



Frequently Asked Questions

1. What is FluMist® (Influenza Virus Vaccine Live, Intranasal)?

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.

2. Who should and should not be vaccinated with FluMist?

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

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.

3. Why did the FDA approve FluMist only for use in healthy populations 5 to 49 years of age?

The FDA approved FluMist for use in healthy children, adolescents and adults 5 to 49 years of age based on clinical trials that evaluated the safety and efficacy of FluMist within these patient populations.¹ Additional clinical trials in other populations are being conducted.

4. Why should healthy people be vaccinated against influenza?

It is important to remember that healthy people – 5 to 49 years of age – are at risk of influenza exposure. Among other groups, this population includes school-aged children, people in large families, adults in frequent contact with other adults (including working adults and college students) and adults in frequent contact with school-aged children (including family members and teachers/childcare providers).

Anyone can catch influenza. Surprisingly, however, school-aged children are rarely vaccinated against influenza in spite of ranking among the most at risk for infection during influenza season.²² In fact, healthy children are two to three times more likely to get influenza⁷ and typically remain infectious for a longer period of time than healthy adults, making them more likely to be “flu

transmitters” who spread the virus to classmates, playmates, siblings, parents, grandparents and others around them.^{12, 19}

5. Can you develop influenza from FluMist?

FluMist does not cause influenza-like illness. In randomized, placebo-controlled clinical trials of approximately 7,500 healthy children and adults between 5 and 49 years of age, there was no significant increase in influenza-like illness as defined by the U.S. Centers for Disease Control and Prevention (CDC) in the FluMist group compared to the placebo group.¹ Additionally, with at least five attenuating genetic points in each strain, the odds of reversion to wild-type influenza are one in 100 quintillion replication cycles.

6. What is an attenuated virus vaccine? Are attenuated vaccines safe?

An attenuated virus vaccine contains vaccine strains that are intentionally attenuated, or weakened, so as not to produce illness. Attenuated live virus vaccines have been effectively produced and used for years in the prevention of diseases such as measles, mumps, rubella and chickenpox. FluMist’s safety profile is partly a result of the fact that it is engineered to be temperature-sensitive, which means that it does not replicate efficiently in the warmer temperatures of the lower airways or lungs where natural, wild-type influenza viruses most often replicate.¹

7. Does FluMist contain thimerosal?

No, FluMist does not contain thimerosal or any other preservative.

8. What is vaccine mismatch?

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 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

9. Has FluMist protected against mismatched strains?

FluMist has demonstrated protection against both matched and mismatched strains of influenza. In published clinical trial results, vaccination with FluMist was shown to be highly effective against the mismatched variant A/Sydney (H3N2) in the 1997-1998 influenza season when tested in both children and adults. For example, in the two-year pivotal clinical trial of children 60 to 84 months of age, the overall efficacy of FluMist against culture-confirmed wild-type influenza, regardless of antigenic match, was 87 percent for each year.¹ FluMist also demonstrated protection against mismatched A/H1N1 and B strains during the 2000-01 influenza season in a large community study.³²

10. To what extent has FluMist been studied?

FluMist has been studied in more than 29,000 children and adults in clinical trials (with more studies currently in progress). The population evaluated included 10,297 healthy children, 5 to 17 years of age, and 3,297 healthy adults, 18 to 49 years of age, who received at least one dose of vaccine.¹

In addition to the large clinical trials, FluMist has substantial “real-world” use with more than two million doses distributed to healthy children and adults during the last two influenza seasons (2003-2004 and 2004-2005).

11. What safety data exists for FluMist?

The safety of FluMist was evaluated during clinical trials in approximately 7,500 healthy children and adults between 5 and 49 years of age.¹ 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

Overall, 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

12. Is FluMist included as part of the Vaccines for Children (VFC) program?

Yes, FluMist is included in the VFC program for the first time starting during the 2005-2006 influenza season and should continue into the future.

13. How much does FluMist cost?

The wholesale price of FluMist for the 2005-2006 influenza season ranges from \$18.95 to \$24.50 depending on whether returnable or non-returnable vaccine is purchased. Doctors’ offices and pharmacies will set the retail price for consumers; therefore MedImmune cannot anticipate what consumers might pay for the vaccine this influenza season.

14. Why has the price of FluMist increased for the 2005-2006 influenza season?

The new price of FluMist is based on several factors, including the escalating cost of maintaining current good manufacturing practices (CGMP’s) and MedImmune’s costs for development and production of the vaccine. FluMist is the first advancement in influenza prevention in more than 50 years and MedImmune has spent more than one billion dollars to bring FluMist to market.

15. How does influenza spread?

Influenza spreads from one person to another when an infected person expels microscopic droplets when coughing, sneezing or even talking,³ and other individuals inhale the virus.² Once the influenza virus enters a person’s nose, it invades the lining of the throat, nasal passages and sometimes the lungs, and can quickly cause an infection.²

16. How does influenza differ from a cold?

Although often confused with the common cold, influenza is more severe and potentially poses a greater health risk.

Symptoms of influenza can include sudden onset of cold-like respiratory symptoms, such as runny nose, sneezing, coughing and sore throat;¹¹ however, influenza is typically marked by more intense symptoms, such as abrupt onset of fever, chills, severe fatigue, headache, muscle aches and profound weakness.^{3, 11} Although it may be rare, influenza can lead to potentially serious health complications, such as hospitalization for acute respiratory disease and death in otherwise healthy children and adults.¹⁶

17. When should people be vaccinated against influenza?

Although historically the inactivated vaccine has been prioritized for use in high-risk populations, FluMist can be given to healthy children and adults 5 to 49 years of age as soon as it becomes available, which is usually close to the month of September.

Because influenza season varies across the country, generally peaking between December and March, vaccinations still offer protection against influenza even if administered late in the season or after influenza activity has been documented in the community.⁶ Therefore, individuals can benefit from being vaccinated well into the winter months.

18. Where can people get more information about FluMist?

For general information about FluMist, visit flumist.com or contact FluMist customer service at 1-877-FLUMIST.