FLUZONE® HIGH-DOSE (INFLUENZA VACCINE) FACT SHEET

As people age, the immune system weakens. For this reason, adults 65 years of age and older do not respond as well as younger adults to influenza vaccine, leaving them more vulnerable to infection and its associated complications.

Fluzone® High-Dose is the first influenza vaccine designed specifically for people 65 years of age and older. It is an inactivated influenza vaccine that provides superior efficacy against influenza compared with Fluzone vaccine and contains four times the antigen of a regular flu shot to help promote a stronger immune response to influenza.

Approximately 50 million doses of Fluzone High-Dose vaccine were distributed since it was first licensed by the U.S. Food and Drug Administration (FDA) in 2009 and during the 2015-2016 influenza season an estimated 50 percent of immunized seniors nationwide received the vaccine. Following licensure, Fluzone High-Dose vaccine has met a number of milestones, including publication of several studies in peer-reviewed scientific journals:

Dec. 2009: FDA Licensure
In response to the unmet medical need in older adults, Fluzone High-Dose vaccine was licensed by the FDA in December 2009 under the agency's accelerated approval process. Licensure was based on the vaccine's safety profile and superior immunogenicity compared to Fluzone vaccine.

Jan. 2010: U.S. Commercial Launch
Fluzone High-Dose vaccine was introduced in 2010 and made available to healthcare providers to vaccinate their patients in the 2010-2011 influenza season.

Aug. 2014: Data Publication on Safety & Efficacy
The New England Journal of Medicine (NEJM) published results from a large multi-center, double-blind, post-licensure efficacy trial demonstrating the clinical benefit of Fluzone High-Dose vaccine compared to Fluzone vaccine in the prevention of influenza disease conducted over two flu seasons involving nearly 32,000 participants 65 years of age and older (“FIM12”).

Fluzone High-Dose vaccine was found to be 24.2 percent more effective than Fluzone vaccine in preventing laboratory-confirmed influenza caused by any influenza viral type or subtype in association with protocol-defined influenza-like illness, in adults 65 years of age and older. A secondary endpoint demonstrated Fluzone High-Dose vaccine was 51.1 percent more effective than Fluzone vaccine against culture-confirmed influenza caused by viral strains antigenically similar to those contained in the vaccine using a modified Centers for Disease Control and Prevention (CDC) influenza-like illness definition.

Nov. 2014: FDA Label Update
FDA approved the supplemental biologics license application for Fluzone High-Dose vaccine to include the efficacy data published in NEJM in the Prescribing Information.

Dec. 2014: Data Publication in Long-Term Care Population
Journal of Infectious Diseases published data from a University of Pittsburgh School of Medicine study demonstrating that Fluzone High-Dose vaccine is significantly more effective than Fluzone vaccine in frail, older residents of long-term care facilities.

Aug. 2015: Data Publication on Cardio-Respiratory Events
Vaccine published a sub-analysis of the efficacy data in which significantly fewer serious cardio-respiratory events, all-cause hospitalizations and pneumonia, possibly related to influenza, were observed in study participants 65 years of age and older who received Fluzone High-Dose vaccine compared to Fluzone vaccine.

Sept. 2015: Data Publication on Health Economics
The Lancet Infectious Diseases published a sub-analysis of the efficacy data demonstrating the cost-effectiveness of Fluzone High-Dose vaccine versus Fluzone vaccine in study participants 65 years of age and older.

Visit www.Fluzone.com for more information.
INDICATION

Fluzone High-Dose vaccine is given to people 65 years of age and older to help prevent influenza disease caused by influenza A and B strains contained in the vaccine.

SAFETY INFORMATION

The most common side effects to Fluzone High-Dose vaccine include pain, swelling, and redness at the injection site; muscle aches, fatigue, headache, and fever. Other side effects may occur. Fluzone High-Dose vaccine should not be given to anyone with a severe allergic reaction (eg, anaphylaxis) to any vaccine component, including eggs, egg products, or to a previous dose of any influenza vaccine.

Tell your doctor if you have 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 High-Dose vaccine may not protect all individuals.

For more information about Fluzone High-Dose vaccine, talk to your health care professional and see complete Patient Information.


