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Fluzone High-Dose Seasonal Influenza Vaccine

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This document provides information on the new Fluzone High-Dose seasonal influenza vaccine.

What is Fluzone High-Dose influenza vaccine?

Fluzone High-Dose is a new influenza vaccine, manufactured by Sanofi Pasteur Inc., designed specifically for people 65 years and older.

What is the difference between Fluzone, Fluzone High-Dose, and Fluzone Intradermal?

Fluzone, Fluzone High-Dose, and Fluzone Intradermal are all injectable influenza vaccines, made up of the 3 flu strains most likely to cause illness for that particular flu season, to protect people from influenza. Fluzone High-Dose vaccines contain 4 times the amount of antigen (the part of the vaccine that prompts the body to make antibody) contained in regular flu shots. The additional antigen is intended to create a stronger immune response (more antibody) in the person getting the vaccine.

Fluzone Intradermal was licensed by the FDA for use in the United States for the 2011-2012 flu season. The intradermal flu vaccine is a shot that is injected into the skin instead of the

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muscle. The intradermal shot uses a much smaller needle than the regular flu shot, and it requires less antigen to be as effective as the regular flu shot. It is recommended for adults 18-64 years of age.

Why is a higher dose vaccine available for adults 65 and older?

Human immune defenses become weaker with age, which places older people at greater risk of severe illness from influenza. Also, ageing decreases the body's ability to have a good immune response after getting influenza vaccine. A higher dose of antigen in the vaccine is supposed to give older people a better immune response and therefore better protection against flu.

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Does the higher dose vaccine produce a better immune response in adults 65 years and older?

Data from clinical trials comparing Fluzone to Fluzone High-Dose among persons aged 65 years or older indicate that a stronger immune response (i.e. higher antibody levels) occurs after vaccination with Fluzone High-Dose. Whether or not the improved immune response leads to greater protection against influenza disease after vaccination is not yet known. An ongoing study designed to determine the effectiveness of Fluzone High-Dose in preventing illness from influenza compared to Fluzone is expected to be completed in 2014-2015.

Is Fluzone High-Dose safe?

The safety profile of Fluzone High-Dose vaccine is similar to that of regular flu vaccines, although adverse events (which are also reported after regular flu vaccines) were reported more frequently after vaccination with Fluzone High-Dose. The most common adverse events experienced during clinical studies were mild and temporary and included pain, redness and swelling at the injection site and headache, muscle aches, fever and malaise. Most people had minimal or no adverse events after receiving the Fluzone High-Dose vaccine.

Who can get this vaccine?

Fluzone High-Dose is approved for use in people 65 years of age and older. As with all flu vaccines, Fluzone High-Dose is not recommended for people who have had a severe reaction to the flu vaccine in the past.

Does CDC recommend one vaccine above another for people 65 and older?

CDC and the Advisory Committee on Immunization Practices (ACIP) recommends flu vaccination as the first and most important step in protecting against the flu, however, neither CDC nor ACIP is expressing a preference of one vaccine over another at this time.

How is the Fluzone High-Dose vaccine available?

This vaccine is approved for marketing in 0.5 mL preservative-free, single dose, prefilled syringes.

Where can I find more information about Fluzone High-Dose?

More information about [Fluzone High-Dose](#)  is available on the Food and Drug Administration (FDA) web site.

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