



## Influenza Virus Vaccine Consent 2019-2020 – Fluzone High-Dose

**This vaccine is a "trivalent" vaccine and is made to protect against three flu viruses.** It is an inactivated (killed) vaccine and is formulated to contain HA of each of the following three influenza strains recommended for the 2019-2020 influenza season: A/Brisbane/02/2018 IVR-190 (H1N1), A/Kansas/12/2017 X-327 (H3N2), and B/Maryland/15/2016 BX-69A (a B/Colorado/6/2017 like virus, B Victoria Lineage) The prefilled syringes are **NOT** formulated with preservative. The rubber tip cap and plunger were NOT made with natural rubber latex. Fluzone High Dose is approved for use in persons 65 years or older.

**Why should people get vaccinated against the flu?** Influenza is a serious disease that can lead to hospitalization and sometimes even death. Every flu season is different, and influenza infection can affect people differently. Even healthy people can get very sick from the flu and spread it to others. Over a period of 31 seasons between 1976 and 2007, deaths associated with the flu, in the US, range from a low of about 3,000 to a high of about 49,000. During recent flu seasons, between 80% and 90% of flu related deaths have occurred in people 65 years and older. "Flu season" in the US can begin as early as October and last as late as May. An annual seasonal flu vaccine is the best way to reduce the chances that you will get seasonal flu and spread it to others. When more people get vaccinated against the flu, less flu can spread through that community thereby protecting those at high risk of developing flu complications or death.

**Can this vaccine cause the flu?** Fluzone High Dose is an inactivated vaccine that cannot cause influenza but stimulates the immune system to produce antibodies that protect against influenza.

**When will I be protected from the flu?** The full effect of the vaccine is generally achieved approximately 3 weeks after vaccination.

**What are the risks from an inactivated influenza vaccine?** A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small. Serious problems from inactivated influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine. The most common adverse reactions for adults 18 – 64 include tenderness (≥60%), pain (≥40%), swelling (≥20%), and redness, itching (≥10%). The most common systemic adverse events were muscle aches (≥30%) and headache, malaise (≥20%).

Immunocompromised persons may have a diminished immune response to Fluzone: Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot. In 1976, a type of inactivated influenza (swine flu) vaccine was associated with Guillain-Barre Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated which is much lower than the risk of severe influenza, which can be prevented. Signs of a severe allergic reaction can include difficult breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heartbeat or dizziness. If so, contact a doctor immediately or call 911.

**Who should get vaccinated this season?** Everyone 6 months of age and older should get a flu vaccine every season. This recommendation has been in place since 2010 when the US expanded protection against the flu to more people to create herd immunity to help prevent influenza for those who are at high risk of serious complications from influenza. Persons at risk include those who are 65 yrs and older, those with asthma, diabetes, heart disease, HIV or cancer.

**Who Should Not Be Vaccinated?** Anyone with severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine including egg protein, or to a previous dose of any influenza vaccine should NOT be vaccinated in a flu clinic setting.

**Does this vaccine contain thimerosal?** This prefilled inactivated influenza vaccine contains **NO** thimerosal or other preservative or natural rubber latex.

**Do you have or have you ever had a/an:**

- History of fainting after blood draws or injections?  Y  N
- Guillain-Barre syndrome in the last 6 weeks  Y  N
- Severe (life-threatening) allergies, including a severe allergy to eggs, or any vaccine component?  Y  N
- Are you moderately or severely ill ( > 102 fever):  Y  N

I have read the above information and understand the benefits and risks of the flu vaccine as described. I have answered all questions. I have received the Vaccine Information Sheet (8-7-15). I request that the vaccine be given to:

Print Name

Your Signature

Employee #

Date

Please report any severe or unusual adverse reactions to HSD at Ext 22475.

**HSD USE ONLY**

Give Fluzone High Dose Vaccine 0.5 IM.

Sanofi Pasteur Lot #UJ268AB – Expiration – May 10, 2020

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Rick Watts, M.D.

Provider Signature

9/29/2019  
Date

Date

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

Many Vaccine Information Statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

## 1 Why get vaccinated?

**Influenza vaccine** can prevent **influenza (flu)**.

**Flu** is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it 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 of flu complications.

Pneumonia, bronchitis, sinus infections and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

Each year **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

## 2 Influenza vaccine

CDC recommends everyone 6 months of age and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

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

Influenza vaccine **does not cause flu**.

Influenza vaccine may be given at the same time as other vaccines.

## 3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**.
- Has ever had **Guillain-Barré Syndrome** (also called GBS).

In some cases, your health care provider may decide to postpone influenza vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

## 4 Risks of a vaccine reaction

- Soreness, redness, and swelling where shot is given, fever, muscle aches, and headache can happen after influenza vaccine.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

Young children who get the flu shot along with pneumococcal vaccine (PCV13), and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

## 5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do 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. Visit the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) or call **1-800-338-2382** to learn about the program and about filing a claim. There is a time limit to file a claim for compensation.

## 7 How can I learn more?

- Ask your healthcare 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 [www.cdc.gov/flu](http://www.cdc.gov/flu)

Vaccine Information Statement (Interim)  
**Inactivated Influenza  
Vaccine**



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