

SANOFI PASTEUR: SEASONAL INFLUENZA LEADER

WORLD'S LEADING SEASONAL INFLUENZA VACCINE MANUFACTURER

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

After doubling its global vaccine production capacity over the past 10 years, Sanofi Pasteur now produces more than 200 million doses of seasonal influenza vaccine representing:

- approximately 40% of the global supply
- nearly 70 million doses for the United States (U.S.)
- 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 U.S. 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.

INNOVATIVE SEASONAL INFLUENZA VACCINES HELP SAVE LIVES

In the 2016-2017 season, the U.S. Centers for Disease Control and Prevention (CDC) estimated 30.9 million flu illnesses, 14.5 million flu-associated medical visits and more than 600,000 flu-associated hospitalizations. Additionally, in the same season, there was about 50,000 deaths associated with pneumonia and influenza and more than 110 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 U.S., Sanofi Pasteur's seasonal influenza vaccines provide an influenza vaccine option for persons 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 U.S. 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 August 2017, Sanofi Pasteur acquired Protein Sciences, that developed Flublok Quadrivalent vaccine by using recombinant DNA technology, which provides a more precise genetic match to flu viruses. This acquisition allows Sanofi Pasteur to offer patients a greater range of options in influenza vaccines. Clinical data showed that adults 50 years of age and older, demonstrated better protection against influenza when using Flublok Quadrivalent vaccine compared to a quadrivalent inactivated influenza vaccine. [Flublok Quadrivalent Prescribing Information](#).

PAIDEMIC PREPARATIONS AND RESPONSE

Influenza pandemics are a potential risk to global public health that could occur at any time. 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 U.S. and France, Sanofi Pasteur developed, produced and supplied the A(H1N1) monovalent pandemic flu vaccine.
- 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.

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/>.

IMPORTANT SAFETY INFORMATION FOR FLUBLOK QUADRIVALENT, FLUZONE QUADRIVALENT, AND FLUZONE HIGH-DOSE VACCINES

Flublok Quadrivalent, Fluzone Quadrivalent, and Fluzone High-Dose vaccines should not be administered to anyone who has had a severe allergic reaction (eg, anaphylaxis) to any component (including egg protein for Fluzone Quadrivalent and Fluzone High-Dose vaccines) or previous dose of the respective vaccine. In addition, Fluzone Quadrivalent and Fluzone High-Dose vaccines should not be administered to anyone who has had a severe allergic reaction to a previous dose of any influenza vaccine.

If Guillain-Barré syndrome has occurred within 6 weeks following previous influenza vaccination, the decision to give Flublok Quadrivalent, Fluzone Quadrivalent, or Fluzone High-Dose vaccine should be based on careful consideration of the potential benefits and risks.

In adults, the most common local and systemic adverse reactions to Flublok Quadrivalent, Fluzone Quadrivalent, and Fluzone High-Dose vaccines include pain at the injection site; headache and myalgia. In children, the most common reactions to Fluzone Quadrivalent vaccine include pain, erythema, and swelling at the injection site; myalgia, malaise, and headache (irritability, abnormal crying, drowsiness, appetite loss, vomiting, and fever in young children). Other adverse reactions to these vaccines may occur. Vaccination with Flublok Quadrivalent, Fluzone Quadrivalent, or Fluzone High-Dose vaccine may not protect all individuals.

INDICATION FOR FLUBLOK QUADRIVALENT, FLUZONE QUADRIVALENT, AND FLUZONE HIGH-DOSE VACCINES

Flublok Quadrivalent, Fluzone Quadrivalent, and Fluzone High-Dose vaccines are indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B virus(es) contained in each vaccine. Flublok Quadrivalent vaccine is approved for use in persons 18 years of age and older. Fluzone Quadrivalent vaccine is approved for use in persons 6 months of age and older. Fluzone High-Dose vaccine is approved for use in persons 65 years of age and older.

Before administration, please see the full Prescribing Information for [Flublok Quadrivalent](#), [Fluzone Quadrivalent](#), or [Fluzone High-Dose](#) vaccine. Also, please see complete Patient Information for [Fluzone Quadrivalent](#) or [Fluzone High-Dose](#) vaccine.

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