



Flucelvax® Quadrivalent (influenza vaccine) – Expanded indication

- On October 14, 2021, the [FDA approved](#) Seqirus' [Flucelvax Quadrivalent \(influenza vaccine\)](#), for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and types B contained in the vaccine. Flucelvax Quadrivalent is approved for use in persons 6 months of age and older.
 - Flucelvax Quadrivalent was previously approved for use in persons 2 years of age and older.
- Flucelvax Quadrivalent is a cell-based influenza vaccine.
- The approval of Flucelvax Quadrivalent for the expanded indication was based on immunogenicity data from a randomized, observer-blind study in 2,402 children 6 months through 3 years of age. Patients received Flucelvax Quadrivalent or a U.S.-licensed comparator quadrivalent influenza vaccine. The immunogenicity endpoints were geometric mean antibody titers (GMTs) and percentage of subjects who achieved seroconversion.
 - Flucelvax Quadrivalent was noninferior to the comparator quadrivalent influenza vaccine. Noninferiority was established for all 4 influenza strains as assessed by ratios of GMTs and the differences in the percentages of patients achieving seroconversion at 4 weeks following vaccination.
- In children 6 months through 3 years of age who received Flucelvax Quadrivalent, the most commonly reported injection-site adverse reactions were tenderness, erythema, induration, and ecchymosis. The most common systemic adverse reactions were irritability, sleepiness, diarrhea, and change of eating habits.
- In patients 6 months through 8 years of age, one or two doses of Flucelvax Quadrivalent (0.5 mL each) should be administered intramuscularly. One or two doses depends on vaccination history as per Advisory Committee on Immunization Practices annual recommendations on prevention and control of influenza with vaccines. If 2 doses are required, they should be administered at least 4 weeks apart.
 - Refer to the Flucelvax Quadrivalent label for the dosing schedule in patients 9 years of age and older.



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