

Fluzone[®] High-Dose (Influenza Virus Vaccine) Facts at a Glance

About Fluzone High-Dose Vaccine

Fluzone High-Dose vaccine is indicated for people 65 years of age and older.

Fluzone High-Dose vaccine is an inactivated influenza virus vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

- This indication is based on the immune response elicited by Fluzone High-Dose; there have been no controlled clinical studies demonstrating a decrease in influenza disease after vaccination with Fluzone High-Dose.

Fluzone High-Dose vaccine is designed with four times the antigen content to meet the specific needs of people 65 years of age and older to generate a more robust immune response in this population of adults whose immune systems are weaker compared with younger adults.

Fluzone High-Dose vaccine is produced in the same production facility as Fluzone (Influenza Virus Vaccine).

Fluzone High-Dose vaccine is supplied in a single-dose, no preservative, prefilled syringe.

About the Clinical Trials

The Phase III trial (FIM05) was a multi-center, randomized, active-controlled, double blind trial conducted in the U.S.

- Included 3,876 adults 65 years of age and older and compared Fluzone High-Dose vaccine (n=2,575) to standard-dose Fluzone vaccine (n=1,262).
- The objective of the trial was to evaluate the immunogenicity and safety of high-dose vaccine compared with standard-dose vaccine.
 - The primary endpoint of the study was the statistical superiority of immune responses to at least two of the strains contained in the vaccines when comparing Fluzone High-Dose vaccine to Fluzone vaccine.
 - There are no data demonstrating clinically relevant prevention of culture confirmed influenza or its complications after vaccination with Fluzone High-Dose compared to standard Fluzone vaccine in individuals 65 years of age and older.
- Clinical Trials.gov identification number: NCT00391053
- Published: Falsey, A, et al. Randomized, double-blind controlled phase 3 trial comparing the immunogenicity of high-dose and standard-dose influenza vaccine in adults 65 years of age and older. *Journal of Infectious Diseases*. 2009;200:172-180.

Reimbursement Information

The Centers for Medicare and Medicaid Services (CMS) is expected to make a coverage decision for its Medicare patients shortly after licensure is granted. If covered, reimbursement will be provided under Medicare Part B.

Fluzone High-Dose vaccine has received a unique CPT^{®a} Code 90662.

Fluzone High-Dose Vaccine Availability

Fluzone High-Dose vaccine will be available for administration during the upcoming 2010-2011 influenza season.

Visit VaccineShoppe.com[®] for more information on ordering Fluzone High-Dose vaccine.

^a CPT = Current Procedural Terminology is a registered trademark of the American Medical Association.