VACCINE INFORMATION STATEMENT

Influenza (Flu) Vaccine (Live, Intranasal): What You Need to Know

1 Why get vaccinated?
Influenza (“flu”) is a contagious disease that spreads around the United States every year, usually between October and May.

Flu is caused by influenza viruses, and is spread mainly by coughing, sneezing, and close contact.

Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms vary by age, but can include:
• fever/chills
• sore throat
• muscle aches
• fatigue
• cough
• headache
• runny or stuffy nose

Flu can also lead to pneumonia and blood infections, and cause diarrhea and seizures in children. If you have a medical condition, such as heart or lung disease, flu can make it worse.

Flu is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk.

Each year thousands of people in the United States die from flu, and many more are hospitalized.

Flu vaccine can:
• keep you from getting flu,
• make flu less severe if you do get it, and
• keep you from spreading flu to your family and other people.

2 Live, attenuated flu vaccine—LAIV, Nasal Spray

A dose of flu vaccine is recommended every flu season. Children younger than 9 years of age may need two doses during the same flu season. Everyone else needs only one dose each flu season.

The live, attenuated influenza vaccine (called LAIV) may be given to healthy, non-pregnant people 2 through 49 years of age. It may safely be given at the same time as other vaccines.

LAIV is sprayed into the nose. LAIV does not contain thimerosal or other preservatives. It is made from weakened flu virus and does not cause flu.

There are many flu viruses, and they are always changing. Each year LAIV is made to protect against four viruses that are likely to cause disease in the upcoming flu season. But even when the vaccine doesn’t exactly match these viruses, it may still provide some protection.

Flu vaccine cannot prevent:
• flu that is caused by a virus not covered by the vaccine, or
• illnesses that look like flu but are not.

It takes about 2 weeks for protection to develop after vaccination, and protection lasts through the flu season.

3 Some people should not get this vaccine

Some people should not get LAIV because of age, health conditions, or other reasons. Most of these people should get an injected flu vaccine instead. Your healthcare provider can help you decide.

Tell the provider if you or the person being vaccinated:
• have any allergies, including an allergy to eggs, or have ever had an allergic reaction to an influenza vaccine.
• have ever had Guillain-Barré Syndrome (also called GBS).
• have any long-term heart, breathing, kidney, liver, or nervous system problems.
• have asthma or breathing problems, or are a child who has had wheezing episodes.
• are pregnant.
• are a child or adolescent who is receiving aspirin or aspirin-containing products.
• have a weakened immune system.
• will be visiting or taking care of someone, within the next 7 days, who requires a protected environment (for example, following a bone marrow transplant).
Sometimes LAIV should be delayed. Tell the provider if you or the person being vaccinated:
1. are not feeling well. The vaccine could be delayed until you feel better.
2. have gotten any other vaccines in the past 4 weeks. *Live* vaccines given too close together might not work as well.
3. have taken influenza antiviral medication in the past 48 hours.
4. have a very stuffy nose.

### Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get LAIV do not have any problems with it. Reactions to LAIV may resemble a very mild case of flu.

**Problems** that have been reported following LAIV:

*Children and adolescents 2-17 years of age:*
- runny nose/nasal congestion
- cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain, vomiting, or diarrhea

*Adults 18-49 years of age:*
- runny nose/nasal congestion
- sore throat
- cough
- chills
- tiredness/weakness
- headache

**Problems that could happen after any vaccine:**
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very small chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: [www.cdc.gov/vaccinesafety/](http://www.cdc.gov/vaccinesafety/)

### What if there is a serious reaction?

**What should I look for?**
- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

**What should I do?**
- If you think it is a severe allergic reaction or other emergency that can’t wait, call 9-1-1 and get the person to the nearest hospital. Otherwise, call your doctor.
- Reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at [www.vaers.hhs.gov](http://www.vaers.hhs.gov), or by calling 1-800-822-7967.

VAERS does not give medical advice.

### The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation). There is a time limit to file a claim for compensation.

### How can I learn more?
- Ask your healthcare provider. He or she 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 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC’s website at [www.cdc.gov/flu](http://www.cdc.gov/flu)

Vaccine Information Statement

Live Attenuated Influenza Vaccine

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