

FLUCELVAX® (Influenza Vaccine)



FLUCELVAX is approved for persons 6 months and older and recommended by ACIP and AAP.^{1,2,3}



Proven Efficacy and Safety in Clinical Trials:

- FLUCELVAX has proven efficacy in both children and adults¹
- FLUCELVAX has a demonstrated safety profile similar to standard egg-based flu vaccines in both children and adults¹



Robust Real-World Evidence (RWE):

- FLUCELVAX is associated with greater protection compared to standard egg-based flu vaccines.^{4,5,6,7*}
- FLUCELVAX has the most RWE in both children and adults showing a clinical benefit over standard egg-based flu vaccines.^{8†}
- FLUCELVAX is the only flu vaccine that has demonstrated greater reductions in flu and flu-related hospitalizations compared to standard egg-based flu vaccines in both children and adults.^{5,6,7}



Closer Match to Circulating Strains:

Cell-grown viruses were shown to be consistently more similar to circulating strains than standard egg-grown viruses.^{9,10§}



Only Cell-Based Flu Vaccine:

FLUCELVAX is made with advanced technology to avoid mutations during production that can reduce vaccine effectiveness.^{11,12,13}



Reimbursement:

FLUCELVAX has a different CPT code (90661) and different reimbursement.¹⁴

*The primary outcomes reported in these studies contain information not included in the Prescribing Information. The data of FLUCELVAX (quadrivalent) are relevant to FLUCELVAX (trivalent) because both vaccines are manufactured using the same process and have overlapping compositions. This is not inclusive of all RWE studies, which include different outcomes and age groups.

†Based on a PubMed search conducted 3/17/25 for published English-language RWE studies that included relative vaccine effectiveness vs a standard flu vaccine comparator.

§Based on CDC antigenic characterization of the percentage of circulating A/H3N2 flu viruses that were similar to egg- or cell-grown reference viruses across the 2012-2013 through 2019- 2020 US influenza seasons.

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 the full Important Safety Information on the back of this page and the accompanying full US Prescribing Information for FLUCELVAX.

FLUCELVAX® (Influenza Vaccine)

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATIONS 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. FLUCELVAX. Package insert. Seqirus Inc. 2. Grohskopf M, et al. MMWR Recomm Rep. 2024;73(5):1-25. 3. Committee on Infectious Diseases. Pediatrics. 2024;154(4):e2024068507. 4. Stein A, et al. Oral presentation presented at: OPTIONS XII Conference; October 1, 2024. 5. Divino V, et al. Vaccine. 2020;38(40):6334-6343. 6. Krishnarajah G, et al. Vaccines (Basel). 2021;9(2):80. 7. Divino V, et al. Open Forum Infect Dis. 2021;9(1):ofab604. 8. Data on file. Seqirus Inc; 2025. 9. Malosh RE, et al. Clin Infect Dis. 2023;76(3):540-549. 10. Rockman S, et al. Vaccines (Basel). 2022;11(1):52. 11. Rockman S, et al. Vaccines (Basel). 2022;11(1):52. 12. Rajaram S, et al. Ther Adv Vaccines Immunother. 2020;8:2515135520908121. 13. CDC. Cellbased flu vaccines. Accessed March 26, 2025. <https://www.cdc.gov/flu/vaccine-types/cell-based.html>