About FluMist® (Influenza Virus Vaccine Live, Intranasal)

First Line of Defense Against Influenza

In 2003, FluMist was approved by the U.S. Food and Drug Administration (FDA) for active immunization for the prevention of disease caused by influenza A and B viruses in healthy children and adolescents, 5 to 17 years of age, and healthy adults, 18 to 49 years of age.[1] For the 2004-2005 influenza season, the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices' (ACIP) recommendations encouraged the use of FluMist in healthy, non-pregnant people 5 to 49 years of age, including out-of-home caregivers and household contacts of persons in high-risk groups, and most health care workers.[28]

The first innovation in influenza vaccine technology in more than 50 years, FluMist is administered as a fine mist where influenza virus usually enters the body – the nose.[2] As an attenuated, or weakened, live virus vaccine, FluMist is designed to work in the nasal passages, stimulating the natural defense pathways for influenza and providing an immune response that closely resembles the body's response to natural infection, without causing disease. Other attenuated live virus vaccines have been highly successful in the prevention of diseases such as measles, mumps, rubella and chickenpox.

The Problem of Vaccine Mismatch

FluMist has demonstrated protection against both matched and mismatched strains of influenza in clinical trials. Vaccine mismatch is a potentially serious problem. Because strains for the annual influenza vaccines are chosen by world public health organizations well in advance of the influenza season, the strains contained in the vaccine often do not match those circulating in the community. New, unpredictable strains can emerge during influenza season as circulating strains of influenza evolve and mutate. If these new variant strains are significantly different, the vaccine strains may not match the circulating influenza strains. This is known as a **vaccine mismatch**.

Vaccine mismatch is common: It has occurred in four of the last eight influenza seasons (1997-1998, 2000-2001, 2003-2004, and 2004-2005).[31]

FluMist has been studied in more than 29,000 children and adults.[1] In placebo-controlled clinical trials, FluMist demonstrated the following:

- **In healthy children:**[1]
  - **87 percent** efficacy (95 percent CI: 59, 98) against culture-confirmed influenza in healthy children (study year 1) 60 to 71 months of age (FluMist recipients n=163, total participants N=238)
  - **87 percent** efficacy (95 percent CI: 71, 94) against culture-confirmed influenza in healthy children (study year 2) 60 to 84 months of age (FluMist recipients n=375, total participants N=544)

- **In healthy adults:**[1]
  - **20 percent** reduction (95 percent CI: 3, 33) in severe febrile illness and **24 percent** reduction (95 percent CI: 7, 38) in febrile upper respiratory illness in an effectiveness

study in adults 18 to 49 years of age (FluMist recipients n=2,411, total participants N=3,637)
- **18 percent** reduction (95 percent CI: 2, 31) in days of health care provider visits associated with severe febrile illness and **37 percent** reduction (95 percent CI: 24, 47) in days of health care provider visits associated with febrile upper respiratory illness in an effectiveness study in adults 18 to 49 years of age
- **85 percent** protection (95 percent CI: 28, 100) against laboratory-documented influenza in a challenge study in healthy adults 18 to 41 years of age (FluMist recipients n=29, total participants N=60)

The safety of FluMist was evaluated during randomized, placebo-controlled clinical trials in approximately 7,500 healthy children and adults between 5 and 49 years of age.[1] **Since then, more than two million doses of FluMist have been distributed during the past two influenza seasons (2003-2004 and 2004-2005).**

In placebo-controlled clinical trials, the most common solicited adverse events in the indicated population (n=2,762) included runny nose/nasal congestion, headache, cough, sore throat, tiredness/weakness, irritability, decreased activity and muscle aches.[1]

Safety Information
FluMist is approved for the prevention of influenza in healthy children, adolescents, and adults, 5 to 49 years of age. There are risks associated with all vaccines, including FluMist. Like any vaccine, FluMist does not protect 100 percent of individuals vaccinated, and may not protect against viral strains not contained in the vaccine. In studies of people between the ages of 5 and 49, side effects were generally mild and temporary. Runny nose was the most common. Other common side effects included various cold-like symptoms, such as headache, cough, sore throat, tiredness/weakness, irritability, and muscle aches.

FluMist should not be used, under any circumstances, in anyone with an allergy to any part of the vaccine, including eggs; in children and adolescents receiving aspirin therapy; in people who have a history of Guillain-Barré syndrome; and in people with known or suspected immune system problems. Pregnant women and people with certain medical conditions, asthma, or reactive airways disease should not get FluMist.

Please see the Prescribing Information, visit flumist.com, or call 1-877-633-4411 for additional information.