

## Vaccines, Blood & Biologics

### Influenza A (H1N1) 2009 Monovalent Vaccines Questions and Answers

#### *Provide Protection Against Influenza Disease Caused by Pandemic (H1N1) 2009 Virus*

September 15, 2009

#### **What is the U.S. Food and Drug Administration (FDA) announcing?**

FDA has approved supplements to existing vaccine licenses to protect against the pandemic (H1N1) 2009 influenza virus. The Influenza A (H1N1) 2009 Monovalent vaccines contains an A/California/7/09-like virus. [Information on the Influenza A \(H1N1\)2009 Monovalent Vaccine approvals.](#)

#### **Is this vaccine part of the seasonal influenza vaccine that is recommended every year?**

No, this is a stand-alone monovalent vaccine and is separate from the seasonal influenza vaccine.

#### **Will the seasonal influenza vaccine provide protection against the 2009 H1N1 influenza virus?**

No. Although the currently licensed seasonal trivalent influenza vaccines contain an H1N1 subtype, their subtype differs from the 2009 H1N1 influenza virus, which is a new virus strain that has never before circulated among humans. The 2009 H1N1 influenza virus is not the same as previous or current human seasonal influenza viruses and seasonal influenza vaccine does not provide protection against the 2009 H1N1 influenza virus.

#### **Do I still need to get the seasonal influenza vaccine?**

Yes, it is still important that those individuals for whom seasonal influenza vaccine is recommended receive it. According to the U.S. Centers for Disease Control and Prevention (CDC), between 5 and 20 percent of the U.S. population are infected with seasonal influenza each year. More than 200,000 people are hospitalized from its complications and about 36,000 people die. Vaccination is the best protection against influenza and can prevent many illnesses and deaths. Since influenza viruses change almost every season, there is always a possibility of a less than optimal match between the vaccine and the virus strains that end up causing the most illness. However, even if the vaccine and the circulating strains are not an exact match, the vaccine may reduce the severity of the illness or may help prevent influenza-related complications.

## **What information did FDA use to support approval of the Influenza A (H1N1) 2009 Monovalent influenza vaccines?**

Vaccines used in the United States must be licensed by FDA. FDA approved these vaccines as a strain change to each manufacturer's FDA-approved seasonal influenza vaccine. Each of the manufacturers will make the Influenza A (H1N1) 2009 Monovalent vaccines using its well-established, licensed egg-based manufacturing process that is used for seasonal influenza vaccine.

There is considerable experience with seasonal influenza vaccine development and production and influenza vaccines produced by this technology have a long and successful track record of safety and effectiveness in the United States. The safety and effectiveness demonstrated for seasonal influenza vaccine also support the licensure of the Influenza A (H1N1) 2009 Monovalent vaccines produced using the same process as for seasonal vaccine.

Clinical studies of the Influenza A (H1N1) 2009 Monovalent vaccines are ongoing. FDA will be assessing information from these studies to determine the optimal dose of the vaccine based on immunogenicity data (the levels of antibodies produced).

The Influenza A (H1N1) 2009 Monovalent vaccines will undergo the same rigorous testing and lot release procedures that are in place for seasonal influenza vaccines.

## **Does FDA know at this time how many doses individuals should receive?**

Currently available data suggest that children 6 months to 9 years of age have little or no evidence of protective antibodies to the pandemic (H1N1) 2009 virus (MMWR 2009; 58(19) 521-524, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5819a1.htm>). Based on these data, children 9 years of age and younger should be administered 2 doses of the monovalent pandemic (H1N1) 2009 virus vaccine. Adults should be administered 1 dose, as should children and adolescents 10 years of age and older, as we expect that they will respond similarly to adults. Clinical studies are underway and will provide additional information about the optimal number of doses.

## **Will the vaccine be available with and without a preservative?**

Yes. As with the seasonal influenza vaccines, the Influenza A (H1N1) 2009 Monovalent vaccines will be available in formulations that contain thimerosal, a mercury-containing preservative, as well as preservative-free formulations.

## **Is thimerosal safe when used as a preservative in vaccines?**

Yes. A high standard of safety is expected by FDA. We are aware of the concerns that some people have regarding thimerosal in vaccines. The vast majority of research conducted in the U.S. and around the world does not support an association between thimerosal in vaccines and autism. Since 2001, no new vaccine licensed by FDA for use in children has contained thimerosal as a preservative, and all vaccines routinely recommended by CDC for children under six years of age have been thimerosal-free, or contain only trace amounts, except for some formulations of influenza vaccine.

## **Are the Influenza A (H1N1) 2009 Monovalent vaccines safe?**

The Influenza A (H1N1) 2009 Monovalent vaccines are manufactured and tested using the same processes used for the seasonal vaccine. Many millions of doses of seasonal vaccine have been distributed every year for many years, and seasonal vaccines have a well-established safety profile. As for seasonal vaccines, safety will also be monitored as part of the vaccination program (see below).

## **What are the expected side effects of the Influenza A (H1N1) 2009 Monovalent vaccines?**

The expected side effects will be similar to those of the seasonal vaccine, potentially including a mild fever, body aches, and fatigue for a few days after the vaccine, and soreness at the injection site. The most common side effects seen with administration of the nasal vaccine include runny nose or nasal congestion in recipients of all ages, fever more than 100 degrees Fahrenheit in children two to six years of age, and sore throat in adults. As with any medical product, serious adverse events may occur. People who have a severe (life-threatening) allergy to chicken eggs or to any other substance in the vaccine should not be vaccinated.

## **How will the Influenza A (H1N1) 2009 Monovalent vaccines be monitored for safety?**

FDA and CDC will closely monitor the safety of the Influenza A (H1N1) 2009 vaccines. FDA is collaborating with CDC, HHS, and other government agencies to enhance the capacity for adverse event safety monitoring during and after the Influenza A (H1N1) 2009 vaccination program. Efforts are underway to establish a robust network to share information in real-time. The network will build on the well established Vaccine Adverse Event Reporting System and Vaccine Safety Datalink by integrating capabilities from the Department of Defense, the Department of Veterans Affairs, the Center for Medicare and Medicaid Services, State, Territorial, Tribal, and local public health and medical, and private sector healthcare entities. FDA is also engaged with international regulatory partners on pharmacovigilance planning efforts.

## **What makes up the Influenza A (H1N1) 2009 Monovalent vaccines?**

The Influenza A (H1N1) 2009 monovalent vaccines are manufactured using the same approved processes used to produce the seasonal influenza vaccines. Ingredients used during the manufacture of influenza vaccines include substances to help prevent bacterial contamination, to inactivate or "kill" the viruses, and stabilizers to prevent the vaccine from changing. Vaccines that are packaged in multi-dose vials use a preservative to prevent contamination.

The Influenza A (H1N1) 2009 Monovalent vaccines are made from a single influenza virus strain that is an A/California/7/09-like virus. For the injectible vaccines, or shots, the virus is inactivated, using the same processes the manufacturers use for seasonal influenza vaccines. The vaccine administered via nasal spray contains a live, attenuated virus.

People who have a severe (life-threatening) allergy to chicken eggs, or to any other

substance in the vaccine, should not be vaccinated.

### **When will the vaccine be available?**

Although approved by FDA, initial lots of the vaccines may not be immediately available until the end of September to mid-October, when manufacturers complete production and testing.

### **What can be done to prevent getting infected with the 2009 H1N1 influenza virus?**

- Cover your nose and mouth with a tissue when you cough or sneeze. Throw the tissue in the trash after you use it.
- If a tissue is not available cough or sneeze into your elbow.
- Wash your hands often with soap and water, especially after you cough or sneeze. You should wash your hands as long as it takes to sing "Happy Birthday" twice.
- Avoid touching your eyes, nose or mouth. Germs spread this way.
- Try to avoid close contact with sick people.

### **Key Resources**

- [Influenza A \(H1N1\) 2009 Monovalent](#)
- [Influenza A \(H1N1\) 2009 Monovalent Vaccines Composition and Lot Release](#)
- [Influenza A \(H1N1\) 2009 Monovalent Vaccine Safety Monitoring](#)
- [FDA Approves Vaccines for 2009 H1N1 Influenza Virus](#)
- [2009 H1N1 \(Swine\) Flu Virus \(Biologics\)](#)
- [FDA 2009 H1N1 \(Swine\) Flu Page](#)

### **Key Links**

- [Serum Cross-Reactive Antibody Response to a Novel Influenza A \(H1N1\) Virus After Vaccination with Seasonal Influenza Vaccine \(MMWR\)](#)
- [Flu.gov](#)
- [CDC H1N1 Flu Page](#)

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