fluMist®
Influenza Virus Vaccine
Live, Intranasal

About Vaccines and Prevention

How Vaccines Work

The principle behind vaccination is that the patient's immune system is better prepared to deal with a particular infection after successfully overcoming an initial exposure to something resembling the pathogen. Vaccination is designed to stimulate the immune system so that the first natural exposure to a disease-causing organism takes place in the presence of heightened immunity.[4] And generally, the more closely the initial exposure resembles actual infection, the better protection the vaccine will provide.

The History of Inactivated and Attenuated Live Virus Vaccines

Several approaches have been taken for vaccine development. Inactivated, or "killed," viruses have been used to formulate many vaccines such as hepatitis A, rabies and influenza. Attenuated, or weakened, virus vaccine technology has been used successfully in disease prevention and eradication since the 1870s.[5] Today, attenuated virus vaccines are used for measles, mumps, rubella, rabies, chickenpox and now influenza.[4]

FluMist® (Influenza Virus Vaccine Live, Intranasal) At A Glance

In 2003, the U.S. Food and Drug Administration (FDA) approved FluMist as the first live, attenuated influenza vaccine to be available in the United States 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] As an attenuated live virus vaccine, FluMist is designed to stimulate an immune response that closely resembles the body's response to natural infection, without causing disease. The vaccine works in the nasal passages, which represent the body's first line of defense against influenza.

Like other routine attenuated live virus vaccines, FluMist has been shown to be safe and effective in several large trials. In children 5 years of age and older, the most commonly seen adverse events were mild upper respiratory symptoms, and there were no statistically significant differences in adverse events between FluMist and placebo. In adults, the most common adverse events were mild upper respiratory symptoms.[1]

FluMist and the traditional influenza shot contain the same three influenza strains recommended annually by the U.S. Public Health Service; however, these two categories of vaccine differ in both their designs and in their routes of administration.

The unique properties of FluMist include the following:

- **Attenuated:** Using a weakened form of the influenza virus, 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. The traditional influenza shot, a trivalent inactivated influenza vaccine (TIV), uses an inactivated influenza virus to stimulate immunity.[1]

- **Cold-adapted:** FluMist replicates efficiently only in the nose's cooler temperatures, which helps induce protective immunity.[1]

- **Temperature-sensitive:** FluMist is designed to limit the replication of the vaccine virus at 37°C to 39°C, restricting replication in the warmer temperatures of the lower airways or lungs where natural, wild-type influenza viruses most often replicate.[1, 6]

- **Administered intranasally:** FluMist is sprayed into the nose where infection with wild-type influenza usually starts. TIV is administered intramuscularly by injection, typically in the arm.

FluMist has demonstrated protection against both matched and mismatched strains of influenza. 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]

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.