FLUZONE HIGH-DOSE PROVIDES SUPERIOR PROTECTION VS A STANDARD-DOSE FLU VACCINE, EVEN FOR YOUR PATIENTS WHO FEEL INVINCIBLE[1]*

THE ONLY HIGH-DOSE FLU VACCINE SHOWN TO PROTECT AGAINST FLU AND ITS COMPLICATIONS[1-3‡]

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.

- **4x** Contains **4x THE ANTIGEN** of standard-dose flu vaccines[1,2†]
- **RCT** The only flu vaccine to deliver **SUPERIOR PROTECTION VS STANDARD DOSE** in a randomized controlled trial of patients 65+[1,2*]
- **RWE** Real-world evidence in hospitalizations across **12 FLU SEASONS** and **45+ MILLION PEOPLE** in randomized and observational studies[3‡]

ACIP RECOMMENDED‡ **Fluzone High-Dose is among the flu vaccines preferentially recommended by ACIP for those aged 65+ vs unadjuvanted standard-dose flu vaccines.[4]**

*In a randomized, controlled trial conducted in 2011-2012 and 2012-2013 in approximately 32,000 adults 65+, Fluzone High-Dose was 24% (95% CI: 10, 37) more effective (rVE) against influenza due to ANY lab-confirmed circulating strains than standard-dose Fluzone® (Influenza Vaccine). 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]

‡Analysis included studies conducted over 12 influenza seasons (2009-2010 to 2019-2020, and 2021-2022) in adults 65+.[3]

ACIP=Advisory Committee on Immunization Practices; CI=confidence interval; rVE=relative vaccine efficacy.

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.

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]

↓24%
(95% CI: 10, 37)

FEWER INFLUENZA CASES

Primary endpoint: rVE against influenza due to ANY lab-confirmed circulating strains[1,2]

↓51%
(95% CI: 17, 72)

FEWER INFLUENZA CASES

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

*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]

CHOOSE THE SUPERIOR PROTECTION OF FLUZONE HIGH-DOSE FOR YOUR PATIENTS 65+[1,2]

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.

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

Fluzone® High-Dose
Influenza Vaccine

REAL-WORLD EVIDENCE

EVALUATED AGAINST STANDARD-DOSE FLU VACCINES OVER **12 SEASONS**[3]

A META-ANALYSIS OF

>45,000,000 ADULTS AGED 65+[3]

IN

21 RCTs AND OBSERVATIONAL STUDIES[3]

STUDY DESIGN[3]*

- 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[3]

- 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.[3]
RCT=randomized controlled trial.

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

FLUZONE HIGH-DOSE PREVENTED MORE INFLUENZA COMPLICATIONS VS STANDARD-DOSE VACCINES[3]

PRIMARY OBJECTIVE: POOLED rVE (95% CI) AGAINST INFLUENZA-RELATED OUTCOMES[3]

INFLUENZA-LIKE ILLNESS*

14.3% (95% CI: 4.2, 23.3)

INFLUENZA-RELATED HOSPITALIZATIONS

11.2% (95% CI: 7.4, 14.8)

INFLUENZA-RELATED HOSPITALIZATIONS/ER VISITS

10.4% (95% CI: 6.8, 13.9)

PNEUMONIA HOSPITALIZATIONS

27.8% (95% CI: 12.5, 40.5)

PNEUMONIA/INFLUENZA HOSPITALIZATIONS

14.4% (95% CI: 6.8, 20.6)

RESPIRATORY-RELATED HOSPITALIZATIONS

14.7% (95% CI: 8.5, 20.4)

CARDIOVASCULAR-RELATED HOSPITALIZATIONS

12.8% (95% CI: 10.2, 15.3)

CARDIORESPIRATORY-RELATED HOSPITALIZATIONS

16.7% (95% CI: 13.8, 19.5)

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.[3]
ER=emergency room.

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 FLU VACCINES[5]

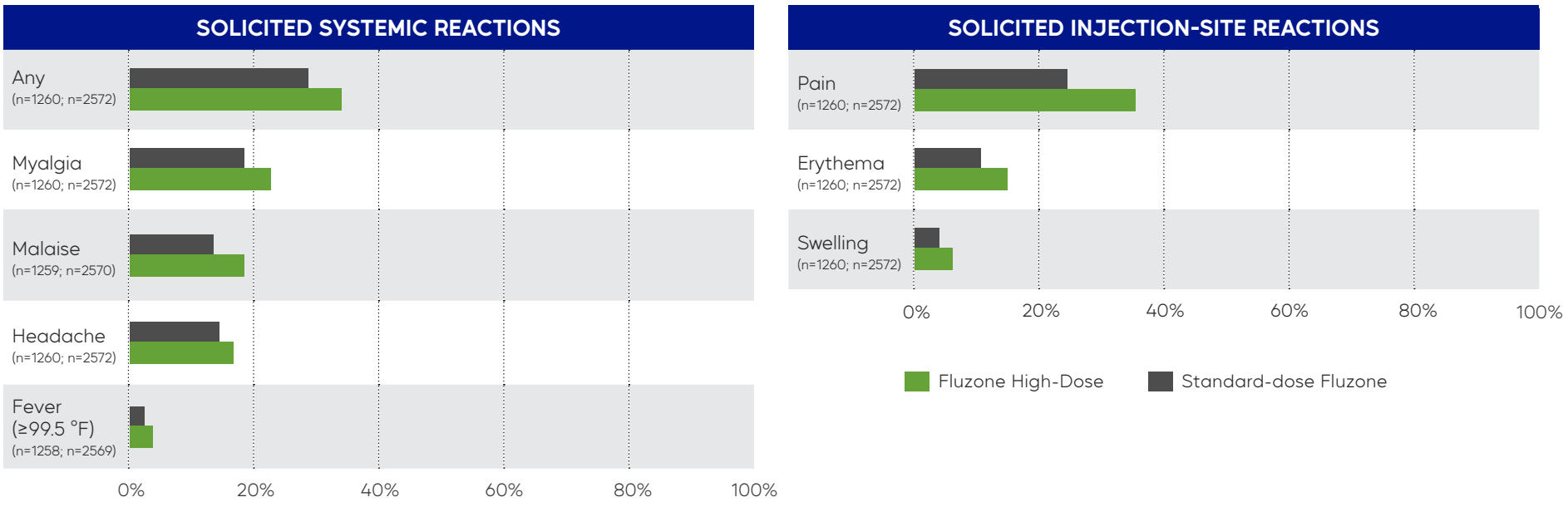
Solicited systemic adverse reactions and solicited injection-site reactions were slightly more frequent after vaccination with Fluzone High-Dose as compared with a standard-dose influenza vaccine.[5]

STUDY DESIGN[5]

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)[5]

- 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).[5]

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

Fluzone® High-Dose
Influenza Vaccine

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.

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.

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.

REFERENCES

1. Fluzone High-Dose. Prescribing Information. Sanofi Pasteur Inc. **2.** DiazGranados CA, et al. *N Engl J Med.* 2014;371(7):635-645. doi:10.1056/NEJMoa1315727 **3.** Lee JKH, et al. *Vaccine X.* 2023;14:100327. doi:10.1016/j.jvacx.2023.100327 **4.** Grohskopf LA, et al. *MMWR Recomm Rep.* 2024;73(5):1-25. doi:10.15585/mmwr.rr7305a1 **5.** Falsey AR, et al. *J Infect Dis.* 2009;200(2):172-180. doi:10.1086/599790 **6.** Sanofi Pasteur Inc. Data on file.

Fluzone® High-Dose
Influenza Vaccine

HEALTH CARE PRACTITIONER NOTES

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.

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

Fluzone® High-Dose
Influenza Vaccine

IN ADULTS 65+,

SUPERIOR FLU PROTECTION VS STANDARD DOSE IN A RANDOMIZED CONTROLLED TRIAL THAT COVERED MULTIPLE SEASONS[1,2*]

4x **Contains 4x the antigen and reduced flu cases by 24%** vs a standard-dose flu vaccine in a study that included a matched and a mismatched season[1,2*†]

RWE **Real-world evidence in hospitalizations** across 12 flu seasons and 45+ million people in randomized and observational studies[3‡]

#1 **The #1-administered flu vaccine** for people aged 65+[6§]

*In a randomized, controlled trial conducted in 2011-2012 and 2012-2013 in approximately 32,000 adults 65+, Fluzone High-Dose was 24% (95% CI: 10, 37) more effective (rVE) against influenza due to ANY lab-confirmed circulating strains than standard-dose Fluzone® (Influenza Vaccine). 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]

‡Analysis included studies conducted over 12 influenza seasons (2009-2010 to 2019-2020, and 2021-2022) in adults 65+.[3]

§Internal calculations by Sanofi based on IQVIA database of total flu vaccines administered from July 2024 to April 2025 in people 65+. Not inclusive of all federal payers. Study details and information maintained by Sanofi.[6]

IMPORTANT SAFETY INFORMATION

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.

sanofi

MAT-US-2502843-v1.0-05/2025

Sanofi 1 Discovery Drive, Swiftwater, Pennsylvania 18370
www.sanofi.us

Fluzone® High-Dose
Influenza Vaccine