FluMist® went head-to-head against the flu shot

with compelling results worth talking about

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.
**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.

---

**Comparative efficacy in children aged 24 months to 59 months during the 2004-2005 influenza season (N=4,166)**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Cases</th>
<th>Efficacy Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FluMist</td>
<td>10.0</td>
<td>54.4% (95% CI: 41.8, 64.5)</td>
</tr>
<tr>
<td>Flu shot</td>
<td>5.0</td>
<td></td>
</tr>
</tbody>
</table>

Overall efficacy against influenza illness

\[ \text{Rate} = \frac{\text{Cases} \times 100}{\text{Vaccine dose}} \]

**FluMist® demonstrated significant reductions in influenza vs the flu shot...**

In a head-to-head clinical study in children published in

THE NEW ENGLAND JOURNAL OF MEDICINE...  

\[ \text{Reduction} = 1 - \frac{\text{Rate}_{\text{FluMist}}}{\text{Rate}_{\text{Flu shot}}} \]

**...against matched and mismatched influenza strains**

\[ \text{Rate}_{\text{FluMist}} = 5.0 \]

\[ \text{Rate}_{\text{Flu shot}} = 10.0 \]

2. 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.
3. 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-naive 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).
4. 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 (H1N1) 1.2% vs 4.9%, and matched B/Yamagata lineage 1.4% vs 1.9%, respectively.
5. 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 (H1N1) 1.2% vs 4.9%, and mismatched B/Yamagata lineage and B/Victoria (2.1% vs 2.3%, NS), respectively.
6. Note: since influenza strains change each year, past clinical trial results are not indicative of future results

Please see Important Safety Information for FluMist on page 12.
Early vaccination with FluMist helps protect children throughout the influenza season.\textsuperscript{1,3,8} In a multicountry, culture-confirmed efficacy study\textsuperscript{†} where influenza circulated through 12 months following vaccination:

- FluMist demonstrated efficacy of 69\% against matched strains.
- Protection was maintained even during outbreaks that occurred 5.5 months to 13 months after vaccination at 74\%.

FluMist\textsuperscript{*} 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.\textsuperscript{§}

**Selected Safety Information**

FluMist\textsuperscript{®} 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 may not protect all individuals receiving the vaccine. FluMist is for intranasal administration only.

\textsuperscript{†} A prospective, randomized, double-blind, placebo-controlled trial in vaccine-naive 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.

\textsuperscript{‡} Attack rates for FluMist vs placebo were 4.1\% and 13.3\%, respectively.

\textsuperscript{§} CDC/ACIP = Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices

The majority of children aged 2 years through 18 years could be considered for FluMist.\textsuperscript{1}  

- Annual vaccination is recommended by the CDC/ACIP as the best way to protect against influenza.\textsuperscript{1}

Please see Important Safety Information for FluMist on page 12.
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

**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

<table>
<thead>
<tr>
<th>Event</th>
<th>Placebo studies 2 years to 6 years of age*</th>
<th>Active-controlled study 2 years to 5 years of age†‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Runny nose/nasal congestion</td>
<td>56</td>
<td>59</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>21</td>
<td>17</td>
</tr>
<tr>
<td>Irritability</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td>Decreased activity (lethargy)</td>
<td>14</td>
<td>11</td>
</tr>
<tr>
<td>Sore throat</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>Headache</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>Muscle aches</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Chills</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Fever†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100°-101°F Oral</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>101°-102°F Oral</td>
<td>4</td>
<td>3</td>
</tr>
</tbody>
</table>

*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, and 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.

*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
Can FluMist cause the flu?

FluMist is engineered not to cause disease—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.
**FLUMIST® IS EFFECTIVE IN ADULTS, TOO**

In healthy adults ≤49 years of age

**Substantial effectiveness in reducing cases of influenza-like illness (ILI)**

**FluMist safety and tolerability in adults**

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

<table>
<thead>
<tr>
<th>Event</th>
<th>FluMist</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Runny nose*</td>
<td>44%</td>
<td>22%</td>
</tr>
<tr>
<td>Headache</td>
<td>40%</td>
<td>38%</td>
</tr>
<tr>
<td>Sore throat*</td>
<td>28%</td>
<td>17%</td>
</tr>
<tr>
<td>Tiredness/weakness</td>
<td>26%</td>
<td>22%</td>
</tr>
<tr>
<td>Muscle aches</td>
<td>17%</td>
<td>16%</td>
</tr>
<tr>
<td>Cough</td>
<td>14%</td>
<td>13%</td>
</tr>
<tr>
<td>Chills</td>
<td>9%</td>
<td>6%</td>
</tr>
</tbody>
</table>

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.

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

Selected Prescribing Information

PATIENT COUNSELING INFORMATION

- Vaccine recipients or their parents/guardians should be informed of the potential benefits and risks of RuMist, and the need for two doses at least 1 month apart in children 2-8 years old who have not previously received influenza vaccine
- 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

Proof. Protection. Progress.
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**¹⁻３⁴

- 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%)

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**⁶

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 (≥10% in FluMist and at least 5% greater than in control) are runny nose or nasal congestion in all ages and fever >100°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**³

- 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](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.

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