IN A RANDOMIZED CONTROLLED TRIAL OF ADULTS AGED 65+

THE FIRST AND ONLY FLU VACCINE TO DELIVER SUPERIOR FLU PROTECTION VS STANDARD DOSE[1,2]*

ACIP RECOMMENDED IN AGES 65+[3]

Fluzone High-Dose is a vaccine indicated for active immunization for the prevention of disease caused by influenza A subtype viruses and type B virus contained in the vaccine. Fluzone High-Dose is approved for use in persons 65 years of age and older.

*Results from a study (2011-2012, 2012-2013) evaluating Fluzone High-Dose (trivalent formulation) vs Fluzone (standard-dose trivalent formulation). The prespecified statistical superiority criterion for the primary endpoint (lower limit of 2-sided 95% CI of the vaccine efficacy of Fluzone High-Dose relative to Fluzone >9.1%) was met.[1,2]

IMPORTANT SAFETY INFORMATION

Do not administer Fluzone High-Dose to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or after previous dose of any influenza vaccine.

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of Fluzone High-Dose.

Please see additional Important Safety Information throughout and full Prescribing Information here.

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Fluzone® High-Dose Influenza Vaccine

PIVOTAL TRIAL

MORE ANTIGEN, MORE PROTECTION

FLUZONE HIGH-DOSE CONTAINS 4x THE ANTIGEN AND REDUCED FLU CASES BY 24% VS A STANDARD-DOSE FLU VACCINE IN A CLINICAL TRIAL OF ADULTS AGED 65+[1,2*†]

STUDY DESIGN

- 1:1 randomized controlled trial to evaluate Fluzone High-Dose vs standard-dose Fluzone[1,2]
- Study population: 31,803 adults aged 65+ during the influenza seasons 2011-2012 and 2012-2013[1,2]

PRIMARY ENDPOINT[1,2]:

Relative vaccine efficacy (rVE) against influenza due to ANY lab-confirmed circulating strains[1,2]

Graphical representations are for illustrative purposes only.

24%
(95% CI: 10, 37)
FEWER INFLUENZA CASES

SECONDARY ENDPOINT[1,2]:

rVE against influenza due to antigenically matched strains[1,2‡]

51%
(95% CI: 17, 72)
FEWER INFLUENZA CASES

*Results from a study evaluating Fluzone High-Dose (trivalent formulation) vs Fluzone (standard-dose trivalent formulation). The prespecified statistical superiority criterion for the primary endpoint (lower limit of 2-sided 95% CI of the vaccine efficacy of Fluzone High-Dose relative to Fluzone >9.1%) was met.[1,2]

† Fluzone High-Dose contains 60 micrograms (mcg) of hemagglutinin (HA) per strain vs 15 mcg of HA per strain in a standard-dose influenza vaccine.[2]

‡ Modified CDC-defined influenza-like illness was based on the Centers for Disease Control and Prevention (CDC) surveillance network definition of an influenza-like illness and was defined as a respiratory illness with cough or sore throat, concurrent with a temperature above 37.2 °C. Influenza was culture-confirmed.[2]

§ Internal calculations by Sanofi based on IQVIA database of total flu vaccines administered from 7/23 to 4/24 in people 65+. Not inclusive of all Federal payers. Study details and information maintained by Sanofi.[4]

CHOOSE THE #1-ADMINISTERED FLU VACCINE IN PATIENTS AGED 65+[4§]

IMPORTANT SAFETY INFORMATION

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

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Fluzone® High-Dose Influenza Vaccine

REAL-WORLD EVIDENCE

EVALUATED AGAINST STANDARD-DOSE VACCINES OVER 12 FLU SEASONS[5]

A META-ANALYSIS OF >45,000,000 ADULTS AGED 65+ IN 21 PUBLISHED STUDIES[5]

STUDY DESIGN[5]*

- Systematic review and meta-analysis of randomized and observational studies to evaluate the relative vaccine effectiveness of Fluzone High-Dose vs standard-dose influenza vaccines against influenza-associated outcomes in more than 45 million adults aged 65+
- Analysis included studies conducted over 12 influenza seasons (2009-2010 to 2019-2020, and 2021-2022)
  - The dominant strains were A/H3N2 and A/H1N1 in 8 and 4 of the seasons studied, respectively
  - In 8 of the 12 seasons, there was a mismatch between vaccine and circulating strains

STUDY LIMITATIONS[5]

- High degree of statistical heterogeneity observed in several of the pooled rVE estimates
- Inclusion of unmeasured confounders, such as health-seeking behavior or selection bias, that could affect the findings of the observational studies

*The study was supported by Sanofi; findings of the study were derived from manuscripts of 21 published studies in the public domain.

IMPORTANT SAFETY INFORMATION

If Fluzone High-Dose is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the expected immune response may not be obtained.

Please see additional Important Safety Information throughout and full Prescribing Information here.

Fluzone® High-Dose Influenza Vaccine

REAL-WORLD EVIDENCE

12 YEARS OF REAL-WORLD EVIDENCE IN PREVENTING MORE INFLUENZA COMPLICATIONS THAN STANDARD-DOSE INFLUENZA VACCINES[5]

PRIMARY OBJECTIVE: POOLED RELATIVE VACCINE EFFECTIVENESS (95% CI) AGAINST INFLUENZA-RELATED OUTCOMES[5]

INFLUENZA-LIKE ILLNESS*

14.3% rVE (95% CI: 4.2, 23.3)

INFLUENZA-RELATED HOSPITALIZATIONS

11.2% rVE (95% CI: 7.4, 14.8)

INFLUENZA-RELATED HOSPITALIZATIONS/ER VISITS

10.4% rVE (95% CI: 6.8, 13.9)

CARDIOVASCULAR-RELATED HOSPITALIZATIONS

12.8% rVE (95% CI: 10.2, 15.3)

CARDIORESPIRATORY-RELATED HOSPITALIZATIONS

16.7% rVE (95% CI: 13.8, 19.5)

RESPIRATORY-RELATED HOSPITALIZATIONS

14.7% rVE (95% CI: 8.5, 20.4)

PNEUMONIA HOSPITALIZATIONS

27.8% rVE (95% CI: 12.5, 40.5)

PNEUMONIA/INFLUENZA HOSPITALIZATIONS

14.4% rVE (95% CI: 6.8, 20.6)

Select endpoints are presented here; all-cause hospitalization and pneumonia were also evaluated.

*Defined as visits with a rapid influenza diagnostic test followed by prescription of antiviral medication.[5]
ER=emergency room, rVE=relative vaccine effectiveness.

IMPORTANT SAFETY INFORMATION

Vaccination with Fluzone High-Dose may not protect all recipients.

Please see additional Important Safety Information throughout and full Prescribing Information here.

Fluzone® High-Dose Influenza Vaccine

SAFETY PROFILE COMPARED TO STANDARD-DOSE VACCINES[6]

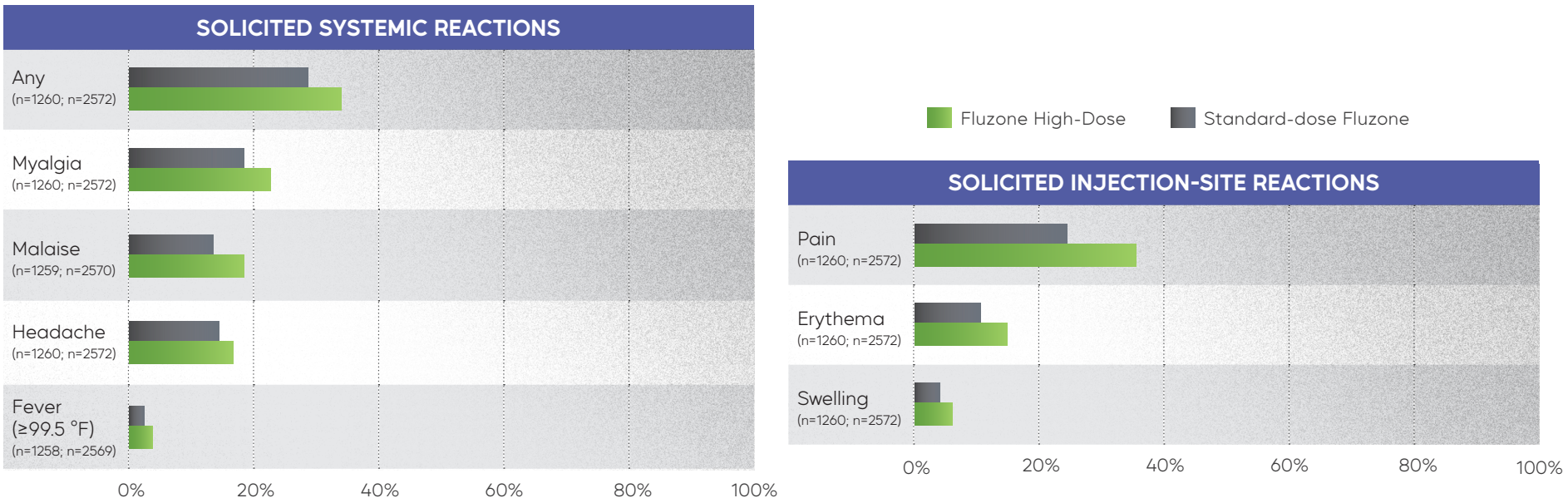
Solicited systemic adverse reactions and solicited injection-site reactions were slightly more frequent after vaccination with Fluzone High-Dose as compared with a standard-dose influenza vaccine.[6]

STUDY DESIGN[6]

Phase 3 controlled study in which 3876 adults aged 65+ were randomized 2:1 to receive Fluzone High-Dose or Fluzone (standard dose) during the influenza season of 2006-2007.*

ADVERSE REACTIONS (WITHIN 7 DAYS)[6]

- Study population values for each solicited adverse reaction are provided for the standard-dose Fluzone cohort, then the Fluzone High-Dose cohort



*Fluzone High-Dose (trivalent formulation) was evaluated against Fluzone (standard-dose trivalent formulation).[6]

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Fluzone® High-Dose Influenza Vaccine

IMPORTANT SAFETY INFORMATION

INDICATION

Fluzone High-Dose is a vaccine indicated for active immunization for the prevention of disease caused by influenza A subtype viruses and type B virus contained in the vaccine. Fluzone High-Dose is approved for use in persons 65 years of age and older.

IMPORTANT SAFETY INFORMATION

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If Fluzone High-Dose is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the expected immune response may not be obtained.

Vaccination with Fluzone High-Dose may not protect all recipients.

Syncope (fainting) has been reported following vaccination with Fluzone High-Dose. Procedures should be in place to avoid injury from fainting.

In adults 65 years of age and older, the most common injection-site reaction was pain; the most common solicited systemic adverse reactions were myalgia, malaise, and headache. Other adverse reactions may occur.

Please see the full Prescribing Information here.

Fluzone® High-Dose
Influenza Vaccine

REFERENCES

References: 1. Fluzone High-Dose. Prescribing Information. Sanofi Pasteur Inc. **2.** DiazGranados CA, Dunning AJ, Kimmel M, et al. Efficacy of high-dose versus standard-dose influenza vaccine in older adults. *N Engl J Med*. 2014;371(7):635-645. doi:10.1056/NEJMoa1315727 **3.** Grohskopf LA, Blanton LH, Ferdinands JM, Chung JR, Broder KR, Talbot HK. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices—United States, 2023–24 influenza season. *MMWR Recomm Rep*. 2023;72(No. RR-2):1-25. doi:10.15585/mmwr.rr7202a1 **4.** Sanofi Pasteur Inc. Data on file. **5.** Lee JKH, Lam GKL, Yin JK, Loiacono MM, Samson SI. High-dose influenza vaccine in older adults by age and seasonal characteristics: systematic review and meta-analysis update. *Vaccine X*. 2023;14:100327. doi:10.1016/j.jvacx.2023.100327 **6.** 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(2):172-180. doi:10.1086/599790

Please see the full Prescribing Information here.

Fluzone® High-Dose
Influenza Vaccine

IN A RANDOMIZED CONTROLLED TRIAL OF ADULTS AGED 65+

THE FIRST AND ONLY FLU VACCINE TO DELIVER SUPERIOR FLU PROTECTION VS STANDARD DOSE[1-3]*

- **Contains 4x the antigen** and reduced laboratory-confirmed flu cases by 24% vs a standard-dose flu vaccine[1,2*†]
- **The #1-administered flu vaccine** for people aged 65+[3‡]
- **More than a decade of real-world evidence**[5§]

ACIP RECOMMENDED IN AGES 65+[3]

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