

2009 H1N1 INFLUENZA VACCINE

INACTIVATED

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 What is 2009 H1N1 influenza?

2009 H1N1 influenza (which was earlier called Swine Flu) is a type of flu caused by a new strain of influenza virus. Because it has spread to many countries, it has been declared a pandemic influenza strain.

Like other flu viruses, 2009 H1N1 spreads from person to person through coughing, sneezing, nasal secretions, and sometimes through handling objects contaminated with the virus.

Signs of 2009 H1N1 can include:

- Fatigue
- Fever
- Sore Throat
- Muscle Aches
- Chills
- Coughing
- Sneezing

Some people also have diarrhea and vomiting.

Most people recover within a week. But some people get pneumonia or other serious illnesses. Some people have to be hospitalized and some die.

2 How is 2009 H1N1 different from regular (seasonal) flu?

Seasonal flu viruses change from year to year, but they are closely related to each other.

People who have had prior flu infections usually have some immunity to seasonal flu viruses.

The 2009 H1N1 flu virus is a new virus strain. It is very different from seasonal flu viruses.

Most people have little or no immunity to 2009 H1N1 flu.

3 2009 H1N1 influenza vaccine

Vaccines are being made to protect against 2009 H1N1 influenza.

- These vaccines are produced just like seasonal flu vaccines.
- They are expected to be as effective as seasonal flu vaccines.

- They will not prevent “influenza-like” illnesses caused by other viruses.
- They will not prevent seasonal flu. *You should also get seasonal influenza vaccine, if recommended.*

Inactivated (killed) vaccine is injected into the muscle, like the annual flu shot. **This statement describes the inactivated vaccine.**

A **live, intranasal** vaccine is also available. It is described in a separate statement.

Some inactivated H1N1 vaccine contains a preservative called thimerosal. While some people have suggested that thimerosal may be related to developmental problems in children, that theory has not been supported by research. Thimerosal-free vaccine is also available.

4 Who should get 2009 H1N1 influenza vaccine and when?

WHO

Groups recommended to receive 2009 H1N1 vaccine first are:

- Pregnant women
- People who live with or care for infants younger than 6 months of age
- Health care and emergency personnel
- Anyone from 6 months through 24 years of age
- Anyone from 25 through 64 with certain chronic medical conditions or a weakened immune system

These groups should also be vaccinated:

- Healthy 25-64 year olds
- Adults 65 and older

WHEN

Get vaccinated as soon as the vaccine is available.

Recommendations may change if we learn that other groups of people are at particularly high risk.

Some people may need **two doses** of vaccine.

5 Some people should not get the vaccine or should wait

You should not get 2009 H1N1 flu vaccine if you have a **severe (life-threatening) allergy** to **eggs**, or to **any other substance in the vaccine**. *Tell the person giving you the vaccine if you have any severe allergies.*

Also tell them if you have ever had:

- a life-threatening allergic reaction after a dose of seasonal flu vaccine,
- Guillain Barré Syndrome (a severe paralytic illness also called GBS).

These may not be reasons to avoid the vaccine, but the medical staff can help you decide.

If you are moderately or severely ill, you might be advised to wait until you recover before getting the vaccine. If you have a mild cold or other illness, there is usually no need to wait.

Pregnancy or breastfeeding are *not* reasons to avoid getting 2009 H1N1 flu vaccine.

2009 H1N1 vaccine may be given at the same time as other vaccines, including seasonal influenza vaccine.

6 What are the risks from 2009 H1N1 influenza vaccine?

A vaccine, like any medicine, could cause a serious problem, such as a severe allergic reaction. But the risk of any vaccine causing serious harm, or death, is extremely small.

The virus in inactivated 2009 H1N1 vaccine has been killed, so you cannot get influenza from the vaccine.

The risks from 2009 H1N1 vaccine are expected to be similar to those from seasonal flu vaccine:

Mild problems:

- soreness, redness, tenderness, or swelling where the shot was given
- fainting (mainly adolescents)
- headache, muscle aches
- fever
- nausea

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

Severe problems:

- Life-threatening allergic reactions to vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- In 1976, an earlier type of swine flu vaccine was associated with cases of Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS.

7 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe 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** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

8 Vaccine injury compensation

The Federal government is providing this vaccine for receipt on a voluntary basis. However, state law or employers may require vaccination for certain persons.

If you or your child has a reaction to the vaccine, your ability to sue is limited by law.

However, a federal program has been created to help pay for the medical care and other specific expenses of certain persons who have a serious reaction to this vaccine. For more information about this program, call 1-888-275-4772 or visit the program's website at www.hrsa.gov/countermeasurescomp/default.htm.

9 How can I learn more?

- Ask your 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 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/h1n1flu or www.cdc.gov/flu
- Visit the web at www.flu.gov



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Vaccine Information Statement (Pre-Licensure)
2009 H1N1 Influenza Vaccine

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