FLUCELVAX®
Influenza Vaccine

APPROVED FOR
6+ MONTHS[1]

AVAILABLE THROUGH VFC*

REAL-WORLD EVIDENCE SUPPORTS THE CELL-BASED SOLUTION[2-14]

Avoid the risk of egg adaptation with a cell-based influenza vaccine[15]

*Confirm availability with your state's Vaccines for Children (VFC) program.

FLUCELVAX® (Influenza Vaccine)
INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE
FLUCELVAX is an inactivated vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUCELVAX is approved for use in persons 6 months of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Do not administer FLUCELVAX to anyone with a history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

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

For US Healthcare Professional Use Only

CSL Seqirus

PROVEN IN CLINICAL TRIALS

Demonstrated efficacy of FLUCELVAX® QUADRIVALENT (Influenza, Vaccine) in children 2 through 17 years published in *The New England Journal of Medicine*[1,16]

Noninferior immunogenicity and seroconversion of FLUCELVAX QUADRIVALENT to a US-licensed comparator influenza vaccine in children 6 months through 3 years as seen in *Pediatrics*[1,17]

Demonstrated efficacy of FLUCELVAX against culture-confirmed influenza in adults 18 through 49 years[1]

Noninferior immunogenicity and seroconversion of FLUCELVAX to a US-licensed comparator influenza vaccine in adults 18 years and older[1]

Scan this code to access the full study results in *Pediatrics* or visit **CellBasedFluShotStudy.com**.

The data of FLUCELVAX QUADRIVALENT are relevant to FLUCELVAX, as both vaccines are manufactured using the same process and have overlapping compositions.

WARNINGS AND PRECAUTIONS

If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLUCELVAX should be based on careful consideration of the potential benefits and risks.

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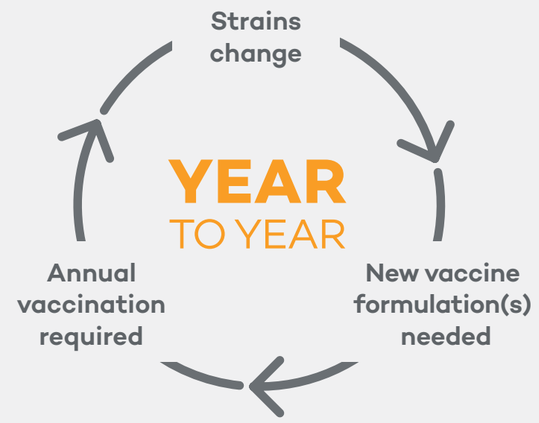
BACKED BY REAL-WORLD EVIDENCE

FLUCELVAX QUADRIVALENT vs standard-dose influenza vaccines

Clinically meaningful outcomes evaluated in over **38.1 million patients** across 3 influenza seasons*[2-14]

Look to both clinical trial and RWE data when choosing an influenza vaccine[18-20]



Given the variable nature of influenza, randomized clinical trials (RCTs) can only provide data from a snapshot in time.

By offering ever-growing data of large, diverse patient populations outside clinical trials, RWE presents a complementary approach to RCTs to assess seasonal influenza vaccine effectiveness.[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 October 2022. All of the RWE data is published in peer-reviewed journals. The RWE studies of FLUCELVAX QUADRIVALENT were conducted in patients 4 years and older because that was the age indication at the time the studies were being conducted. The FDA has since approved FLUCELVAX QUADRIVALENT for patients 6 months and older in October 2021. The data of FLUCELVAX QUADRIVALENT are relevant to FLUCELVAX, as both vaccines are manufactured using the same process and have overlapping compositions.

WARNINGS AND PRECAUTIONS (continued)

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

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FLUCELVAX®
Influenza Vaccine

VS TRADITIONAL, EGG-BASED INFLUENZA VACCINES

Hospitalizations and/or ER Visits

End Points	Study Results	Study Design	Key Limitations
	Favors egg-based influenza vaccines ◀ ▶ Favors FLUCELVAX QIV -30 -20 -10 0 10 20 30 40 50		
15% **fewer laboratory-confirmed influenza hospitalizations**[2] (rVE 15%; 95% CI -26, 43)		Test-negative case-control study of **5,471 persons** ≥4 years in the US* (2017-2018)	• Results did not account for all residual confounding (eg, frailty) • Selection bias in hospitalizations and testing
14% **fewer influenza-related hospitalizations or ER visits**[3] (rVE 14.4%; 95% CI 8.8, 19.6)		Retrospective cohort study of **over 3 million persons** 4-64 years old in the US (2017-2018)	• Results were not adjusted by unmeasurable confounders • Findings may not be representative of uninsured, Medicaid, or Medicare populations
11% **fewer influenza-related hospital encounters**[4] (rVE 11%; 95% CI 7.9, 14)		Retrospective cohort study of **over 2.5 million adults** ≥65 years in the US (2017-2018)	• Potential for residual confounding • Medicare claims may not be representative of private or uninsured populations
3% **fewer influenza-related hospitalizations or ER visits**[5] (rVE 2.5%; 95% CI -2.4, 7.3)		Retrospective cohort study of **over 2.2 million adults** ≥65 years from the US (2018-2019)	• Potential for residual confounding • Lack of laboratory confirmation
7% **fewer influenza-related hospitalizations or ER visits**[6] (rVE 6.5%; 95% CI 0.1, 12.5)		Retrospective cohort study of **over 3.7 million persons** 4-64 years old in the US (2018-2019)	• Results were not adjusted by unmeasurable confounders • Findings may not be representative of uninsured, Medicaid, or Medicare populations
3% **fewer influenza-related hospital encounters**[7] (rVE 2.8%; 95% CI -2.8, 8.2)		Retrospective cohort study of **over 2.4 million adults** ≥65 years from the US (2019-2020)	• Potential for residual confounding • Lack of laboratory confirmation
5% **fewer influenza-related hospitalizations or ER visits**[8] (rVE 5.3%; 95% CI 0.5, 9.9)		Retrospective study of **over 5 million persons** 4-64 years old in the US (2019-2020)	• Potential for unmeasured confounders • Lack of laboratory confirmation
6% **fewer influenza-related hospitalizations**[9] (rVE 5.7%; 95% CI 2.1, 9.2)		Retrospective cohort study of **over 5.6 million persons** ≥18 years in the US (2019-2020)	• Lack of laboratory confirmation • Findings may not be representative of uninsured populations

US FLU SEASON WITH EGG-ADAPTED STRAIN MISMATCH

*There was also an unvaccinated arm in this study.

CI=confidence interval; ER=emergency room; rVE=relative vaccine effectiveness

WARNINGS AND PRECAUTIONS (continued)

Syncope (fainting) has been reported following vaccination with FLUCELVAX. Procedures should be in place to avoid injury from fainting.

After vaccination with FLUCELVAX, immunocompromised individuals, including those receiving immunosuppressive therapy, may have a reduced immune response.

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Office Visits

End Points	Study Results	Study Design	Key Limitations
	Favors egg-based influenza vaccines ◀ ▶ Favors FLUCELVAX QIV -30 -20 -10 0 10 20 30 40 50		
8% **fewer laboratory-confirmed Influenza A illnesses***[10] (rVE 8%; 95% CI -10, 23)		Retrospective cohort study of over **1 million persons** 4-64 years old in the US† (2017-2018)	• Low proportion of vaccinees received QIVc, limiting study power • Potential for bias if providers preferentially gave either vaccine to higher-risk individuals
40% **fewer laboratory-confirmed Influenza B illnesses***[10] (rVE 39.6%; 95% CI 27.9, 49.3)		Retrospective cohort study of **888,233 persons** 4-64 years old in the US† (2017-2018)	• Low proportion of vaccinees received QIVc, limiting study power • Potential for bias if providers preferentially gave either vaccine to higher-risk individuals
No difference in the relative VE for laboratory-confirmed influenza[11] (rVE 0%; 95% CI -30, 20)‡[11]		Test-negative case-control study of **1508 DoD healthcare beneficiaries** ≥6 months old in the US† (2017-2018)	• Due to a limited supply of vaccine, the DoD asked persons ≥9 years to receive QIVc • Results did not account for comorbidities and health status
36% **fewer influenza-like illnesses within a primary care setting**[12] (rVE 36.2%; 95% CI 26.1, 44.9)		Retrospective cohort study of **over 1.3 million persons** ≥4 years in the US (2017-2018)	• Results were not adjusted by unmeasurable confounders • Inability to reliably estimate absolute influenza VE from the ambulatory EMR dataset

Medical Encounters

End Points	Study Results	Study Design	Key Limitations
	Favors egg-based influenza vaccines ◀ ▶ Favors FLUCELVAX QIV -30 -20 -10 0 10 20 30 40 50		
8% **fewer influenza-related medical encounters**[13] (rVE 7.6%; 95% CI 6.5, 8.6)		Retrospective cohort study of **over 10.1 million** persons ≥4 years in the US (2018-2019)	• Analyses did not specifically adjust for frailty • Unmeasured confounding is a potential source of bias
12% **fewer influenza-related medical encounters**[14] (rVE 12.2%; 95% CI 7.5, 16.6)		Retrospective cohort study of **over 1.3 million children and adolescents** 4-17 years old in the US (2019-2020)	• Lack of laboratory confirmation * Findings may not be representative of uninsured populations

These RWE studies found that FLUCELVAX QUADRIVALENT was generally more effective than traditional, egg-based flu vaccines.[2-14]

US FLU SEASON WITH EGG-ADAPTED STRAIN MISMATCH

*These results are from the same study. The rVE for influenza A compared QIVc to both TIVe and QIVe and the rVE for influenza B compared QIVc to TIVe only.
†There was also an unvaccinated arm in this study.
‡rVE calculated as (1-adjusted odds ratio) x 100.
The data being shown is not inclusive of all peer-reviewed RWE studies, which include different outcomes and age groups.

CI=confidence interval; DoD=Department of Defense; EMR=electronic medical records; QIVc=cell-based, quadrivalent influenza vaccine; QIVe=egg-based, quadrivalent influenza vaccine; rVE=relative vaccine effectiveness; TIVe=egg-based, trivalent influenza vaccine; VE=vaccine effectiveness

WARNINGS AND PRECAUTIONS (continued)

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

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FLUCELVAX®
Influenza Vaccine

ADVANCING FLU VACCINE TECHNOLOGY WITH

THE CELL-BASED SOLUTION

The only influenza vaccine available in the US for all eligible patients 6 months and older that:

Provides an exact antigenic match to WHO-selected flu strains[1,15,21-23]

Avoids the impact of strain mismatch due to egg adaptation[15]

Tends to reduce the risk of flu-related outcomes vs traditional, egg-based vaccines in the real world*†[2-14]

WHO=World Health Organization
*2017-2018 through 2019-2020 US influenza seasons.
†The data of FLUCELVAX QUADRIVALENT are relevant to FLUCELVAX, as both vaccines are manufactured using the same process and have overlapping compositions.

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Syncope (fainting) has been reported following vaccination with FLUCELVAX. Procedures should be in place to avoid injury from fainting.

After vaccination with FLUCELVAX, immunocompromised individuals, including those receiving immunosuppressive therapy, may have a reduced immune response.

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

ADVERSE REACTIONS

Data for FLUCELVAX QUADRIVALENT are relevant to FLUCELVAX because both vaccines are manufactured using the same process and have overlapping compositions.

In children 6 months through 3 years of age who received FLUCELVAX QUADRIVALENT, the most commonly reported injection-site adverse reactions were tenderness (28%), erythema (26%), induration (17%) and ecchymosis (11%). The most common systemic adverse reactions were irritability (28%), sleepiness (27%), diarrhea (18%) and change of eating habits (17%).

In children 4 through 8 years of age who received FLUCELVAX, the most commonly reported local injection-site adverse reactions were pain (29%) and erythema (11%). The most common systemic adverse reaction was fatigue (10%).

In children and adolescents 9 through 17 years of age who received FLUCELVAX, the most commonly reported injection-site adverse reactions were pain (34%) and erythema (14%). The most common systemic adverse reactions were myalgia (15%) and headache (14%).

In adults 18 through 64 years of age who received FLUCELVAX, the most commonly reported injection-site adverse reactions were pain (28%) and erythema (13%). The most common systemic adverse reactions were headache (16%), fatigue (12%), myalgia (11%) and malaise (10%).

In adults ≥65 years who received FLUCELVAX the most commonly reported injection-site reaction was erythema (10%). The most common systemic adverse reactions were fatigue (11%), headache (10%) and malaise (10%).

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 or www.vaers.hhs.gov.

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

REFERENCES: 1. FLUCELVAX. Package insert. Seqirus Inc. **2.** Bruxvoort KJ, et al. *Vaccine*. 2019;37(39):5807-5811. **3.** Divino V, et al. *Vaccine*. 2020;38(40):6334-6343. **4.** Izurieta HS, et al. *J Infect Dis*. 2019;220(8):1255-1264. **5.** Izurieta HS, et al. *J Infect Dis*. 2020;222(2):278-287. **6.** Krishnarajah G, et al. *Vaccines (Basel)*. 2021;9(2):80. **7.** Izurieta HS, et al. *Clin Infect Dis*. 2020;19:ciaa1727. **8.** Divino V, et al. *Open Forum Infect Dis*. 2021;9(1):ofab604. **9.** Imran M, et al. *Open Forum Infect Dis*. 2022;9(10):ofac532. **10.** Klein NP, et al. *PLoS ONE*. 2020;15(2):e0229279. **11.** DeMarcus L, et al. *Vaccine*. 2019;37(30):4015-4021. **12.** Boikos C, et al. *Clin Infect Dis*. 2020;ciaa371. **13.** Boikos C, et al. *Clin Infect Dis*. 2021;ciaa1944. **14.** Imran M, et al. *Pediatr Infect Dis J*. 2022;41(9):769-774. **15.** Rajaram S, et al. *Ther Adv Vaccines Immunother*. 2020;8:2515135520908121. **16.** Nolan T, et al. *N Engl J Med*. 2021;385(16):1485-1495. **17.** Essink BJ, et al. *Pediatrics*. 2022;150(5):e2022057509. **18.** Katkade VB, et al. *J Multidiscip Healthc*. 2018;11:295-304. **19.** Frieden TR. *N Engl J Med*. 2017;377(5):465-475. **20.** US Food and Drug Administration. Real-world evidence. Accessed March 13, 2024. https://www.fda.gov/science-research/science-and-research-special-topics/realworld-evidence **21.** Rockman S, et al. *Vaccines (Basel)*. 2022;11(1):52. **22.** CDC. Cell-based flu vaccines. Accessed March 1, 2024. https://www.cdc.gov/flu/prevent/cell-based.htm **23.** Data on file. Seqirus Inc; 2024.

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