

Afluria[®] Quadrivalent (influenza vaccine) – Expanded indication

- On August 31, 2017, the <u>FDA approved</u> Seqirus' <u>Afluria Quadrivalent (influenza vaccine)</u> for active immunization against influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine in persons 5 years of age and older.
 - Previously, Afluria Quadrivalent was approved for persons 18 years of age and older.
- The efficacy of the expanded indication for Afluria Quadrivalent was demonstrated in a study of 2,278 children ages 5 – 17 years. Patients received one or two doses of Afluria Quadrivalent or a U.S.-licensed comparator quadrivalent influenza vaccine. The primary objective was to demonstrate that vaccination with Afluria Quadrivalent elicits an immune response that is not inferior to that of a comparator vaccine.
 - Immune responses to Afluria Quadrivalent were non-inferior to the comparator vaccine for all influenza strains.
- The recommended dosage of Afluria Quadrivalent is 1 or 2 doses at least one month apart for ages 5 8 years and 1 dose for ages 9 years and older by intramuscular injection.
 - Administration by needle and syringe is for 5 years of age and older.
 - Administration by the PharmaJet[®] Stratis[®] Needle-Free Injection System is for ages 18 through 64 years.
 - The preferred site for intramuscular injection is the deltoid muscle of the upper arm.



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