

APPROVED FOR  
CHILDREN AS YOUNG  
AS 24 MONTHS

# ***FluMist<sup>®</sup> went head-to-head against the flu shot***

***with compelling results worth talking about***



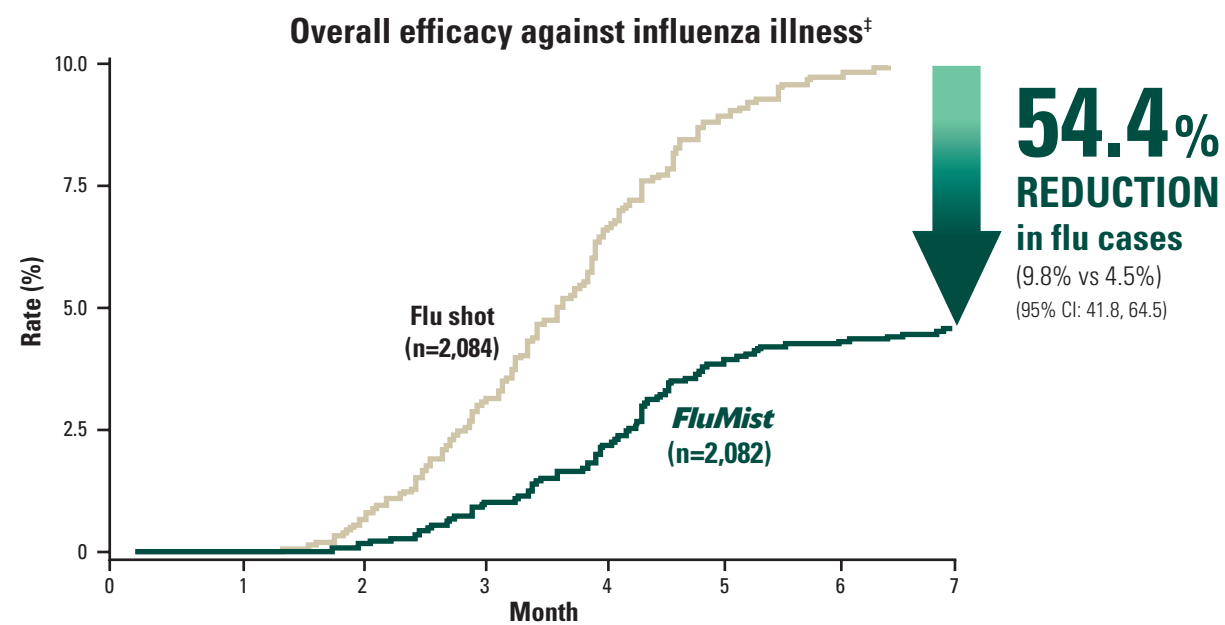
**FLUMIST<sup>®</sup>**  
*Influenza Virus Vaccine Live,  
Intranasal*

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.

In a head-to-head clinical study in children published in  
**THE NEW ENGLAND JOURNAL OF MEDICINE...**\*

## FluMist® demonstrated significant reductions in influenza vs the flu shot...<sup>1-3†</sup>

Comparative efficacy in children aged 24 months to 59 months  
during the 2004-2005 influenza season (N=4,166)<sup>1,3\*</sup>



Adapted from Belshe RB et al. *N Eng J Med*. 2007;356:685-696.

\*Data are representative of the indicated population (children aged 24 months to 59 months); full study population is represented in the Prescribing Information and *The New England Journal of Medicine*—February, 2007.

†Study Design: Randomized, double-blind, double-dummy comparison of the relative efficacy of FluMist and TIV intramuscular injection that included children 24 months to 59 months of age, with a 42-day and a 6-month follow-up for safety through the end of the influenza surveillance period for the 2004-2005 influenza season (N=4,166). Vaccine-naïve children in both groups received 2 doses. Comparative efficacy vs culture-confirmed modified CDC influenza-like illness due to matched and mismatched strains [ATP population].

‡The attack rates for FluMist vs the flu shot for all strains circulating during the 2004-2005 flu season were as follows: A/New Caledonia (H1N1) (0.0% vs 1.0%), A/Wyoming (H3N2) (0% vs 0%), A/California-like (H3N2) (1.2% vs 4.9%), matched B/Yamagata lineage (1.4% vs 1.9%, NS), and mismatched B/Yamagata lineage and B/Victoria (2.1% vs 2.3%, NS), respectively.

## Selected Safety Information

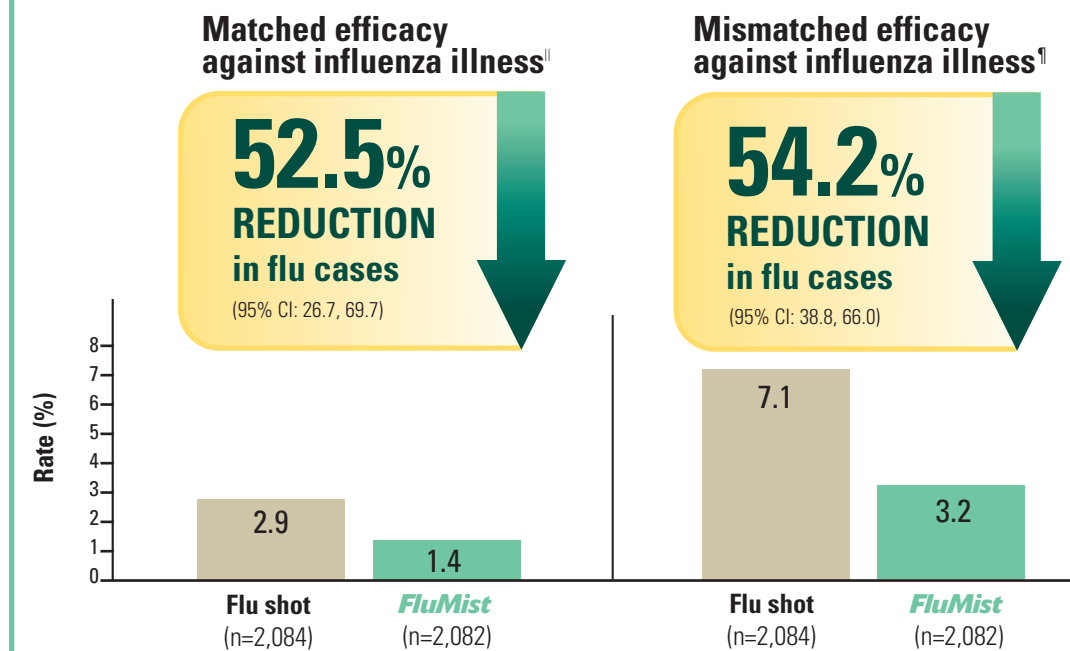
FluMist is a live attenuated influenza virus vaccine indicated for active immunization of individuals 2-49 years of age against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

Do not administer to children <24 months of age due to an increased risk of hospitalization and wheezing that was observed in clinical trials or to individuals with severe asthma or active wheezing.

FluMist should not be administered to any individuals with asthma and to children <5 years of age with recurrent wheezing because of the potential for increased risk of wheezing post vaccination.

## ...against matched and mismatched influenza strains<sup>2-3§</sup>

Comparative efficacy in children aged 24 months to 59 months  
during the 2004-2005 influenza season (N=4,166)<sup>2§</sup>



§Data are representative of the indicated population (children aged 24 months to 59 months); full study population is represented in the Prescribing Information and *The New England Journal of Medicine*—February, 2007.

¶The attack rates for FluMist vs the flu shot for all matched strains circulating during the 2004-2005 flu season were as follows: A/New Caledonia (H1N1) (0.0% vs 1.0%), A/Wyoming (H3N2) (0% vs 0%), and matched B/Yamagata lineage (1.4% vs 1.9%, NS), respectively.

¶The attack rates for FluMist vs the flu shot for all mismatched strains circulating during the 2004-2005 flu season were as follows: A/California-like (H3N2) (1.2% vs 4.9%), and mismatched B/Yamagata lineage and B/Victoria (2.1% vs 2.3%, NS), respectively.

• Note: since influenza strains change each year, past clinical trial results are not indicative of future results

**VACCINE MISMATCH**  
occurred in 5 of the last 11 influenza seasons<sup>4,5</sup>

**Please see Important Safety Information for FluMist on page 12.**

**FLUMIST®**  
Influenza Virus Vaccine Live,  
Intranasal

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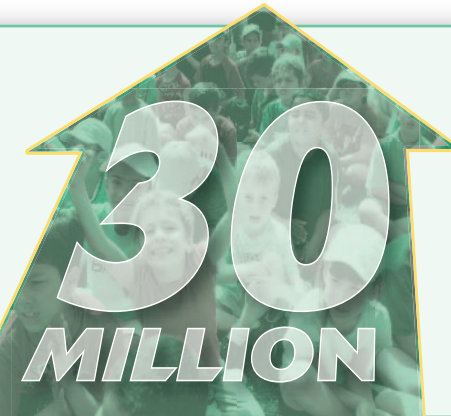


# EXPANDED CDC/ACIP\* RECOMMENDATIONS TO BE IMPLEMENTED AS SOON AS FEASIBLE (BUT NO LATER THAN 2009-2010 INFLUENZA SEASON)<sup>6</sup>



**“The new recommendation [to include all school-aged children through the age of 18 years] increases the number of children recommended for vaccination by approximately 30 million.”<sup>6</sup>**

—CDC press release, February 27, 2008



## Help protect more children by starting vaccinations early

FluMist<sup>®</sup> is expected to be available before the typical vaccination period, so you can vaccinate at regularly scheduled visits

- Well-child visits
- Back-to-school
- Sports physicals

**CDC/ACIP encourages vaccination to begin as soon as vaccine is available and continue throughout the season<sup>7</sup>**

\*CDC/ACIP = Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices

## Selected Safety Information

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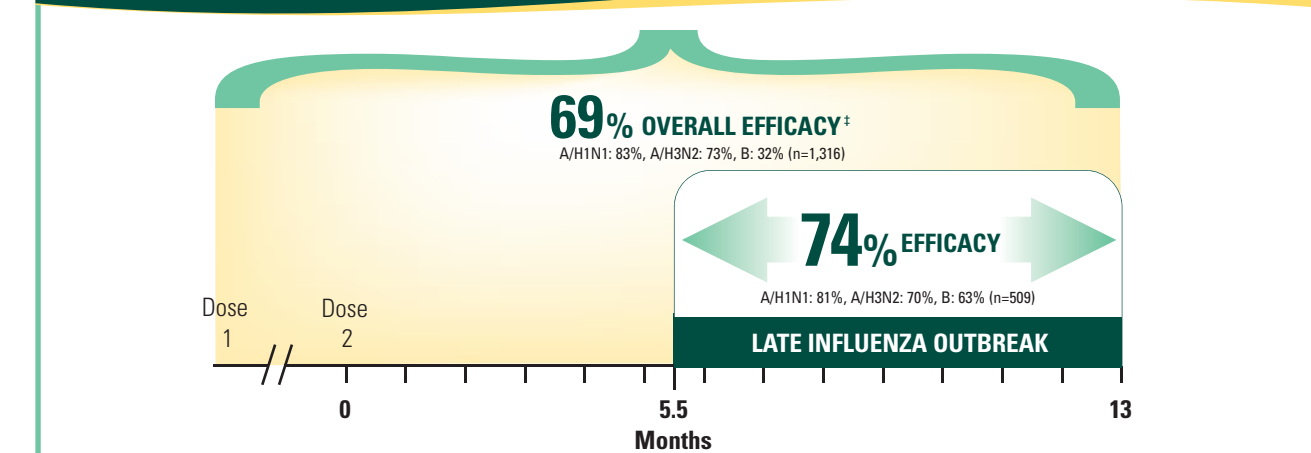
FluMist may not protect all individuals receiving the vaccine. FluMist is for intranasal administration only.

## Early vaccination with FluMist helps protect children throughout the influenza season<sup>1,3,8</sup>

In a multicountry, culture-confirmed efficacy study<sup>1</sup> where influenza circulated through 12 months following vaccination:

- FluMist demonstrated efficacy of 69%<sup>†</sup> against matched strains
- Protection was maintained even during outbreaks that occurred 5.5 months to 13 months after vaccination at 74%

### Efficacy of FluMist vs placebo in 3,174 children between 24 months and 35 months of age<sup>3,8†</sup>



Adapted from Tam JS et al. *Pediatr Infect Dis J.* 2007;26:619-628.

<sup>†</sup>A prospective, randomized, double-blind, placebo-controlled trial in vaccine-naïve children 24 months to 35 months of age for the 2000-2001 influenza season. Data are representative of the indicated population; full study population is represented in the Prescribing Information.

<sup>‡</sup>Attack rates for FluMist vs placebo were 4.1% and 13.3%, respectively.

- Annual vaccination is recommended by the CDC/ACIP as the best way to protect against influenza<sup>7</sup>

**The majority of children aged 2 years through 18 years could be considered for FluMist<sup>§</sup>**

<sup>§</sup> See page 6 for more details.

**Please see Important Safety Information for FluMist on page 12.**

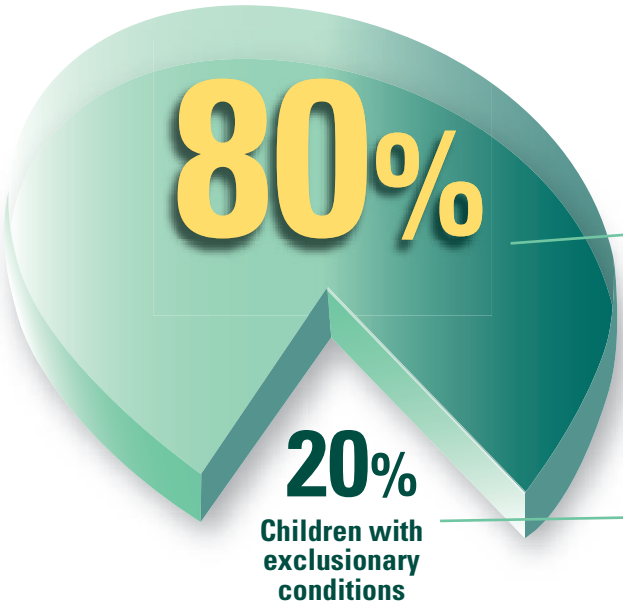
**FLUMIST<sup>®</sup>**  
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Intranasal

**Proof. Protection. Progress.**

THE MAJORITY OF CHILDREN  
AGED 2 YEARS THROUGH 18 YEARS  
MAY BE ELIGIBLE FOR FLUMIST®



Children aged 2 years through 18 years



Approximately 80% of children aged 2 years through 18 years may be appropriate candidates for FluMist

Approximately 20% of children aged 2 years through 18 years have medical conditions that may preclude the use of FluMist<sup>7,9-13\*</sup>

\*CONTRAINDICATIONS

- Hypersensitivity to eggs, egg proteins, gentamicin, gelatin or arginine or life-threatening reactions to previous influenza vaccination
- Concomitant aspirin or aspirin-containing therapy in children and adolescents

\*WARNINGS AND PRECAUTIONS

- Asthma (at any age) and recurrent wheezing (asthma equivalent) between 2 years and 5 years of age
- Experienced Guillain-Barré syndrome within 6 weeks after any prior influenza vaccination
- Administration of FluMist, a live virus vaccine, to immunocompromised persons should be based on careful consideration of potential benefits and risks
- Safety has not been established in individuals with underlying medical conditions predisposing them to wild-type influenza infection complications
- Is pregnant

Selected Safety Information

FluMist is a live attenuated influenza virus vaccine indicated for active immunization of individuals 2-49 years of age against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. Do not administer to children <24 months of age due to an increased risk of hospitalization and wheezing that was observed in clinical trials or to individuals with severe asthma or active wheezing.

FluMist safety profile generally comparable to the flu shot and placebo in over 7,000 children studied<sup>1</sup>

Summary of solicited events in children				
Event	Placebo studies 2 years to 6 years of age*		Active-controlled study 2 years to 5 years of age <sup>††</sup>	
	FluMist (N=876-1,764)	Placebo (N=424-1,036)	FluMist (N=2,170)	Flu shot (N=2,165)
	%	%	%	%
Runny nose/nasal congestion <sup>§</sup>	58	50	51	42
Decreased appetite	21	17	13	12
Irritability	21	19	12	11
Decreased activity (lethargy)	14	11	7	6
Sore throat	11	9	5	6
Headache	9	7	3	3
Muscle aches	6	3	2	2
Chills	4	3	2	2
Fever <sup>§</sup>				
100°-101°F Oral	9	6	6	4
101°-102°F Oral	4	3	4	3

\*Solicited events observed within 10 days after dose 1 for vaccine and placebo recipients occurred in at least 1% of FluMist recipients and at a higher rate compared to placebo.

<sup>†</sup> A randomized, double-blind, double-dummy comparison of FluMist intranasal mist and TIV intramuscular injection that included children 24 months to 59 months of age in the 2004-2005 influenza season (N=4,335 participants who submitted solicited response cards).

<sup>††</sup> Solicited events observed within 10 days after dose 1 in children 24 months to 59 months of age.

<sup>§</sup> Most common adverse reactions (≥10% in FluMist and at least 5% greater than in control) are runny nose or nasal congestion and fever >100°F in children 2-6 years of age and sore throat in adults.

Additional adverse reactions observed in the above trials that occurred in at least 1% of FluMist recipients and at a higher rate compared to placebo were abdominal pain, otitis media, diarrhea and sneezing.

In a trial in children 9 years to 17 years of age, and in a trial comparing the refrigerated and frozen formulation in children and adults aged 5 years to 49 years, solicited events and other adverse reactions were generally consistent with observations from previous trials.

Please see Important Safety Information for FluMist on page 12.

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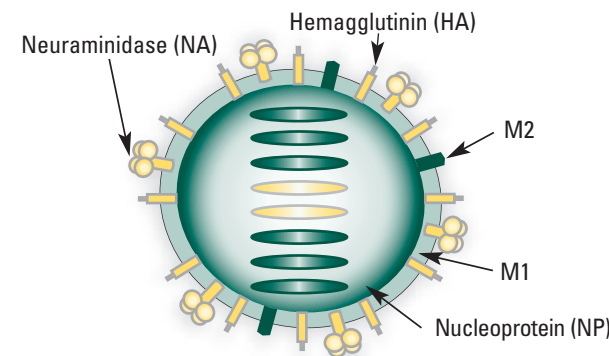
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# FLUMIST®: QUESTIONS AND ANSWERS

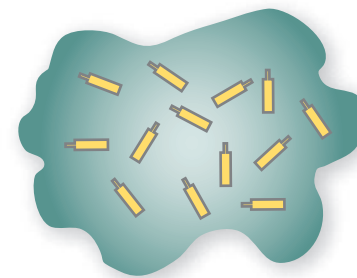
## Q How is FluMist engineered?

FluMist is designed to help stimulate a natural immune response<sup>1</sup>



FluMist\*

• Attenuated vaccine with multiple antigens<sup>14</sup>



Traditional inactivated flu vaccine

• HA is the only standardized antigenic component; other antigens may be present<sup>15,16</sup>

\*Image adapted from *Clinical Virology*, 6th ed.

## Q Can FluMist cause the flu?

FluMist is engineered not to cause disease<sup>17</sup>—each of the 3 vaccine strains in FluMist is attenuated in multiple ways:

- Attenuated—weakened so as not to cause influenza-like illness
- Cold adapted—replicates efficiently only in the cooler temperatures of the nasopharynx
- Temperature sensitive—does not replicate efficiently in warmer temperatures of the lower respiratory tract

**Please see accompanying complete Prescribing Information.**

## Q Can individuals in close contact with immunocompromised persons (eg, patients on chemotherapy) receive FluMist?

According to the patient counseling section within the complete Prescribing Information, vaccine recipients or their parents/guardians should be informed by the healthcare provider that FluMist is an attenuated live virus vaccine and has the potential for transmission to immunocompromised household contacts.

The CDC/ACIP states that individuals who are in contact with immunocompromised persons—including those with immunosuppression due to chemotherapy—may receive FluMist.<sup>7</sup>

- All individuals are included except those who have close contact with **severely** immunocompromised persons (eg, hematopoietic stem cell transplants) during those periods when the immunocompromised persons are in a protective environment<sup>7,17</sup>

## Q What is the storage and administration of FluMist?

FluMist should be refrigerated between 2°-8°C (35°-46°F) upon receipt and until use before the expiration date on the sprayer label.

FluMist is intranasally delivered, which permits normal breathing during administration—active inhalation (ie, sniffing) is not required by the patient.

## Q What is the shelf life of FluMist?

FluMist has a shelf life of up to 18 weeks. Please refer to actual expiration date on sprayer label. Unused doses expiring through January 2009 may be eligible for replacement with new doses with later expiry (certain restrictions apply). Contact your distributor for more information.

## Q What is the volume of FluMist?

FluMist contains a volume 0.2 mL per sprayer.

## Q Does FluMist contain preservatives?

FluMist does not contain thimerosal or other preservatives.

**Please see Important Safety Information for FluMist on page 12.**

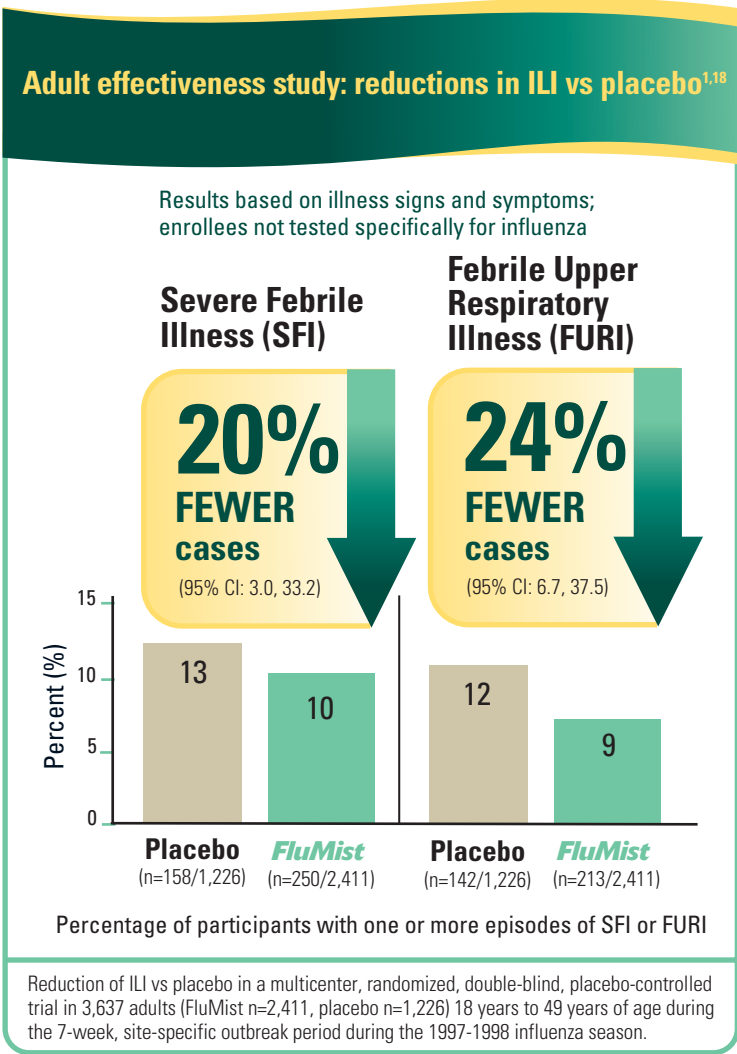
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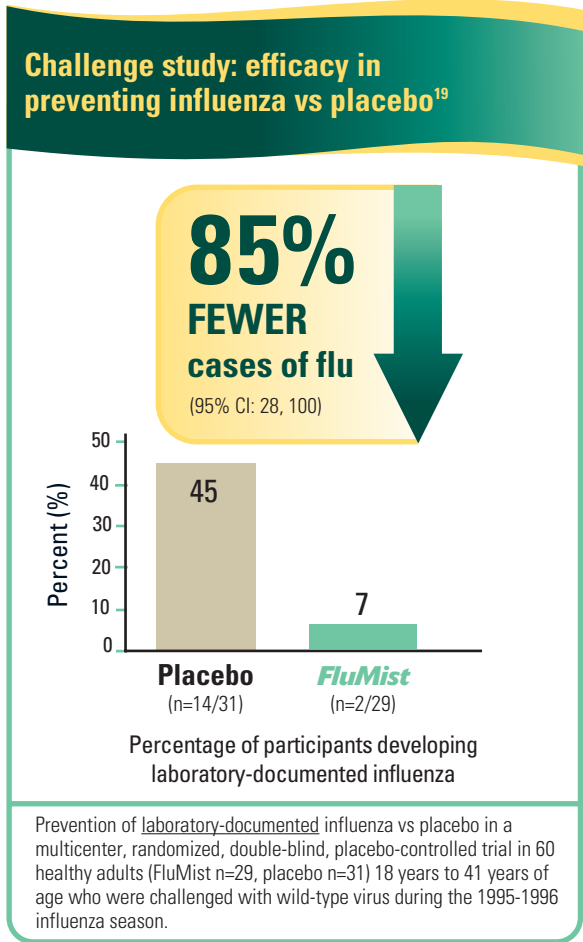
FLUMIST® IS EFFECTIVE  
IN ADULTS, TOO



In healthy adults ≤49 years of age  
**Substantial effectiveness in reducing cases of influenza-like illness (ILI)**



Effectiveness was not demonstrated in a subgroup of adults 50 years to 64 years of age.



**FluMist safety and tolerability in adults<sup>1</sup>**

**Summary of solicited adverse events in healthy adults aged 18 years to 49 years**

Event	FluMist (n=2,458) %	Placebo (n=1,290) %
Runny nose*	44	27
Headache	40	38
Sore throat*	28	17
Tiredness/weakness	26	22
Muscle aches	17	15
Cough	14	11
Chills	9	6

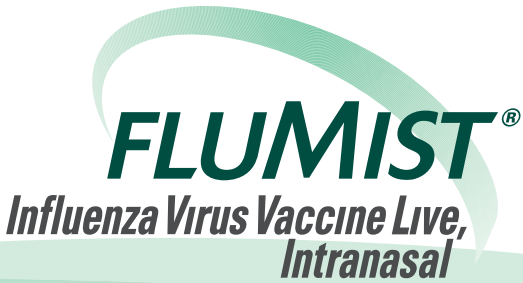
Summary of solicited events reported within 7 days of either vaccine or placebo (normal egg allantoic fluid) administration in healthy adults 18 years to 49 years of age.  
All solicited events were transient.

**Selected Safety Information**

\*Most common adverse reactions (occurring at ≥10% in individuals receiving FluMist and at least 5% greater than in placebo) are runny nose or nasal congestion in recipients of all ages, fever >100°F in children 2-6 years of age, and sore throat in adults.

FluMist may not protect all individuals receiving the vaccine. FluMist is for intranasal administration only.

**Please see Important Safety Information for FluMist on page 12 and accompanying complete Prescribing Information.**



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# SAFETY AND PRESCRIBING INFORMATION

## Important Safety Information

FluMist® is a live attenuated influenza virus vaccine indicated for active immunization of individuals 2-49 years of age against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

FluMist is contraindicated in individuals with history of hypersensitivity to eggs, egg proteins, gentamicin, gelatin or arginine or with life-threatening reactions to previous influenza vaccinations, and in children and adolescents receiving concomitant aspirin or aspirin-containing therapy.

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. FluMist should not be administered to any individual with asthma and to children <5 years of age with recurrent wheezing unless the potential benefit outweighs the potential risk. Do not administer FluMist to individuals with severe asthma or active wheezing.

If Guillain-Barré syndrome has occurred with prior influenza vaccination or if an individual is immunocompromised, the decision to give FluMist should be based on careful consideration of the potential benefits and risks. FluMist should not be administered to individuals with underlying medical conditions predisposing them to wild-type influenza infection complications unless the potential benefit outweighs the potential risk. FluMist should be given to a pregnant woman only if clearly needed.

Most common adverse reactions (occurring at ≥10% in individuals receiving FluMist and at least 5% greater than in placebo) are runny nose or nasal congestion in recipients of all ages, fever >100°F in children 2-6 years of age, and sore throat in adults.

FluMist may not protect all individuals receiving the vaccine. FluMist is for intranasal administration only.

**References:** 1. Prescribing Information for FluMist, Influenza Virus Vaccine Live, Intranasal. MedImmune Vaccines, Inc., Gaithersburg, Md. 2. Belshe RB, Edwards KM, Vesikari T, et al; for the CAIV-T Comparative Efficacy Study Group. Live attenuated versus inactivated influenza vaccine in infants and young children. *N Engl J Med*. 2007;356:685-696. 3. Data on file. MedImmune Inc., Gaithersburg, Md. 4. Centers for Disease Control and Prevention. Flu activity (Influenza Season Summaries 2000-2006). <http://www.cdc.gov/flu/weekly/fluactivity.htm>. Accessed March 25, 2008. 5. Centers for Disease Control and Prevention. Update: influenza activity—United States and worldwide, 1997–1998 season, and composition of the 1998–99 influenza vaccine. *MMWR*. 1998; 47(14):280-284. 6. Centers for Disease Control and Prevention. CDC's Advisory Committee recommends influenza vaccination for children 6 months through 18 years of age. <http://www.cdc.gov/od/oc/media/pressrel/2008/r080227.htm>. Accessed February 27, 2008. 7. Centers for Disease Control and Prevention. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2007. *MMWR*. 2007;56(RR-6):1-54. 8. Tam JS, Capeding MR, Lum LC. 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. 9. Vezina RM, Lasko SM, Corwin MJ, Gottlieb DJ. Association of early infant exposures to wheezing and asthma by age five. *Pediatr Perinat Epidemiol*. 2001;15(4):A34-A35. 10. Yawn BP, Wollan P, Scanlon P, Kurland M. Are we ready for universal school-based asthma screening? An outcome evaluation. *Arch Pediatr Adolesc Med*. 2002;156:1256-1262. 11. U.S. Census-Intercensal Estimates of the United States Resident Population by Age and Sex. <http://www.census.gov/popest/archives/EST90INTERCENSAL/US-EST90INT-07/US-EST90INT-07.csv>. Accessed April 7, 2008. 12. Savage JH, Matsui EC, Skripak JM, Wood RA. The natural history of egg allergy. *J Allergy Clin Immunol*. 2007;120:1413-1417. 13. Centers for Disease Control and Prevention. Estimates of Influenza Vaccination Target Population Sizes in 2006 and Recent Vaccine Uptake Levels. [www.cdc.gov/flu/professionals/vaccination/pdf/targetpopchart.pdf](http://www.cdc.gov/flu/professionals/vaccination/pdf/targetpopchart.pdf). Accessed April 7, 2008. 14. Hayden FG, Palese P. Influenza virus. In: Richman DD, Whitley FJ, Hayden FG, eds. *Clinical Virology*. 6th ed. New York, NY: Churchill Livingstone Inc.; 1997:911-942. 15. Fluzone®, Influenza Virus Vaccine (Zonal Purified Subvirion) Prescribing Information. 16. Fluvirin® (Purified Surface Antigen Vaccine, Trivalent, Types A and B) Prescribing Information. 17. Centers for Disease Control and Prevention. Influenza (flu) Q&A: the nasal-spray flu vaccine (live attenuated influenza vaccine [LAIV]). <http://www.cdc.gov/flu/about/qa/nasalspray.htm>. 18. Nichol KL, Mendelman PM, Mallon KP, et al. Effectiveness of live, attenuated intranasal influenza virus vaccine in healthy, working adults: a randomized controlled trial. *JAMA*. 1999;282:137-144. 19. Treanor JJ, Kotloff K, Betts RF, 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*. 2000;18:899-906.

## Selected Prescribing Information

### PATIENT COUNSELING INFORMATION

- Vaccine recipients or their parents/guardians should be informed by the health care provider of the potential benefits and risks of FluMist, and the need for two doses at least 1 month apart in children 2-8 years old who have not previously received influenza vaccine
- Ask the vaccinee or their parent/guardian if the vaccinee has asthma. For children <5 years of age, also ask if the vaccinee has recurrent wheezing since this may be an asthma equivalent in this age group
- Vaccine recipients or their parents/guardians should be informed by the health care provider that FluMist is a live attenuated virus vaccine and has the potential for transmission to immunocompromised household contacts

### ADVERSE REACTIONS

- To report SUSPECTED ADVERSE REACTIONS, contact MedImmune at 1-877-633-4411 or VAERS at 1-800-822-7967 and <http://vaers.hhs.gov>

### USE IN SPECIFIC POPULATIONS

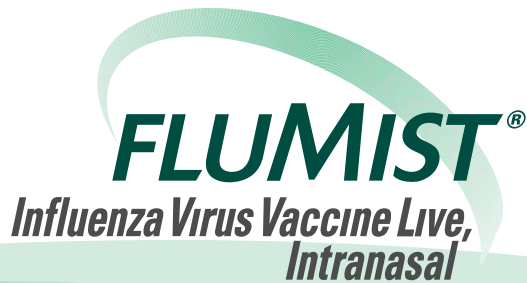
- Safety and effectiveness of FluMist have not been studied in pregnant women or nursing mothers (8.1, 8.3)
- FluMist is not indicated for use in children <2 years of age (8.4)
- FluMist is not indicated for use in individuals ≥50 years of age (8.5, 8.6)

### STORAGE AND HANDLING

- FluMist should be stored in a refrigerator between 2°-8°C (35°-46°F) upon receipt and until use before the expiration date on the sprayer label
- Do not freeze
- The cold chain (2°-8°C) must be maintained when transporting FluMist

FluMist may not protect all individuals receiving the vaccine. FluMist is for intranasal administration only.

**Please see accompanying complete Prescribing Information.**



**Proof. Protection. Progress.**



# FLUMIST® WENT HEAD-TO-HEAD AGAINST THE FLU SHOT



In a study published in *The New England Journal of Medicine* that included 4,166 children 24 months to 59 months of age during the 2004-2005 influenza season...

## **FluMist demonstrated significant reductions in influenza vs the flu shot<sup>1-3\*</sup>**

- Overall efficacy: 54.4% reduction in flu cases vs the flu shot (4.5% vs 9.8%)
- Matched strains: 52.5% reduction in flu cases vs the flu shot (1.4% vs 2.9%)
- Mismatched strains: 54.2% reduction in flu cases vs the flu shot (3.2% vs 7.1%)

\* Data are representative of the indicated population (children aged 24 months to 59 months); full study population is represented in the Prescribing Information and *The New England Journal of Medicine*—February, 2007.

Study design: Randomized, double-blind, double-dummy comparison of the relative efficacy of FluMist and TIV intramuscular injection.

## **Expanded CDC/ACIP recommendations for influenza vaccination include all school-aged children through the age of 18 years<sup>6</sup>**

Please note: not all influenza vaccines are indicated for all children. Please refer to complete Prescribing Information.

- A majority of these children may be eligible for FluMist

## **FluMist demonstrated a safety and side-effect profile generally comparable to the flu shot and placebo in eligible children**

- Most common adverse reactions ( $\geq 10\%$  in FluMist and at least 5% greater than in control) are runny nose or nasal congestion in all ages and fever  $>100^{\circ}\text{F}$  in children 2-6 years of age (and sore throat in adults)

## **Most patients that have flu vaccination coverage also have coverage for FluMist<sup>3</sup>**

- FluMist is covered for approximately 94% of eligible patients who have health insurance with immunization benefits
- Available through Vaccines for Children (VFC)
- Check with applicable providers to confirm local coverage

**Let your patients know you have FluMist —**  
sign up on the FluMist Finder at <http://www.flumist.com/flumistfinder>

## **Selected Safety Information**

Do not administer to children  $<24$  months of age due to an increased risk of hospitalization and wheezing that was observed in clinical trials or to individuals with severe asthma or active wheezing.

FluMist should not be administered to any individuals with asthma and to children  $<5$  years of age with recurrent wheezing because of the potential for increased risk of wheezing post vaccination.

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