CSL Seqirus

Product Brief for Maine Vaccine Board 2026

FLUCELVAX® is the only influenza vaccine in the United States produced using cell-culture technology. It is FDA-approved for individuals 6 months of age and older[1], allowing use across a broad patient population. Because it is manufactured without eggs, this technology leads to a close match to seasonal influenza strains recommended by the World Health Organization (WHO) and the U.S. Food and Drug Administration (FDA).[2]
More than 323 million doses of Flucelvax® have been distributed worldwide. The vaccine has a well-established safety profile and is supplied as a preservative-free 0.5 mL prefilled syringe, stored under standard refrigeration.

Clinical Efficacy[1]

Flucelvax® demonstrated **83.8% efficacy** against laboratory-confirmed antigenically-matched strains of influenza in a randomized, blinded, placebo-controlled Phase III trial conducted during the 2007–2008 influenza season in the United States, Finland, and Poland. The study enrolled adults aged 18–50 years.
Subsequent randomized clinical trials have confirmed the safety, efficacy, and immunogenicity of Flucelvax® in children, supporting extension of its licensure down to 6 months of age. The safety profile is consistent with other standard-dose influenza vaccines, with side effects including injection site pain and tenderness (see references in footnotes).

Real-World Evidence: Cell-Based vs Egg-Based Influenza Vaccines in Recent Seasons[3-5]

Multiple observational studies conducted during the 2017–2018 through 2023–2024 U.S. influenza seasons evaluated the effectiveness of the cell-based influenza vaccine compared with standard egg-based vaccines. These retrospective, test-negative studies included over 240,000 vaccinated individuals seeking outpatient care for influenza-like illness (see figure).

- Across all evaluated seasons, fewer test-confirmed influenza cases were observed among recipients of the cell-based vaccine.
- Cell-based vaccines showed 8-20% higher effectiveness (rVE = relative vaccine effectiveness) than standard egg-based vaccines.
- This benefit was consistent across age groups, risk categories, and care settings, and was confirmed by sensitivity analyses.

A modeling analysis estimated that replacing standard egg-based vaccines with the cell-based influenza vaccine among individuals aged 6 months to 64 years during the 2023–2024 U.S. season could have prevented approximately 14,930 influenza related hospitalizations.[5]

Season	Age	Cases	Controls	Adjusted rVE (95% CI)
2017-18	4 – 64y	9,116	22,708	14.8% (7.0 – 22.0)
2018-19	4 – 64y	10,003	23,385	12.5% (4.7 – 19.6)
2019-20	4 – 64y	10,966	23,432	10.0% (2.7 – 16.7)
Down to 6m age indication				
2022-23	6m – 64y	7,423	35,663	7.7% (0.9–13.9)
2023-24	6m – 64y	16,678	90,101	19.8% (15.7 – 23.8)

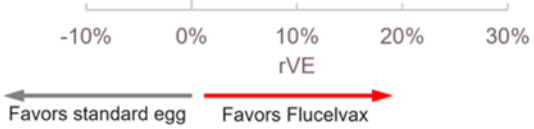

Figure- Summary of recent studies[3-5] comparing effectiveness of egg-based and cell-based vaccines for the prevention of test-confirmed influenza in an outpatient setting. Results show statistically significant benefit of FLUCELVAX® compared to standard egg-based vaccine in every season. Abbreviations: rVE; relative vaccine effectiveness; CI, confidence interval; m, months; y, years. Potential limitations include: retrospective, nonrandomized, claims design with potential residual confounding, exposure misclassification, selection bias, and incomplete capture of strain-specific or severe outcomes. Commercial, US outpatient, test-seeking population, potentially limiting generalizability to uninsured or publicly insured patients, non–healthcare–seeking individuals, and non-US settings

Summary

Flucelvax® is the only FDA-approved cell-based influenza vaccine and is indicated for individuals 6 months of age and older. Clinical trials and real-world studies demonstrate strong efficacy, a favorable safety profile, and consistent effectiveness advantages over standard egg-based influenza vaccines in adults and children.

For additional information, please see the sources below, the full FLUCELVAX US Prescribing Information, and the CSL Seqirus flu360 website.

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.

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.
Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of FLUCELVAX.
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. Seqirus USA Inc. Flucelvax. Package insert. 2025
2. Rockman S, et al. Cell-Based Manufacturing Technology Increases Antigenic Match of Influenza Vaccine and Results in Improved Effectiveness. Vaccines (Basel). 2022 Dec 26;11(1):52. doi: 10.3390/vaccines11010052.
3. Stein AN, MIlls, CW, McGovern I, et al. Relative vaccine effectiveness of cell- vs egg-based quadrivalent influenza vaccine against test-confirmed influenza over 3 seasons between 2017 and 2020 in the United States. Open Forum Infect Dis. 2024;11(5). doi:10.1093/ofid/ofae175.
4. Stein AN, Thanataveerat A, McDermott KW, et al. Relative vaccine effectiveness of cell-based versus egg-based quadrivalent influenza vaccines against test-confirmed influenza in the United States 2022-23 influenza season. Open Forum Infect Dis. 2025;12(1). doi:10.1093/ofid/ofae631.824.
5. Stein AN, Thanataveerat A, McDermott KW, et al. Superior effectiveness and estimated public health impact of cell- versus egg-based influenza vaccines in children and adults during the US 2023-2024 season. Infect Dis Ther. 2025;14:2693-2718. doi:10.1007/s40121-025-01230-2.