

SANOFI PASTEUR, SEASONAL INFLUENZA LEADER FACT SHEET

WORLD'S LEADING SEASONAL INFLUENZA VACCINE MANUFACTURER

The Swiftwater site, today owned by Sanofi Pasteur and formerly the Pocono Biological Laboratories founded in 1897, created its first influenza vaccine in 1947.

After doubling its global vaccine production capacity over the past 10 years, Sanofi Pasteur now produces more than 220 million doses of seasonal influenza vaccine representing:

- approximately 40% of the global supply
- at least 60 million doses for the United States (US)
- more than one third of the Northern Hemisphere's supply
- and approximately 70% of the Southern Hemisphere's total supply.

Sanofi Pasteur's seasonal influenza vaccines are licensed and distributed in more than 150 countries.

- Sanofi Pasteur produces seasonal influenza vaccine in the US at the historic Swiftwater, Pennsylvania site and at sites in France, Mexico and China.
- All Sanofi Pasteur production sites are designed and built to standards that allow Sanofi Pasteur to switch from production of seasonal influenza vaccine to pandemic influenza vaccine.

SANOFI PASTEUR'S INNOVATIVE SEASONAL INFLUENZA VACCINES HELP SAVE LIVES

The 2014-2015 US influenza season was the most severe in recent history and preliminary data indicates at least 17,000 laboratory-confirmed influenza virus infections required hospitalization and more than 140 laboratory-confirmed, influenza-associated pediatric deaths.

As the world leader in the research, development and manufacturing of seasonal influenza vaccines, Sanofi Pasteur is developing new and innovative vaccines to help save lives. In the US, Sanofi Pasteur's seasonal influenza vaccines provide an influenza vaccine option for everyone six months and older and helps contribute to the Healthy People 2020 vaccination target.

- Fluzone® High-Dose was introduced in 2010 and is specially formulated for adults 65 years of age and older. As people age, the immune system weakens, which can put older adults at risk for influenza-related complications. Clinical data demonstrated that Fluzone High-Dose vaccine was 24.2% more effective than Fluzone vaccine in preventing laboratory-confirmed influenza caused by any influenza viral type or subtype in association with influenza-like illness, in adults 65 years of age and older. [Fluzone High-Dose Prescribing Information](#).

- In June 2013, the US FDA licensed Fluzone® Quadrivalent to help protect against four influenza strains (two A strains and two B strains). The influenza B strain is associated with high hospitalization and mortality rates, especially in children and young adults. Fluzone Quadrivalent vaccine is licensed for use in people six months of age and older. [Fluzone Quadrivalent Prescribing Information](#).

- In December 2014, the US FDA licensed Fluzone® Intradermal Quadrivalent vaccine for adults 18 through 64 years of age. Fluzone Intradermal Quadrivalent vaccine offers four-strain protection in a microinjection system that is convenient, efficient, and easy to use, allowing for streamlined administration by health care providers. The vaccine is administered directly into the skin through a 90% smaller, 1.5 mm microneedle. [Fluzone Intradermal Quadrivalent Prescribing Information](#).

SANOFI PASTEUR'S PANDEMIC PREPARATIONS AND RESPONSE

Influenza pandemics are a potential risk to global public health that could occur at any time and Sanofi Pasteur works closely with health authorities to monitor and prepare for potential pandemics.

The most recent pandemic occurred in 2009. To help health authorities address the A(H1N1) 2009 pandemic, Sanofi Pasteur worked 24/7 to produce more than 250 million doses of vaccine.

Sanofi Pasteur's response to the A(H1N1) 2009 pandemic demonstrated the flexibility of our influenza vaccine production capabilities and the ability to meet public health needs during the pandemic while simultaneously meeting our seasonal influenza vaccine commitments.

- Using facilities in the US and France, Sanofi Pasteur developed, produced and supplied the A(H1N1) monovalent pandemic flu vaccine in support of meeting the public health needs.
- In accordance with WHO and Health authorities' recommendations, Sanofi Pasteur produced and supplied the committed number of doses of seasonal influenza vaccines for the 2009-2010 Northern Hemisphere and the 2010 Southern Hemisphere influenza seasons.

The continuation of the seasonal flu vaccine production for the Northern and Southern Hemispheres in parallel of the pandemic vaccine production was a priority for the WHO and health authorities around the globe throughout the A (H1N1) 2009 pandemic.

SANOFI PASTEUR'S INFLUENZA VACCINE INVESTMENT & INNOVATION (RESEARCH AND DEVELOPMENT)

While Sanofi Pasteur stands at the forefront of innovation by developing new vaccines designed to provide improved protection against influenza, it is also actively exploring several leading universal influenza vaccine developments. The company seeks to develop innovative vaccines and technologies through internal and external collaborations. As Sanofi Pasteur explores the immune response to key protective antigens, this collaborative approach complements our existing and wide-ranging product line.

ADDITIONAL INFLUENZA RESOURCES

- Centers for Disease Control and Prevention (CDC). Influenza (Flu). <http://www.cdc.gov/flu/>.
- National Foundation for Infectious Diseases (NFID). Infectious Disease Information: Influenza (Flu). <http://www.nfid.org/idinfo/influenza>.
- World Health Organization (WHO). Global Influenza Programme. <http://www.who.int/influenza/en/>.

INDICATION

Fluzone Quadrivalent, Fluzone Intradermal Quadrivalent, and Fluzone High-Dose vaccines are given to help prevent influenza disease caused by influenza A and B strains contained in each vaccine.

Fluzone Quadrivalent vaccine is given to people 6 months of age and older. Fluzone Intradermal Quadrivalent vaccine is given to people 18 through 64 years of age. Fluzone High-Dose vaccine is given to people 65 years of age and older.

SAFETY INFORMATION

Side effects to Fluzone Quadrivalent, Fluzone Intradermal Quadrivalent, and Fluzone High-Dose vaccines include pain and swelling at the injection site (also itching in adults receiving Fluzone Intradermal Quadrivalent vaccine); muscle aches, fatigue, headache, and fever (also irritability, abnormal crying, drowsiness, appetite loss, and vomiting in young children receiving Fluzone Quadrivalent vaccine). Itching, redness, swelling, and firmness at the injection site occurred more frequently with Fluzone Intradermal vaccine (containing 3 influenza strains) than with Fluzone vaccine. Other side effects may occur.

Fluzone Quadrivalent, Fluzone Intradermal Quadrivalent, and Fluzone High-Dose, vaccines should not be administered to anyone with a severe allergic reaction (eg, anaphylaxis) to any vaccine component, including eggs, egg products, or thimerosal (the multidose vial is the only presentation containing thimerosal), or to a previous dose of any influenza vaccine.

Tell the doctor if you/your child has ever experienced Guillain-Barré syndrome (severe muscle weakness) after a previous dose of influenza vaccine. If you notice any other problems or symptoms following vaccination, please contact your health care professional immediately. Vaccination with Fluzone Quadrivalent, Fluzone Intradermal Quadrivalent, or Fluzone High-Dose vaccine may not protect all individuals.

For more information about [Fluzone Quadrivalent](#), [Fluzone Intradermal Quadrivalent](#), or [Fluzone High-Dose](#) vaccine, talk to your health care professional and see complete Patient Information.

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