

## Vaccine Information Statement

### **Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know 2014-15**

#### **1. Why get vaccinated?**

Influenza (“flu”) is a contagious disease that spreads around the United States every winter, 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, but the risk of getting flu is highest among children. Symptoms come on suddenly and may last several days. They can include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Flu can make some people much sicker than others. These people include young children, people 65 and older, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease, nervous system disorders, or a weakened immune system. Flu vaccination is especially important for these people, and anyone in close contact with them.

Flu can also lead to pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children.

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

**Flu vaccine** is the best protection against flu and its complications. Flu vaccine also helps prevent spreading flu from person to person.

#### **2. Inactivated and recombinant flu vaccines**

You are getting an injectable flu vaccine, which is either an “**inactivated**” or “**recombinant**” vaccine. These vaccines do not contain any live influenza virus. They are given by injection with a needle, and often called the “flu shot.”

A different, **live, attenuated** (weakened) influenza vaccine is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

Flu vaccination is recommended every year. Some children 6 months through 8 years of age might need two doses during one year.

Flu viruses are always changing. Each year's flu vaccine is made to protect against 3 or 4 viruses that are likely to cause disease that year. Flu vaccine cannot prevent all cases of flu, but it is the best defense against the disease.

It takes about 2 weeks for protection to develop after the vaccination, and protection lasts several months to a year.

Some illnesses that are not caused by influenza virus are often mistaken for flu. Flu vaccine will not prevent these illnesses. It can only prevent influenza.

Some inactivated flu vaccine contains a very small amount of a mercury-based preservative called thimerosal. Studies have shown that thimerosal in vaccines is not harmful, but flu vaccines that do not contain a preservative are available.

### **3. Some people should not get this vaccine**

Tell the person who gives you the vaccine:

- **If you have any severe, life-threatening allergies.** If you ever had a life-threatening allergic reaction after a dose of flu vaccine, or have a severe allergy to any part of this vaccine, including (for example) an allergy to gelatin, antibiotics, or eggs, you may be advised not to get vaccinated. Most, but not all, types of flu vaccine contain a small amount of egg protein.
- **If you ever had Guillain-Barré Syndrome** (a severe paralyzing illness, also called GBS). Some people with a history of GBS should not get this vaccine. This should be discussed with your doctor.
- **If you are not feeling well.** It is usually okay to get flu vaccine when you have a mild illness, but you might be advised to wait until you feel better. You should come back when you are better.

### **4. Risks of a vaccine reaction**

With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own.

#### **Problems that could happen after any vaccine:**

- Brief fainting spells can happen after any medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Severe shoulder pain and reduced range of motion in the arm where a shot was given can happen, very rarely, after a vaccination.
- Severe allergic reactions from a vaccine are very rare, estimated at less than 1 in a million doses. If one were to occur, it would usually be within a few minutes to a few hours after the vaccination.

**Mild problems** following inactivated flu vaccine:

- soreness, redness, or swelling where the shot was given
- hoarseness
- sore, red or itchy eyes
- cough
- fever
- aches
- headache
- itching
- fatigue

If these problems occur, they usually begin soon after the shot and last 1 or 2 days.

**Moderate problems** following inactivated flu vaccine:

- Young children who get inactivated flu vaccine and pneumococcal vaccine (PCV13) at the same time may be at increased risk for seizures caused by fever. Ask your doctor for more information. Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

Inactivated flu vaccine does not contain live flu virus, so you cannot **get the flu from this vaccine**.

## **5. 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 behavior changes.

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 usually 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.
- Afterward, the reaction 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.*

## **6. 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.

#### **7. How can I learn more?**

- Ask your health care provider.
- 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 (Interim)

Inactivated Influenza Vaccine

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