



Media Backgrounder: About FluMist®

FluMist® (Influenza Vaccine Live, Intranasal) is the only nasal spray influenza vaccine available in the United States to help prevent seasonal influenza. It is approved by the U.S. Food and Drug Administration (FDA) for eligible individuals two to 49 years of age.*¹ See page 3 for Importation Safety and Eligibility Information.

FluMist is a gentle mist sprayed into the nose, where the influenza virus usually enters the body. It is administered while breathing normally and does not need to be actively “inhaled.”

FluMist Quick Facts

- Nasal spray administration¹
 - Needle- and preservative-free¹
 - Available for eligible children as young as two years of age*.¹
 - Approximately 18 million doses distributed since its FDA approval in 2003⁷
 - FluMist has been widely used by the U.S. military and in school-based seasonal influenza vaccination programs, as well as by private practice physicians, group health care providers, and the federal Vaccines for Children (VFC) program⁷
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The influenza virus strains in seasonal FluMist are the same as those contained in the “flu shot” and are determined each season by the FDA based on recommendations from the World Health Organization (WHO).

FluMist uses live vaccine virus strains that are weakened so as not to cause the flu.² One does not get a case of “the flu” when vaccinated with either FluMist or the injectable influenza vaccine.²

FluMist helps protect against seasonal flu, but not the novel A/H1N1 strain (also known as “swine flu”).³ Flu vaccines to help protect against the novel A/H1N1 are being developed and public health authorities will make recommendations on their potential use.⁴

FLUMIST MANUFACTURING AND AVAILABILITY

FluMist is manufactured using a proprietary process known as “reverse genetics,” a method by which viruses such as influenza can be generated from segments of DNA. The process improves efficiency at the front-end of the vaccine manufacturing process and allows FluMist to be made available as early as late summer.

This early availability of FluMist gives healthcare providers an expanded window of opportunity to vaccinate eligible individuals during routine annual medical check-ups. Data show that FluMist can help provide protection throughout the entire flu season, even when administered prior to the typical influenza vaccination season.⁵ In 2008, the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices expanded annual flu vaccination recommendations to include children between 5-18 years of age. Early administration of vaccine may be especially helpful in vaccinating these additional 30 million children.⁶

HELPS PROTECT CHILDREN AS YOUNG AS TWO AND ADULTS UP TO 49 YEARS OF AGE

To date, FluMist has been studied in more than 70 completed and ongoing clinical and post-marketing trials involving more than 141,000 children and adults.⁷

Key findings from clinical trials in children include:



Select Safety and Efficacy Information

- FluMist is not for children under 2 or children less than 5 years of age with recurrent wheezing
 - FluMist is not for people with asthma or active wheezing
 - See page 3 for Important Safety and Eligibility Information
 - Multiple trials have demonstrated efficacy of FluMist in children as young as two and adults 18 to 49 years of age^{1,7-10}
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- In a pivotal study that included more than 4,000 children between two and five years of age during the 2004-2005 influenza season, there was a 54 percent reduction in cases of flu in children who received FluMist compared with those who received the traditional flu shot (4.5 percent vs. 9.8 percent, respectively).

In the study, FluMist demonstrated a reduction in influenza rates compared to the inactivated vaccine against strains that were both matched and mismatched to the vaccine.^{*,**8}

- In a two-year, placebo-controlled clinical trial that included 1,300 children aged 24 to 71 months without high-risk medical conditions, FluMist demonstrated a 93 percent reduction in flu illness, regardless of strain, in year one of the study.^{**9}

Key findings from clinical trials in adults include:

- In a placebo-controlled clinical trial that included 3,600 adults 18 to 49 years of age without high-risk medical conditions, those who received FluMist experienced 20 percent fewer cases of severe febrile illness and 24 percent fewer cases of febrile upper respiratory illness.¹⁰
- In a clinical trial among adults 18 to 41 years of age without high-risk medical conditions who were challenged with (subjected to) wild-type influenza virus in a laboratory setting (n=60), vaccination with FluMist resulted in 85 percent fewer cases of influenza, compared to placebo.¹¹

PROTECTION AGAINST MATCHED AND MISMATCHED STRAINS OF FLU

- New, unpredicted strains of flu can emerge during flu season. If these new strains are different than those used in manufacturing of the season's flu vaccine, the vaccine strains may not match the circulating flu strains, potentially reducing efficacy.¹²
- According to CDC data, vaccine mismatch has occurred to varying degrees in six of the last 12 flu seasons, most recently during the 2007-2008 season.¹³
- In young children, FluMist has demonstrated that it could help offer protection against both matched and mismatched strains of the flu.⁸

Note: Since influenza strains change each year, past clinical trial results are not necessarily indicative of future results.

- In the pivotal study, among children two to five years of age, for matched flu strains,[†] there was a 52.5 percent reduction in cases of flu in those who received FluMist compared with those who received the flu shot (2.9 percent vs. 1.4 percent). For mismatched flu strains,[‡] there was a 54.2 percent reduction in cases of flu among children who received FluMist compared with children who received the flu shot (7.1 percent vs. 3.2 percent).^{*,8}



- During the second year (primarily mismatched strain)[§] of the two-year, placebo-controlled clinical study spanning the 1996-1998 seasons, there were 87 percent fewer cases of culture confirmed influenza in children two to six years of age who received FluMist¹⁴

IMPORTANT SAFETY AND ELIGIBILITY INFORMATION

Who may be eligible for FluMist?

FluMist is a vaccine approved for the prevention of certain types of influenza disease in children, adolescents and adults 2-49 years of age. FluMist may not protect everyone who gets it. FluMist is for intranasal administration only.

Who may not be able to get FluMist?

FluMist is not right for everyone. FluMist must not be given to: people with history of hypersensitivity to eggs, egg proteins, gentamicin, gelatin or arginine; people with life-threatening reactions to previous influenza vaccinations; and children and adolescents receiving aspirin or aspirin-containing therapy.

Children less than 24 months of age are not eligible for FluMist.

The following people may not be able to get FluMist or may be able to get it only in certain situations: people with asthma or active wheezing, or children less than 5 years of age with recurrent wheezing; people with a history of Guillain-Barré syndrome; people with a weakened immune system; people with long-term medical conditions including heart disease, kidney disease, and metabolic diseases, such as diabetes; and pregnant women.

If your child falls into one of these groups, **be sure to tell your healthcare provider**. They will decide if FluMist is right for your child.

What are the most common side effects of FluMist?

Most common side effects included runny nose or nasal congestion, sore throat, and fever. For a full list of side effects, please see section 6.1 in the following product information.

Please see the accompanying complete [product information](#).

For more information, please visit www.FluMist.com.

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* Do not administer FluMist to children <24 months of age due to an increased risk of hospitalization and wheezing that was observed in clinical trials.

** Data is representative of the indicated population; full study population is represented in the Prescribing Information.

† New Caledonia (H1N1), A/Wyoming (H3N2) and matched B/Yamagata lineage.

‡ A/California-like (H3N2) and mismatched B/Yamagata lineage and B/Victoria.

§ The primary circulating strain was A/Sydney (H3N2).



- 1 Prescribing Information for FluMist, Influenza Vaccine Live, Intranasal, MedImmune, LLC., Gaithersburg, Maryland.
- 2 Centers for Disease Control and Prevention (CDC). Fact Sheet: Misconceptions about Influenza and Influenza Vaccine. Available at <http://www.cdc.gov/flu/about/qa/misconceptions.htm>. Accessed August 3, 2009.
- 3 Centers for Disease Control and Prevention (CDC). Selecting the Viruses in the Influenza (Flu) Vaccine. Available at <http://www.cdc.gov/flu/professionals/vaccination/virusqa.htm>. Accessed August 5, 2009.
- 4 Centers for Disease Control and Prevention (CDC). Questions & Answers: Novel H1N1 Influenza Vaccine. Available at http://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm. Accessed August 14, 2009.
- 5 Tam JS, et al. Efficacy and safety of a live attenuated, cold-adapted influenza vaccine, trivalent against culture-confirmed influenza in young children in Asia. *Pediatr Infect Dis J*. 2007;26:619-628.
- 6 Centers for Disease Control and Prevention (CDC): Advisory Committee Recommends Influenza Vaccination for Children 6 months through 18 years of age. <http://www.cdc.gov/media/pressrel/2008/r080227.htm>. Accessed August 5, 2009.
- 7 Data on file at MedImmune.
- 8 Belshe R, et al. Live attenuated versus inactivated influenza vaccine in infants and young children. *N Engl J Med*. 2007;356:685-696.
- 9 Belshe R, et al. The efficacy of live attenuated, cold-adapted, trivalent, intranasal influenza virus vaccine in children. *N Engl J Med*. 1998;338:1405-1412.
- 10 Nichol K, et al. Effectiveness of live, attenuated, intranasal influenza virus vaccine in healthy, working adults. *JAMA*. 1999;282:137-144.
- 11 Treanor JJ, et al. Evaluation of trivalent, live, cold adapted (CAIV-T) and inactivated (TIV) influenza vaccines in prevention of virus infection and illness following challenge of adults with wild-type influenza A (H1N1), A (H3N2), and B viruses. *Vaccine*. 1999;18:899-906.
- 12 Centers for Disease Control and Prevention (CDC) Pink Book 2009. Chapter 10: Influenza, page 136.
- 13 Centers for Disease Control and Prevention (CDC). Flu Activity & Surveillance. Available at <http://www.cdc.gov/flu/weekly/fluactivity.htm>. Accessed August 5, 2009.
Flu Activity Summaries by year:
1997-98 <http://www.cdc.gov/mmwr/preview/mmwrhtml/00052002.htm>
2000-01 <http://www.cdc.gov/ncidod/diseases/flu/weeklyarchives2000-2001/00-01summary.htm>
2003-04 <http://www.cdc.gov/flu/weekly/weeklyarchives2003-2004/03-04summary.htm>
2004-05 <http://www.cdc.gov/flu/weekly/weeklyarchives2004-2005/04-05summary.htm>
2005-06 <http://www.cdc.gov/flu/weekly/weeklyarchives2005-2006/05-06summary.htm>
2006-07 <http://www.cdc.gov/flu/weekly/weeklyarchives2006-2007/06-07summary.htm>
2007-08 <http://www.cdc.gov/flu/weekly/weeklyarchives2007-2008/07-08summary.htm>
- 14 Belshe R, et al. Efficacy of vaccination with live attenuated, cold-adapted, trivalent, intranasal influenza virus vaccine against a variant (A/Sydney) not contained in the vaccine. *J Pediatr*. 2000;136:168-175.