

LIVE, INTRANASAL INFLUENZA VACCINE

WHAT YOU NEED TO KNOW

2004-2005

1 Why get vaccinated?

Influenza (“flu”) is a serious disease.

It is caused by a virus that spreads from infected persons to the nose or throat of others.

Influenza can cause:

- fever
- sore throat
- chills
- cough
- headache
- muscle aches

Anyone can get influenza. Most people are ill with influenza for only a few days, but some get much sicker and may need to be hospitalized. Influenza causes an average of 36,000 deaths each year in the U.S., mostly among the elderly.

Influenza vaccine can prevent influenza.

2 Live, intranasal influenza vaccine

Two types of influenza vaccine are now available, an inactivated vaccine and a live vaccine.

Live, intranasal influenza vaccine (trade-name FluMist™) was licensed in 2003. FluMist contains live, attenuated (weakened) influenza virus. It is sprayed into the nostrils rather than injected into the muscle.

Inactivated influenza vaccine, sometimes called the “flu shot,” has been used for many years, and is given by injection. It contains killed influenza virus.

3 Who can get live, intranasal influenza vaccine?

Live, intranasal influenza vaccine is approved for healthy children and adults from 5 through 49 years of age, including household contacts of most people at high risk for influenza complications. However, FluMist should not be used by people with some medical conditions, pregnant women, or others at risk of influenza-related complications (see Section 4).

4 Who should *not* get live, intranasal influenza vaccine?

The following people should not get intranasal influenza vaccine. They should check with their health care provider about getting **inactivated influenza vaccine**.

- **Adults 50 years of age or older or children younger than 5.**
- People who have **long-term health problems** with:
 - heart disease
 - kidney disease
 - lung disease
 - metabolic disease, such as diabetes
 - asthma
 - anemia, and other blood disorders
- People with a **weakened immune system** due to:
 - HIV/AIDS or another disease that affects the immune system
 - long-term treatment with drugs that weaken the immune system, such as steroids
 - cancer treatment with x-rays or drugs
- Children or adolescents on **long-term aspirin treatment** (these people could develop Reye syndrome if they get the flu).
- **Pregnant women.**
- Anyone with a history of **Guillain-Barré Syndrome (GBS)**.

The flu shot (inactivated vaccine) is preferred over live, intranasal influenza vaccine for physicians, nurses, family members, or anyone else coming in **close contact with anyone with a severely weakened immune system** (that is, requiring care in a protected environment).

The following people should talk with a doctor before getting *either* flu vaccine:

- Anyone who has ever had a serious allergic reaction to **eggs** or to a **previous dose** of influenza vaccine.
- If you have a fever or are severely ill at the time the vaccination is scheduled, you should probably wait until you recover before getting influenza vaccine. Talk to your doctor or nurse about whether to reschedule the vaccination.

5 When should I get influenza vaccine?

The best time to get flu vaccine is in **October** or **November**. The flu season can peak anywhere from December through March, but most often peaks in February. So getting the vaccine in December, or even later, can be beneficial in most years.

Most people need only one flu vaccination each year to prevent influenza. But **children under 9 years of age getting influenza vaccine for the first time** should get 2 doses of vaccine. For the live influenza vaccine, these doses should be 6-10 weeks apart. These children should get their first dose in October or earlier. Children in this age group who got one dose the previous year, even if it was the first time they got the vaccine, need only one dose this year.

Live, intranasal flu vaccine may be given at the same time as other vaccines. This includes other live vaccines, such as MMR or chickenpox. But if two live vaccines are not given on the same day, they should be given at least 4 weeks apart.

Influenza viruses change often. Therefore, influenza vaccines are updated every year, and an annual vaccination is needed.

6 What are the risks from live, intranasal influenza vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. However, the risk of a vaccine causing serious harm, or death, is extremely small.

Chances of live influenza vaccine viruses spreading from person to person are very small. Even if such spread should occur, it is unlikely to cause illness.

Live, intranasal influenza vaccine can cause mild symptoms in the recipient (see below).

Mild problems:

Some children and adolescents 5-17 years of age have reported mild reactions, including:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

These symptoms did not last long and went away on their own. Even when they occur after vaccination, they may not have been caused by the vaccine.

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.
- If rare reactions occur with any new product, they may not be identified until many thousands, or millions, of people have used the product. Like all vaccines, live, intranasal influenza vaccine is being monitored for unusual or severe problems.

7 What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at www.vaers.org, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

8 How can I learn more?

- Ask your immunization provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-2522** (English)
 - Call **1-800-232-0233** (Español)
 - Visit CDC's website at www.cdc.gov/flu



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