

FluMist[®]

Influenza Virus Vaccine Live, Intranasal

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For Nasal Administration Only

Please read this information carefully before you receive FluMist[®]. Even if you have received FluMist in the past, some of this information may be new. Be advised that this patient information is a summary. It does not take the place of discussions with your doctor or health care professional about this vaccine, and does not list all the potential benefits and risks of FluMist. This vaccine can be prescribed only by a licensed health care professional who has information about your health status and full prescribing information about the vaccine, including how FluMist will be administered, what to expect, and potential side effects. Talk to your doctor or health care professional if you have any questions or want to learn more about FluMist.

What is influenza?

Influenza, or the "flu," strikes about 1 in every 10 persons in the United States each winter. Although it is often confused with the common cold, the flu is more severe. Typical flu symptoms include:

- fever
- severe muscle aches
- fatigue
- headache
- cough
- sore throat
- runny nose

Most people recover from flu symptoms in a few days, but the coughing and fatigue can last even longer.

Vaccination is the principal means of influenza prevention and associated complications.

What is FluMist?

FluMist is a vaccine that is given as a nasal mist. It is indicated for healthy children and adolescents, 5-17 years of age, and healthy adults, 18-49 years of age, to help protect them from disease caused by influenza infection. FluMist contains three live flu virus strains, which have been weakened. After the weakened influenza viruses in FluMist enter the nose, the body develops an immune response that helps prevent the flu for the entire season. As with any vaccine, FluMist may not protect all individuals receiving the vaccine. FluMist does not cause the flu.

Who can get FluMist?

Healthy children and adolescents, 5-17 years of age, and healthy adults, 18-49 years of age who have met the required screening criteria as provided by their doctor or health care professional can get FluMist.

FluMist is not recommended for people less than 5 years of age, or 50 years of age and older, or for therapy of influenza. It will not protect against infections and illness caused by organisms other than influenza virus strains contained in the vaccine.

Who should not get FluMist?

You should not receive FluMist if you:

- are less than 5 years of age. In one study, an increase in asthmatic events was seen in children under 5.
- are 50 years of age or older
- have an allergy or history of allergic reaction to chicken eggs or egg products or any component of the vaccine (see **Additional Information**). Symptoms of a severe allergic reaction may include shortness of breath, wheezing, or difficulty breathing; swelling of the face, lips, tongue, or other parts of the body; skin rash, itching, or hives.
- are a child or adolescent who regularly takes aspirin, or products containing aspirin
- have a history of Guillain-Barré syndrome
- have a known or suspected immune deficiency disease or condition such as combined immunodeficiency, agammaglobulinemia, HIV infection, thymic abnormalities, malignancy, leukemia, or lymphoma
- are immunosuppressed or have altered or compromised immune status due to treatment with systemic corticosteroids, alkylating drugs, antimetabolites, radiation or other immunosuppressive therapies
- have a history of asthma or reactive airways disease
- have underlying medical conditions such as but not limited to chronic disorders of the lungs and heart; or have had regularly scheduled follow-up visits or have been hospitalized in the past year because of chronic metabolic diseases (including diabetes), kidney dysfunction, or a hemoglobinopathy such as sickle cell disease
- are pregnant

Due to the possible transmission of vaccine virus, FluMist recipients should avoid being in close (for example, within the same household) contact with immunocompromised individuals for 3 weeks following vaccination.

Who should wait to get FluMist?

FluMist should not be given to anyone who has an illness with fever or a respiratory illness until 3 days after symptoms have subsided.

Since anti-influenza drugs may interfere with FluMist, it is recommended that FluMist not be given until 48 hours following the end of antiviral therapy and that antivirals not be given until 2 weeks after receiving FluMist (unless otherwise directed by your health care professional).

What should I tell my doctor or health care professional before my child or I get FluMist?

Before receiving FluMist, tell your doctor or health care professional if:

- you are taking intranasal preparations, including steroids
- you are nursing
- you, or your child, have had an allergic reaction to any previous vaccination with FluMist

You should also tell your doctor or health care professional about:

- the previous immunization history of you or your child
- any medical problems you, your child, or household members and close contacts have now or have had in the past (including immune status)
- all medicines that you, or your child, are taking or plan to take, including those you can get without a prescription

This information will help you and your doctor or health care professional decide if the expected benefits of FluMist are greater than the possible risks.

When can my child or I get FluMist?

To help ensure protection from the flu, you may get vaccinated as soon as vaccine is available, before the flu season starts; in the U.S., the flu season usually peaks between December and March each year.¹

What are the possible side effects of FluMist?

In studies, the most common side effects that occurred in healthy children 5 years of age and older were:

- runny nose/nasal congestion
- cough
- irritability
- headache
- decreased activity
- sore throat
- low grade fever (>100°F oral)
- muscle aches
- chills
- vomiting

In studies, the most common side effects that occurred in healthy adults 18-49 years of age were:

- runny nose
- headache
- sore throat
- a feeling of tiredness/weakness
- muscle aches
- cough
- chills
- low grade fever (>100°F oral)

Not all of the side effects reported for FluMist are listed above. Not all of these side effects were greater than those seen in the placebo group. Your doctor or health care professional can discuss with you any additional side effects that were reported. If at any time you or your child experiences a symptom or medical problem that you think may be related to FluMist, tell your doctor or health care professional.

Can FluMist be given with other medicines or vaccines?

Some medicines that should not be given with FluMist include:

- drugs that weaken the immune system
- aspirin and aspirin-containing therapy (taken by children and adolescents)
- influenza antiviral drugs

FluMist vaccination should be delayed for at least 14 days after you have received an inactivated vaccine (a vaccine in which the virus or organism is killed) and at least 30 days after receiving a live vaccine. Ask your doctor for guidance if you've received or plan to receive a vaccination within 30 days of receiving FluMist, or if you have other questions.

Additional Information

Each 0.5 mL FluMist dose contains the flu strains recommended by the U.S. Public Health Service for the 2004-2005 flu season:

A/New Caledonia/20/99 (H1N1), A/Wyoming/3/2003 (H3N2) (A/Fujian/411/2002-like), and B/Jilin/20/2003 (B/Shanghai/361/2002-like) viruses. Inactive ingredients include egg allantoic fluid, sucrose, potassium phosphate, monosodium glutamate (MSG) and gentamicin sulfate. FluMist does not contain preservatives.

FluMist is administered as a nasal mist. Approximately 0.25 mL is administered into each nostril while the recipient is in an upright position.

If you have any questions or concerns, or want more information about FluMist, your doctor or health care professional has the complete Prescribing Information from which this patient information was created. You may want to read it and discuss it with your doctor or other health care professional. Keep in mind that no written summary can take the place of a discussion with your doctor. You may also visit the FluMist Web site at www.FluMist.com for additional information.

Reporting by vaccine recipients or the parents/guardians of vaccinees and health care providers of all adverse events occurring after vaccine administration is encouraged. The U.S. Department of Health and Human Services (DHHS) has established a Vaccine Adverse Event Reporting System (VAERS) to accept all reports of suspected adverse events after the administration of any vaccine. The VAERS toll-free number is 1-800-822-7967. Reporting forms may also be obtained at the FDA Web site at: <http://www.vaers.org>

Manufactured and Marketed by MedImmune Vaccines, Inc., Gaithersburg, MD 20878 U.S. Govt. License No. 1652

This brief summary is based on FluMist Prescribing Information dated September 2004.

¹ Centers for Disease Control and Prevention. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2004;53(No. RR-6):1-40.