Favors TIV/QIV ← → Favors aTIV (-50, -25, 0, 25, 50, 75, 100)	Subjects	Season(s)
22% outbreaks more effective than SD[g*#16] (rVE 22%; 95% CI -2, 40)		737 nursing homes	1 (2016-2017)
6% all-cause hospitalizations more effective than SD[h*§17] (rVE 6%; 95% CI 1, 11)		50,012	1 (2016-2017)

These RWE studies show that FLUAD® is more effective than standard-dose influenza vaccines at reducing flu-related outcomes.[2-17]

Study Design: [a]Test-negative, case-control, Italy. [b]Retrospective cohort study, US. [c]Nested, case-control study, Italy. [d]Retrospective cohort study, Italy. [e]Prospective, cohort study, Italy. [f]Test-negative, case-control, Canada. [g]Pragmatic cluster-randomized trial, US. [h]Prospective, randomized study, US

Key Limitations: [*]Potential confounding. [†]Low influenza B. [‡]Not lab-confirmed. [§]Low frequency of events. [‖]FLUAD subjects more frail. [¶]Small population. [#]Reporting bias

WARNINGS AND PRECAUTIONS (continued)

The immune response to FLUAD in immunocompromised persons, including individuals receiving immunosuppressive therapy, may be lower than in immunocompetent individuals.

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FLUAD®
influenza vaccine, adjuvanted

VS HIGH-DOSE INFLUENZA VACCINE

FLU-RELATED HOSPITALIZATIONS/ER VISITS

Results	Favors HD-TIV ← → Favors aTIV (-30 -20 -10 0 10 20 30)	Subjects	Season(s)
3% fewer influenza-related hospitalizations and ER visits[a*†18] (rVE 3.1%; 95% CI -2.8, 8.6)		>2.4 million	1 (2019-2020)
2% fewer influenza-related hospitalizations and ER visits[a*†3] (rVE 1.6%; 95% CI -1.6, 4.8)		>9.7 million	1 (2019-2020)
3% fewer influenza-related hospitalizations and ER visits[a*†4] (rVE 3%; 95% CI 0, 6.1)		>10 million	1 (2018-2019)
2% fewer influenza-related hospitalizations and ER visits[a*†19] (rVE 2%; 95% CI -3.7, 7.3)		>2.2 million	1 (2018-2019)
5% more influenza-related hospitalizations and ER visits[a*†5] (rVE -5.3%; 95% CI -7.3, -3.3)		9.9 million	1 (2017-2018)
3% fewer influenza-related hospitalizations and ER visits[a*†6] (rVE 3.2%; 95% CI -2.7, 8.9)		1.5 million	1 (2017-2018)
6% fewer influenza-related hospitalizations and ER visits[a*†7] (rVE 6%; 95% CI -31, 32)		122,956	1 (2017-2018)
2% more influenza-related hospitalizations and ER visits[a*†7] (rVE -2%; 95% CI -24, 26)		187,266	1 (2016-2017)

OTHER RESPIRATORY HOSPITALIZATIONS

Results	Favors HD-TIV ← → Favors aTIV (-30 -20 -10 0 10 20 30)	Subjects	Season(s)
1% fewer cardio-respiratory hospitalizations or ER visits[a*†18] (rVE 0.9%; 95% CI 0.01, 1.7)		>2.4 million	1 (2019-2020)
3% fewer cardio-respiratory hospitalizations or ER visits[a*†19] (rVE 2.6%; 95% CI 2, 3.2)		>2.2 million	1 (2018-2019)
2% fewer cardio-respiratory hospitalizations or ER visits[a*†6] (rVE 2.4%; 95% CI 0.7, 4)		>1.5 million	1 (2017-2018)
12% more respiratory hospitalizations[a*†‡20] (rVE -12%; 95% CI -20, -3.3)		>2.1 million	2 (2016-2018)

aTIV=adjuvanted trivalent influenza vaccine; CI=confidence interval; ER=emergency room; HD-TIV=high-dose trivalent influenza vaccine; rVE=relative vaccine effectiveness

WARNINGS AND PRECAUTIONS (continued)

Vaccination with FLUAD may not protect all vaccine recipients against influenza disease.

Please see Important Safety Information throughout and full US Prescribing Information for FLUAD.

FLU-RELATED MEDICAL ENCOUNTERS includes hospitalizations, ER visits, and office visits

Results	Favors HD-TIV ← → Favors aTIV (-30 -20 -10 0 10 20 30)	Subjects	Season(s)
14% fewer influenza-related medical encounters[a*†12] (rVE 13.9%; 95% CI 10.7, 17.0)		>2.7 million	1 (2019-2020)
7% fewer influenza-related medical encounters[a*†13] (rVE 6.9%; 95% CI 3.1, 10.6)		>4.8 million	1 (2018-2019)
3% fewer influenza-related medical encounters[a*†14] (rVE 2.7%; 95% CI -2.7, 7.8)		>1.7 million ≥1 comorbidity	1 (2018-2019)
8% fewer influenza-related medical encounters[a*†13] (rVE 7.7%; 95% CI 2.3, 12.8)		>3.9 million	1 (2017-2018)
1% more influenza-related medical encounters[a*†14] (rVE -0.8%; 95% CI -8.9, 6.6)		>1.3 million ≥1 comorbidity	1 (2017-2018)

FLU-RELATED OFFICE VISITS

Results	Favors HD-TIV ← → Favors aTIV (-30 -20 -10 0 10 20 30)	Subjects	Season(s)
7% fewer influenza-related office visits[a*†19] (rVE 6.6%; 95% CI 2.7, 10.3)		>2.2 million	1 (2018-2019)
17% fewer influenza-related office visits[a*†6] (rVE 16.6%; 95% CI 10.8, 22)		>1.5 million	1 (2017-2018)

FLUAD® is comparable to high-dose influenza vaccines at reducing flu-related outcomes, but RWE studies across 2 recently mismatched flu seasons generally favored FLUAD.[3-7,12-14,18-20]

ONE OR MORE FLU SEASONS IMPACTED BY ANTIGENIC MISMATCH (IE, ANTIGENIC DRIFT OR STRAIN SELECTION MISMATCH)

Study Design: [a]Retrospective cohort study, US

Key Limitations: *Potential confounding. †Not lab-confirmed. ‡Uneven cohort sizes made results heavily skewed

ADVERSE REACTIONS

The most common (≥10%) local and systemic adverse reactions in adults 65 years of age and older who received FLUAD were injection site pain (25%), injection site tenderness (21%), myalgia (15%), fatigue (13%) and headache (13%).

Please see Important Safety Information throughout and full US Prescribing Information for FLUAD.

Give adults 65 years and older

THE ADJUVANT ADVANTAGE*[1]

FLUAD® influenza vaccine, adjuvanted

Help address the key challenges in adults 65+ with FLUAD®[35-37]

Adjuvant Technology	Designed to strengthen, broaden, and lengthen immune response[35-37]
Boosted Response	Helps address weakened immune systems and strain mismatch in adults 65+[35-37]
Clinically Effective	Backed by 20+ years of real-world evidence[2-20]

*Preferentially recommended by ACIP for adults 65+ over non-adjuvanted, standard-dose influenza vaccines.

FLUAD® (Influenza Vaccine, Adjuvanted)
INDICATION and IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

FLUAD is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD is approved for use in adults 65 years of age and older.

This indication is approved under accelerated approval based on the immune response elicited by FLUAD. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Do not administer FLUAD to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or to a previous influenza vaccine.

WARNINGS AND PRECAUTIONS

If Guillain-Barré Syndrome (GBS) has occurred within six weeks of previous influenza vaccination, the decision to give FLUAD should be based on careful consideration of the potential benefits and risks.

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of FLUAD.

Syncope (fainting) may occur in association with administration of injectable vaccines including FLUAD. Procedures should be in place to avoid injury from fainting.

The immune response to FLUAD in immunocompromised persons, including individuals receiving immunosuppressive therapy, may be lower than in immunocompetent individuals.

Vaccination with FLUAD may not protect all vaccine recipients against influenza disease.

ADVERSE REACTIONS

The most common (≥10%) local and systemic adverse reactions in adults 65 years of age and older who received FLUAD were injection site pain (25%), injection site tenderness (21%), myalgia (15%), fatigue (13%) and headache (13%).

Other adverse events may occur.

To report SUSPECTED ADVERSE REACTIONS, contact CSL Seqirus at 1-855-358-8966 or VAERS at 1-800-822-7967 and www.vaers.hhs.gov.

Before administration, please see the full US Prescribing Information for FLUAD.

REFERENCES: 1. Grohskopf LA, et al. *MMWR Recomm Rep*. 2023;72(2)1-25. **2.** Domnich A, et al. *Int J Infect Dis*. 2022;125:164-169. **3.** Izurieta HS, et al. *Clin Infect Dis*. 2020;ciaa1727. **4.** Izurieta HS, et al. *J Infect Dis*. 2020;222(2):278-287. **5.** Izurieta HS, et al. *J Infect Dis*. 2019;220(8):1255-1264. **6.** Pelton SI, et al. *Vaccines (Basel)*. 2020;8(3):E446. **7.** Machado MAA, et al. *NPJ Vaccines*. 2021;6(1):108. **8.** Lapi F, et al. *Expert Rev Vaccines*. 2022;21(3):377-384. **9.** Cocchio S, et al. *Vaccines (Basel)*. 2020;8(3):E344. **10.** Lapi F, et al. *Expert Rev Vaccines*. 2019;18(6):663-670. **11.** Mannino S, et al. *Am J Epidemiol*. 2012;176(6):527-533. **12.** Imran M, et al. *Open Forum Infect Dis*. 2022;9(5):ofac167. **13.** Boikos C, et al. *Clin Infect Dis*. 2021;73(5):816-823. **14.** Boikos C, et al. *Vaccines (Basel)*. 2021;9(8):862. **15.** Van Buynder PG, et al. *Vaccine*. 2013;31(51):6122–6128. **16.** Gravenstein S, et al. *Clin Infect Dis*. 2021;ciaa1916. **17.** McConeghy KW, et al. *Clin Infect Dis*. 2020;ciaa1233. **18.** Levin MJ, et al. *Vaccines*. 2021;9(10):1146. **19.** Pelton SI, et al. *Vaccine*. 2021;39(17):2396-2407. **20.** Van Aalst VR. *Vaccine*. 2020;38(2):372-379. **21.** FLUAD. Package insert. Seqirus Inc. **22.** CDC. Flu & people 65 years and older. Accessed March 5, 2024. https://www.cdc.gov/flu/highrisk/65over.htm **23.** Monto AS, et al. *Vaccine*. 2009;27(37):5043-5053. **24.** Skowronski DM, et al. *PLoS One*. 2014;9(3):e92153. **25.** CDC. *MMWR Morb Mortal Wkly Rep*. 2011;60(21):705-712. **26.** Ohmit SE, et al. *Clin Infect Dis*. 2014;58(3):319-327. **27.** McLean HQ, et al. *J Infect Dis*. 2015;211(10):1529-1540. **28.** Gaglani M, et al. *J Infect Dis*. 2016;213(10):1546-1556. **29.** Zimmerman RK, et al. *Clin Infect Dis*. 2016;63(12):1564-1573. **30.** Jackson ML, et al. *N Engl J Med*. 2017;377(6):534-543. **31.** Flannery B, et al. *MMWR Morb Mortal Wkly Rep*. 2018;67(6):180-185. **32.** Flannery B, et al. *J Infect Dis*. 2020;221(1):8-15. **33.** Tenforde MW, et al. *Clin Infect Dis*. 2021;73(11):e4244-e4250. **34.** Zost SJ, et al. *Proc Natl Acad Sci USA*. 2017;114(47):12578-12583. **35.** O'Hagan DT, et al. *Vaccine*. 2012;30(29):4341-4348. **36.** O'Hagan DT, et al. *Expert Rev Vaccines*. 2013;12(1):13-30. **37.** Banzhoff A, et al. *Influenza Other Respir Viruses*. 2008;2(6):243-249. **38.** Katkade VB, et al. *J Multidiscip Healthc*. 2018;11:295-304. **39.** Frieden TR. *N Engl J Med*. 2017;377(5):465-475. **40.** US Food and Drug Administration. Real-world evidence. Accessed March 5, 2024. https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence

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