

COVERED UNDER
**MEDICARE
PART B**



65+

Fluzone[®] High-Dose
INFLUENZA VIRUS VACCINE

For 65 years of age and older

Fluzone High-Dose vaccine was designed specifically to generate a more robust immune response to influenza in people 65 years of age and older

Fluzone High-Dose vaccine is an inactivated influenza virus vaccine indicated for active immunization of persons 65 years of age and older 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 vaccine; there have been no controlled clinical studies demonstrating a decrease in influenza disease after vaccination with Fluzone High-Dose vaccine.

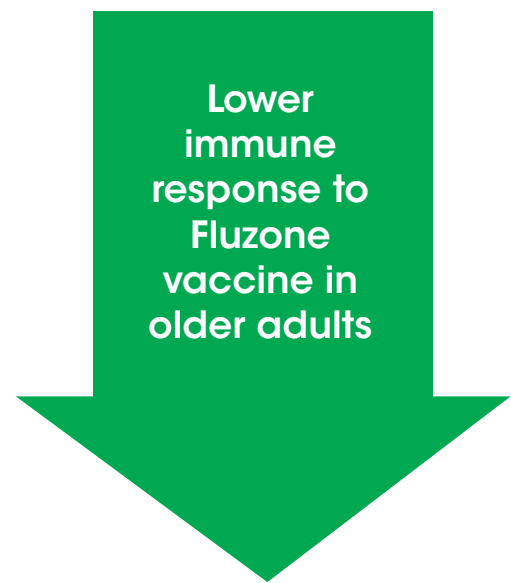
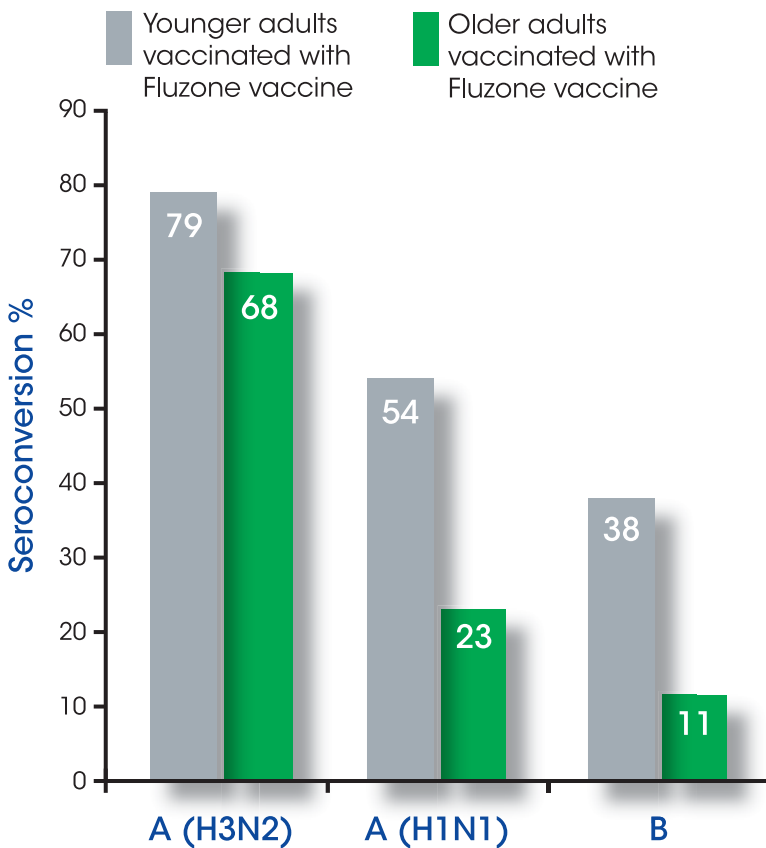
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Older adults have a lower immune response to influenza vaccine as compared to younger adults

Observational Study of Immunogenicity of Fluzone, Influenza Virus Vaccine in Younger and Older Adults¹



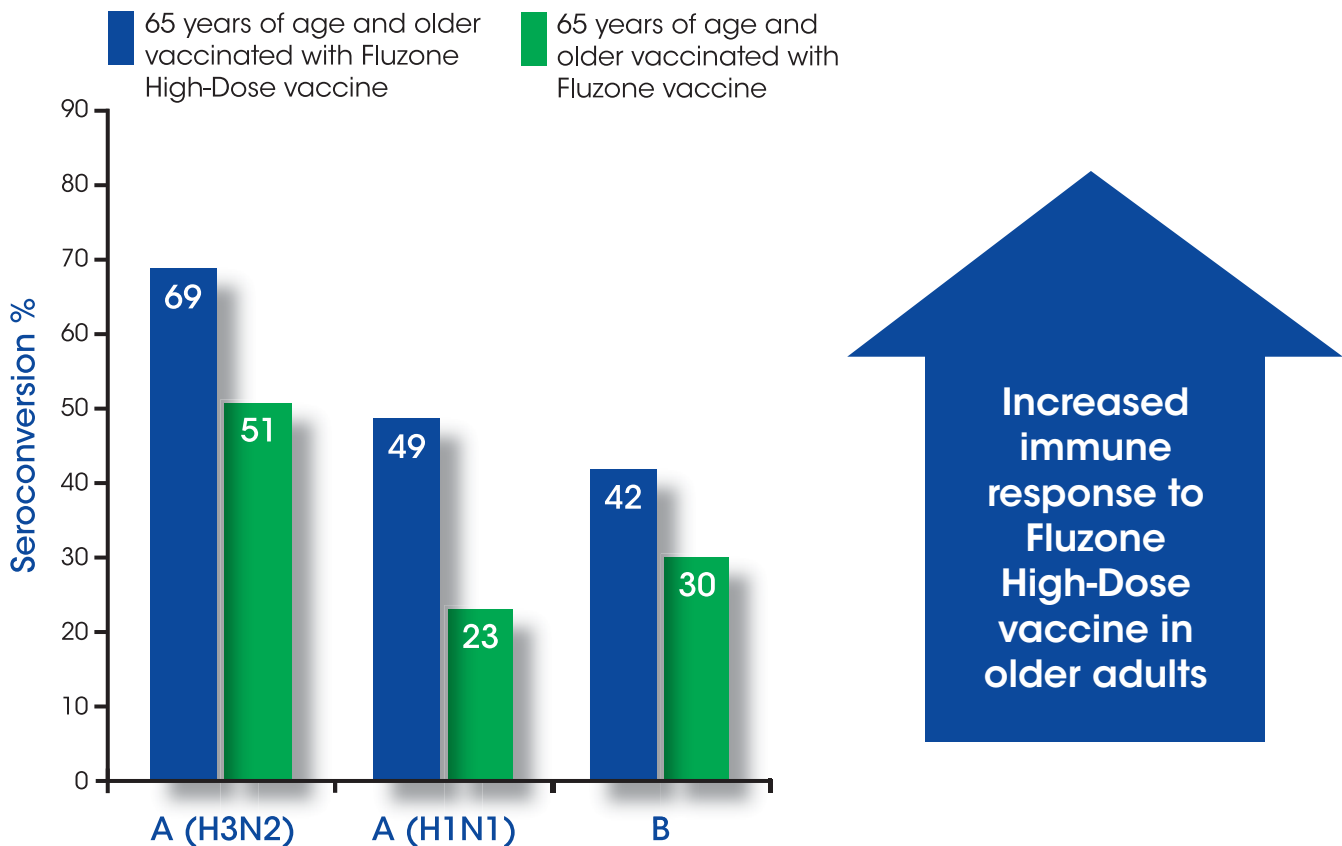
In an observational study of the immunogenicity of Fluzone vaccine, younger patients (median age: 38, range: 19 through 59 years of age) and older adults (median age: 72, range: 61 through 86 years of age) were evaluated. Results were obtained after vaccination with a single dose of the 2000-2001 formulation of Fluzone vaccine.

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Fluzone High-Dose vaccine generates a more robust immune response in adults 65 years of age and older

Phase III Trial of Immunogenicity of Fluzone High-Dose Vaccine^{1,a}



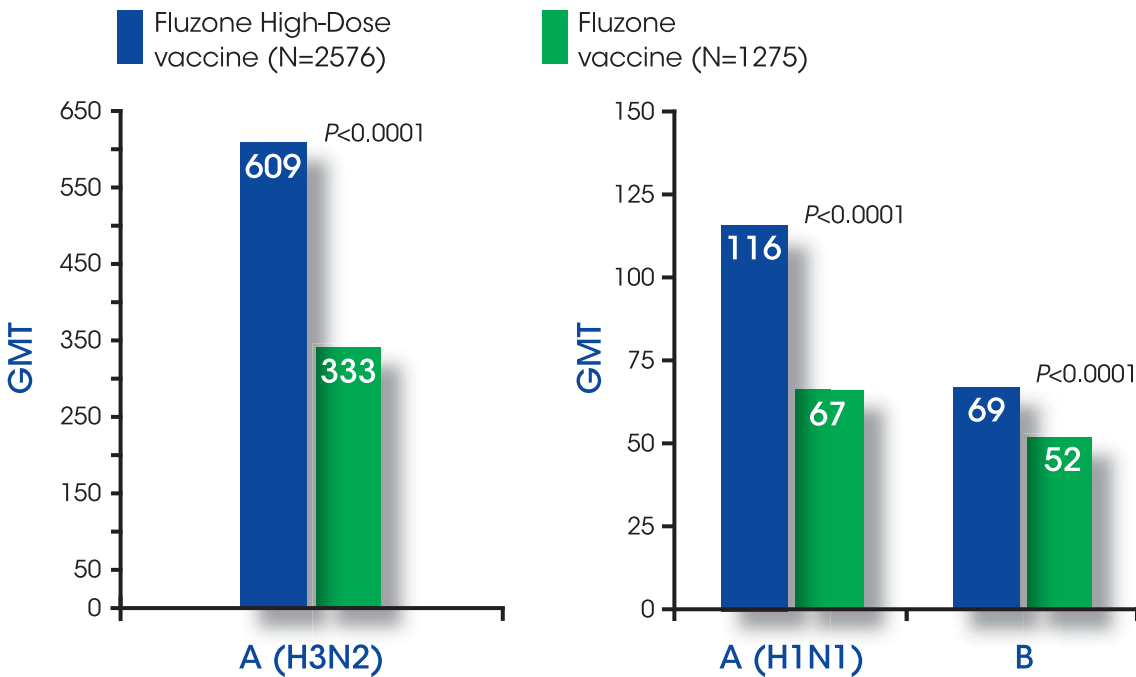
^a The primary endpoint of the study was hemagglutination inhibition (HI) titer 28 days after vaccination. Pre-specified statistical superiority criteria required that (1) the lower limit (LL) of the 2-sided 95% confidence interval (CI) of the geometric mean antibody titers (GMT) ratio of Fluzone High-Dose vaccine to Fluzone vaccine be greater than 1.50 for at least 2 of the strains, and if 1 strain failed, noninferiority of that strain must be demonstrated (LL>0.67), and that (2) the lower limit of the 2-sided 95% CI of the seroconversion rate difference between Fluzone High-Dose vaccine and Fluzone vaccine be greater than 10% for at least 2 of the strains, and if 1 strain failed, noninferiority of that strain must be demonstrated (LL>-10%).

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Fluzone High-Dose vaccine generates higher antibody levels compared to Fluzone vaccine

GMT Post-vaccination in Adults 65 Years of Age and Older (Phase III)^{1,b}



^b The primary endpoint of the study was HI titer 28 days after vaccination. Pre-specified statistical superiority criteria required that (1) the LL of the 2-sided 95% CI of the GMT ratio of Fluzone High-Dose vaccine to Fluzone vaccine be greater than 1.50 for at least 2 of the strains, and if 1 strain failed, noninferiority of that strain must be demonstrated (LL > 0.67), and that (2) the lower limit of the 2-sided 95% CI of the seroconversion rate difference between Fluzone High-Dose vaccine and Fluzone vaccine be greater than 10% for at least 2 of the strains, and if 1 strain failed, noninferiority of that strain must be demonstrated (LL > -10%).

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Fluzone[®] High-Dose
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Fluzone High-Dose vaccine safety profile

Frequency of Solicited Systemic and Injection Site Reactions Within 7 Days Post-vaccination¹

	Fluzone High-Dose Vaccine (N ^c =2573) Percent	Fluzone Vaccine (N=1260) Percent
Systemic reactions		
Myalgia	21.4	18.3
Malaise	18.0	14.0
Headache	16.8	14.4
Fever	3.6	2.3
Injection site reactions		
Pain	35.6	24.3
Erythema	14.9	10.8
Swelling	8.9	5.8

^c N = Number of subjects in the Safety Analysis Set.

Solicited injection site reactions and systemic adverse events were more frequent after vaccination with Fluzone High-Dose vaccine compared to Fluzone vaccine in adults 65 years of age and older.¹

Important Safety Information

Indication

Fluzone High-Dose vaccine is an inactivated influenza virus vaccine indicated for active immunization of persons 65 years of age and older 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 vaccine; there have been no controlled clinical studies demonstrating a decrease in influenza disease after vaccination with Fluzone High-Dose vaccine.

Safety Information

The most common local and systemic adverse reactions to Fluzone High-Dose vaccine include soreness, pain, and swelling at the vaccination site; fever, headache, malaise, and myalgia. Other adverse reactions may occur. Fluzone High-Dose vaccine should not be administered to anyone with a history of hypersensitivity to any vaccine component, including eggs, and egg products. The decision to give Fluzone High-Dose 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. The tip caps of the prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals. Vaccination with Fluzone High-Dose vaccine may not protect all individuals.

Before administering Fluzone High-Dose vaccine, please [click here](#) to see full Prescribing Information.

Fluzone High-Dose and Fluzone vaccines are manufactured and distributed by Sanofi Pasteur Inc.

References: 1. Fluzone High-Dose Vaccine [Prescribing Information]. Swiftwater, PA: Sanofi Pasteur Inc.; 2010. 2. Falsey AR, Treanor JJ, Tornieporth N, Capellan J, Gorse GJ. 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. *J Infect Dis.* 2009;200:172-180.

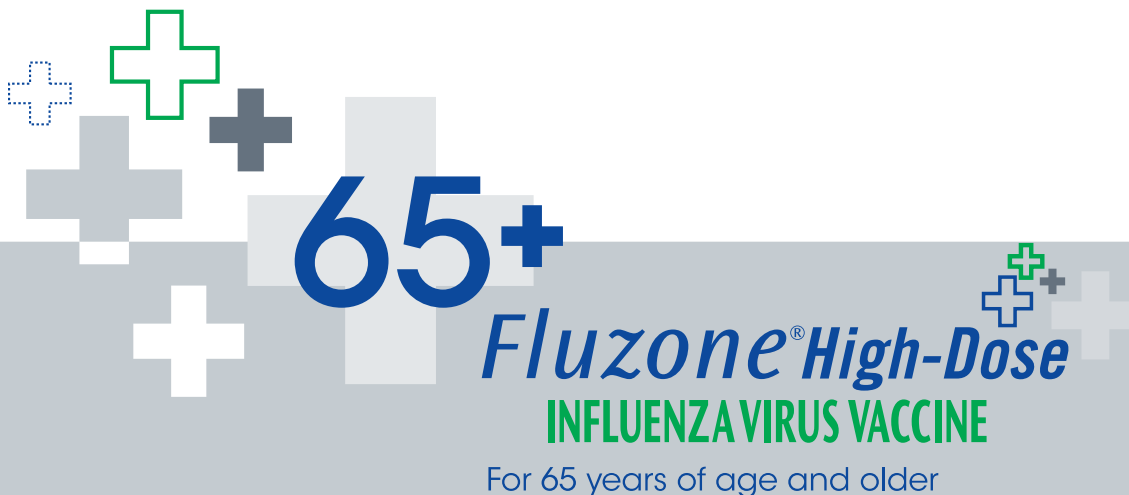
Intended to strengthen the immune response to influenza in adults 65 years of age and older

Fluzone High-Dose vaccine:

- Is an increased antigen formulation¹
- Demonstrated statistically superior HI titers after vaccination with Fluzone High-Dose vaccine compared to Fluzone vaccine for 2 of the 3 influenza strains^{2,d}
- Generates up to 80% higher antibody levels (GMTs) compared to Fluzone vaccine²
- Provides significantly higher antibody responses compared with Fluzone vaccine for people 65 years of age and older regardless of whether they have underlying medical conditions²

^d There are no data demonstrating clinically relevant prevention of culture-confirmed influenza or its complications after vaccination with Fluzone High-Dose vaccine compared to Fluzone vaccine in individuals 65 years of age and older.

Fluzone High-Dose vaccine CPT^{®e} code (90662) is a covered benefit under Medicare Part B.



Fluzone High-Dose vaccine is an inactivated influenza virus vaccine indicated for active immunization of persons 65 years of age and older 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 vaccine; there have been no controlled clinical studies demonstrating a decrease in influenza disease after vaccination with Fluzone High-Dose vaccine.

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

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