

Information for Parents about the 2009 H1N1 Influenza Nasal Spray Vaccine

What is the H1N1 influenza nasal spray vaccine?

The H1N1 nasal spray flu vaccine (sometimes called LAIV for Live Attenuated Influenza Vaccine) is a vaccine made with live, weakened viruses that cannot grow at normal body temperature. The vaccine is given by squirting a little fluid into each nostril. Children and adults like this vaccine because no needles are involved. The H1N1 nasal spray influenza vaccine is approved for prevention of the 2009 H1N1 flu, also known as “swine flu”.

The other type of H1N1 influenza vaccine is the inactivated or killed virus vaccine given as a shot or injection.

Who can get the nasal spray flu vaccine?

Healthy children, adolescents, and adults 2 through 49 years of age who are not pregnant may receive the nasal spray vaccine.

What is a “live virus” vaccine?

A live virus vaccine is a vaccine made from a virus that has been weakened so that it cannot cause illness; but the virus will still be recognized by the immune system and stimulate the body to produce protective antibodies.

Is the live virus H1N1 flu vaccine safe?

The live virus H1N1 flu vaccine is considered to be a safe vaccine option. The safety of the H1N1 nasal spray vaccine was studied in clinical trials before it was licensed and no serious side effects occurred.

Studies of the regular nasal spray vaccine for prevention of seasonal flu found a slightly increased risk for wheezing in children less than 2 years of age and for hospitalization of children with asthma who received the vaccine. Due to these findings, the H1N1 nasal spray vaccine is not licensed for children under 2 years of age and is not intended for use in children younger than five years who have wheezing or people of any age who have asthma. Children in these groups should receive the inactivated vaccine instead of the nasal spray vaccine.

Is this a “new” or “experimental” vaccine?

No, this is not a new or experimental vaccine. The only part of this vaccine that is ‘new’ is the strain of influenza virus that it protects against, which is the 2009 H1N1 strain. When this new strain of H1N1 was identified in April of this year, it was too late to include in the regular flu vaccine.

The H1N1 vaccine is made using the same methods and production facilities as the regular nasal spray flu vaccine.

The regular nasal spray vaccine was first approved in 2003 to provide protection against seasonal influenza viruses as the brand, FluMist®. Tens of millions of doses of FluMist® have been given in the U.S. since then and the safety of the vaccine is monitored continually.

How many doses of the H1N1 flu nasal spray vaccine do children need?

Children under 10 years will need two doses of the vaccine given at least 4 weeks apart. This gives the immune system time to respond to the first dose. Children 10 years of age and older, adolescents, and adults need only one dose of the vaccine.

Is it safe to receive other vaccines at the same time?

Yes, it is safe to receive other injectable vaccines at the same visit as the H1N1 nasal spray vaccine. Our immune systems are capable of responding to many viruses and bacteria at the same time on a daily basis.

However, the live seasonal flu vaccine should not be given on the same day-- not because of safety concerns, but because the vaccines might not work as well if they are given on the same day. These two vaccines should be given at least 4 weeks apart.

If a child needs to receive two live virus vaccines, such as H1N1 nasal spray and MMR or varicella, the vaccines should be given on the same day or separated by at least 4 weeks. This is why it is important for parents to keep a record of their children’s vaccinations and take it with them every time they go to a clinic.

If my child is healthy but will be around children with asthma, should they receive the H1N1 nasal spray vaccine?

Yes, they will not pose a health risk to siblings, classmates or friends who have asthma. Asthmatic children are advised not to receive the nasal spray vaccine because the administration of the vaccine may irritate and inflame the upper airway and trigger a serious wheezing or asthmatic episode. This precaution has nothing to do with the live virus component of the vaccine or being in close contact with someone who has recently received the nasal spray vaccine.

Who should not receive the nasal spray flu vaccine?

The nasal spray H1N1 flu vaccine should not be given to children or adults with any of the following:

- A history of severe allergic reactions to eggs, egg proteins, gentamicin (an antibiotic), gelatin, or arginine (an amino acid);
- A severe allergic reaction to a previous dose of influenza vaccine
- Children 2 through 4 years of age who have had one or more episodes of wheezing within the past year.
- Any of the following health problems:
 - Heart disease
 - Lung disease, including asthma
 - Kidney disease
 - Liver disease
 - Weakened immune system
 - Diabetes
 - Muscle or nerve disorders such as seizure disorders, spinal cord injury, or cerebral palsy that can cause breathing or swallowing problems
- Children and adolescents receiving aspirin or aspirin-containing therapy
- Children less than 2 years of age
- Anyone who is pregnant.

Most of the groups listed above should receive the inactivated, injectable flu vaccine. Persons with allergies to eggs or egg proteins, or a previous history of a severe allergic reaction following a flu vaccine may not be able to get a flu shot.

If you or your child has had Guillain-Barré syndrome (a severe paralytic illness also called GBS) within the 6 weeks following a previous dose of influenza vaccine, you should talk to a doctor about whether or not you or your child should receive any flu vaccine, live or inactivated.

Can the H1N1 live flu vaccine virus be transmitted to other people?

Yes, very rarely the vaccine virus can be transmitted to other people through respiratory droplets the same way that the “wild” influenza virus is transmitted. This is called “shedding”. However, the virus in the live H1N1 vaccine is shed in small quantities so transmission is very rare. Also, the vaccinated person is shedding the weakened, cold-adapted flu virus that doesn’t cause influenza illness.

How long can a person shed the vaccine virus?

Most people shed the vaccine virus for about a week, although the time period can be 3 to 4 days shorter or longer than that average length of time.

Transmission of the vaccine virus is a concern only if there is a possibility of transmission to a severely immunocompromised person. An example of this

would be someone who has just received a bone marrow transplant and is hospitalized in a special “bubble” environment.

If my child receives a nasal spray vaccine, should they stay away from people who have cancer or other medical conditions that suppress the immune system?

No, even though there is a very small risk for the nasal spray vaccine virus to be transmitted from the person who received the vaccine to other people, such a small number of virus particles are shed that there are not enough to infect another person. Only in those rare situations where a person has such a suppressed immune system that they need to be in a protected environment is it necessary to separate them from someone who received a live virus flu vaccine for 7 days.

It is important to note that there have been no documented reports of a nasal spray vaccine virus being shed to another person resulting in illness.

Does someone who just got a dose of the nasal spray vaccine need to stay away from young babies less than 6 months old?

No, even though there is a very small risk of the vaccine virus being transmitted to the baby, the vaccine virus is made so it will not cause illness. The risk of the baby catching influenza from someone who has not been vaccinated is much higher. People with H1N1 flu are contagious for up to 24 hours before they know they have the flu and for as long as they have symptoms. Young children might be contagious for even longer.

To protect babies less than 6 months old from influenza, all household members and caregivers are recommended to receive both the seasonal flu vaccine and the 2009 H1N1 flu vaccine.

What are the side effects of the nasal spray vaccine?

The most common side effects are runny nose or nasal congestion, sore throat, and low-grade fever. These symptoms are much milder than the flu itself and last only one or two days.

Does the H1N1 nasal spray vaccine contain thimerosal?

No, thimerosal is not an ingredient in either the live H1N1 flu vaccine or the seasonal flu nasal spray vaccine. Several inactivated (injectable) flu vaccines are also thimerosal-free.