

1. Introduction

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1.1. Overview

Aviron (Mountain View, California) has developed FluMist™, a live, attenuated intranasal influenza vaccine, for the prevention of influenza in healthy children and healthy adults. FluMist is the product of six years of development by Aviron and over 25 years of study of cold-adapted influenza virus (CAIV) vaccines by the National Institutes of Health and others.

Influenza is a highly infectious illness that can cause disease in all age groups. Annual influenza epidemics in the US typically affect 10 to 20 percent of the general population. Influenza is particularly infectious in young children. Children suffer high influenza attack rates, increased rates of medically attended illness and are thought to be an important vector in the spread of influenza, yet do not generally receive influenza vaccine. FluMist provides an opportunity to increase vaccine coverage and prevent illness in currently unvaccinated segments of the population because of the appealing delivery system.

Clinically, FluMist has a compelling record of safety and efficacy with nearly 25,000 participants receiving the vaccine in 25 clinical trials:

- FluMist has demonstrated efficacy and effectiveness against influenza in healthy children and significant protection from influenza-associated disease including lower respiratory illness and otitis media.
- FluMist has demonstrated efficacy and effectiveness against influenza in healthy adults.
- FluMist is safe and well-tolerated.

1.2. Product Information

FluMist is an intranasal vaccine for active immunization for the prevention of influenza. FluMist contains three strains of live, attenuated, cold-adapted, temperature-sensitive influenza virus: two Type A (H1N1 and H3N2) and one Type B. Each 0.5 mL dose contains approximately 10^7 TCID₅₀ (median tissue culture infectious dose) of each of the influenza virus strains recommended by the US Public Health Service and selected by the Food and Drug Administration for the influenza season.

FluMist is prepared by growing the attenuated, cold-adapted, and temperature-sensitive virus strains containing the recommended hemagglutinin (HA) and neuraminidase (NA) proteins in specific pathogen-free chicken eggs. The virus is harvested from egg allantoic fluid, clarified by

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centrifugation, and stabilized with sucrose, potassium phosphate and monosodium glutamate. The virus harvests for each strain are then blended, diluted to strength, filled into individual nasal sprayers, labeled, and stored frozen.

Gentamicin sulfate is added early in the manufacturing process, but is not detectable in the final product using current assay methods. This product does not contain thimerosal or other preservative.

Each pre-filled FluMist sprayer contains a 0.5mL single dose; 0.25 mL of FluMist is delivered as a fine mist to each nostril. When thawed for administration, FluMist is colorless to pale yellow and is clear to slightly cloudy. FluMist is intended for nasal administration only and is not for injection.

Annual vaccination with FluMist is recommended to maximize protection against the epidemic influenza strains. FluMist should be administered according to the following schedule:

Age Group	Dosage Schedule
12 months through 8 years	0.5 mL (1 or 2 doses)*
9 through 17 years	0.5 mL (1 dose)
18 through 64 years	0.5 mL (1 dose)

* Two doses of FluMist administered at least one month apart are recommended for children under 9 years of age who have not previously received influenza vaccination. The two-dose regimen is recommended for maximum protection.