

Fluzone[®] Intradermal (Influenza Virus Vaccine) Facts at a Glance

About Fluzone Intradermal Vaccine

Fluzone Intradermal vaccine is the first influenza vaccine licensed in the United States that uses a new microinjection system for intradermal delivery of vaccine.¹

Fluzone Intradermal vaccine is indicated for active immunization of persons 18 through 64 years of age against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.¹

The microinjection system uses an ultra-thin needle of 0.06 inches (1.5 mm) in length, or less than one-tenth the length of the standard needles used for the traditional intramuscular route of administration.¹

Fluzone Intradermal vaccine is supplied as a single-dose, preservative-free, prefilled syringe.¹

Sanofi Pasteur already has licensed a microinjection system influenza vaccine marketed as Intanza or ID flu[®] in more than 40 countries including Australia, Canada, and countries in Europe.¹

About Intradermal Microinjection

Intradermal vaccination delivers the vaccine into the dermal layer of the skin. The dermal layer contains a high concentration of specialized cells, known as dendritic cells, which play a key role in generating an immune response.¹

Fluzone vaccine contains 15 mcg of hemagglutinin per strain of influenza in a 0.5 mL dose. Fluzone Intradermal vaccine contains 9 mcg of hemagglutinin per strain of influenza in a 0.1 mL dose.

Fluzone Intradermal Vaccine Availability

Fluzone Intradermal vaccine will be available to health-care providers this fall for immunizations administered during the upcoming 2011-2012 influenza season.¹

Visit VaccineShoppe.com[®] for more information on ordering Fluzone Intradermal vaccine.¹

About Fluzone Intradermal Vaccine Clinical Trials

The safety and immunogenicity of Fluzone Intradermal vaccine in comparison to Fluzone vaccine has been evaluated in clinical trials featuring 4,276 adults 18 years through 64 years of age (2,855 participants received Fluzone Intradermal vaccine and 1,421 participants received Fluzone vaccine via intramuscular administration).¹

Fluzone Intradermal vaccine was shown in adults 18 through 64 years of age to provide an immune response similar (non inferior) to Fluzone vaccine administered via the intramuscular route. Hemagglutination inhibition antibody geometric mean titers (GMTs) were non-inferior to those following Fluzone for all three strains. Seroconversion rates following Fluzone Intradermal were non-inferior to those following Fluzone for both A strains but not for strain B.

Fluzone Intradermal vaccine is safe, with a comparable systemic reaction profile to the intramuscular vaccine. Intradermal microinjection deposits influenza vaccine near the surface of the skin; therefore, local reactions are more easily visible. In clinical trials, the most common solicited injection-site reactions reported in participants given the intradermal vaccine were erythema (redness) (>75%), swelling (>50%), induration (hardness) (>50%), pain (>50%), and pruritus (itching) (>40%). Injection-site and systemic

reactions with intradermal administration were transient, resolving in three to seven days without sequelae. The injection-site reactions were more frequent with participants given the intradermal vaccine compared to the intramuscular vaccine, with the exception of pain, which was similar.¹

Important Safety Information

The most common local and systemic adverse reactions to Fluzone Intradermal vaccine include erythema (redness), induration (hardness), swelling, pain, and pruritus (itching) at the vaccination site; headache, myalgia (muscle ache), and malaise. Other adverse reactions may occur. Fluzone Intradermal vaccine should not be administered to anyone with a severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine, including egg protein, or to a previous dose of any influenza vaccine. The decision to give Fluzone Intradermal vaccine should be based on the potential benefits and risks, especially if Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine. Vaccination with Fluzone Intradermal vaccine may not protect all individuals.

Before administering Fluzone Intradermal vaccine or Fluzone vaccine, please see full Prescribing Information available at www.sanofipasteur.us or www.vaccineshoppe.com.

About Influenza

Influenza is a serious respiratory illness that is easily spread and can lead to severe complications, even death.^{3,4}

Each year in the U.S., 5 to 20 percent of the population gets the flu and an average of 226,000 people are hospitalized from flu-related complications.⁵

Depending on virus severity during the influenza season, deaths can range from 3,000 to a high of about 49,000 people.⁵

— Combined with pneumonia, influenza is the nation's eighth leading cause of death.⁶

References

1. Fluzone Intradermal vaccine [Prescribing Information]. Swiftwater, PA: Sanofi Pasteur Inc.; 2011.
2. Nestle FO, Nickoloff BJ. Deepening our understanding of immune sentinels in the skin. *The Journal of Clinical Investigation*. 2007;117:2382-2385.
3. Centers for Disease Control and Prevention (CDC). Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. *MMWR*. 2009;58(RR-8):1-52.
4. CDC. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2008. *MMWR*. 2008;57(RR-7):1-64.
5. CDC. Estimates of deaths associated with seasonal influenza . United States, 1976-2007. *MMWR*. 2010;59(33):1057-1062.
6. CDC. Deaths: Final data for 2006. National vital statistic reports. 2009. http://www.cdc.gov/nchs/data/nvsr/nvsr57/nvsr57_14.pdf. Accessed March 30, 2010.

###