

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Fluzone (Influenza Virus Vaccine) safely and effectively. See full prescribing information for Fluzone.

**Fluzone (Influenza Virus Vaccine)
Suspension for Intramuscular Injection
2009-2010 Formula**

Initial US Approval: 1980

INDICATIONS AND USAGE

Fluzone is a vaccine indicated for active immunization in persons 6 months of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. (1)

DOSAGE AND ADMINISTRATION

Children

- 6 through 35 months of age (0.25 mL dose, intramuscular injection):
 - Previously unvaccinated children – should receive two 0.25 mL doses, one on day 1 followed by another 0.25 mL dose at least one month later. (2.2)
 - Previously vaccinated children should receive only one 0.25 mL dose. (2.2)
- 36 months through 8 years of age (0.5 mL dose, intramuscular injection):
 - Previously unvaccinated children – should receive two 0.5 mL doses, one on day 1 followed by another 0.5 mL dose at least one month later. (2.2)
 - Previously vaccinated children should receive only one 0.5 mL dose. (2.2)
- 9 years of age and older
 - A single 0.5 mL dose, intramuscular injection. (2.2)

Adults

- A single 0.5 mL dose, intramuscular injection. (2.2)

DOSAGE FORMS AND STRENGTHS

Fluzone, a sterile suspension for intramuscular injection, is supplied in four presentations:

- Prefilled syringe, 0.25 mL, no preservative, pediatric dose, distinguished by a pink syringe plunger rod (3)
- Prefilled syringe, 0.5 mL, no preservative (3)
- Single-dose vial, 0.5 mL, no preservative (3)
- Multi-dose vial, 5 mL, contains thimerosal, a mercury derivative, added as a preservative. Each 0.5 mL dose contains 25 mcg mercury. (3)

Each 0.25 mL dose contains 7.5 mcg of influenza virus hemagglutinin (HA) and each 0.5 mL dose contains 15 mcg HA of each of the following 3 viruses: A/Brisbane/59/2007, IVR-148 (H1N1), A/Uruguay/716/2007, NYMC X-175C (H3N2) (an A/Brisbane/10/2007-like virus) , and B/Brisbane/60/2008. (3, 11)

CONTRAINDICATIONS

- Severe hypersensitivity to egg proteins or any component of the vaccine or life-threatening reactions after previous administration of any influenza vaccine. (4)

WARNINGS AND PRECAUTIONS

- If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of previous influenza vaccination, the decision to give Fluzone should be based on careful consideration of the potential benefits and risks. (5.1)
- Immunocompromised persons may have a reduced immune response to Fluzone. (5.2)

ADVERSE REACTIONS

- Most common ($\geq 10\%$) local reactions were soreness at injection site, tenderness, pain, and swelling. (6)
- Most common ($\geq 10\%$) systemic events were malaise, headache, and myalgia. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Sanofi Pasteur Inc., Discovery Drive, Swiftwater, PA 18370 at 1-800-822-2463 (1-800-VACCINE) or VAERS at 1-800-822-7967 or <http://vaers.hhs.gov>.

DRUG INTERACTIONS

- Do not mix with other vaccines in the same syringe or vial. (7.1)
- Immunosuppressive therapies may reduce the immune response to Fluzone. (7.2)

USE IN SPECIFIC POPULATIONS

- Safety and effectiveness of Fluzone have not been established in pregnant women or nursing mothers or children <6 months of age. (8.1, 8.3, 8.4)
- Antibody responses were lower in the geriatric population than in younger adults. (8.5)

See 17 PATIENT_COUNSELING_INFORMATION.

Revised: May 2009

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*Sections or subsections omitted from the full prescribing information are not listed.

1 **FULL PRESCRIBING INFORMATION:**

2 **1. INDICATIONS AND USAGE**

3 Fluzone® is an inactivated influenza virus vaccine indicated for active immunization in persons 6
4 months of age and older against influenza disease caused by influenza virus subtypes A and type
5 B contained in the vaccine.

6
7 **2. DOSAGE AND ADMINISTRATION**

8 **2.1. Preparation for Administration**

9 Inspect Fluzone vaccine syringes and vials visually for particulate matter and/or discoloration
10 prior to administration. If either of those conditions exists, the vaccine should not be
11 administered.

12
13 Shake the syringe and single-dose vials well before administering the vaccine and shake the
14 multi-dose vial each time before withdrawing a dose of vaccine.

15
16 **2.2. Recommended Dose and Schedule**

17 ***Children***

18 Children 6 through 35 months of age not previously vaccinated with an influenza vaccine or
19 vaccinated for the first time last season with only one dose should receive two 0.25 mL doses,
20 one on day 1 followed by another 0.25 mL dose at least 1 month later. Children 6 through 35
21 months of age given two doses of any influenza vaccine last season or at least one dose two or
22 more years ago should receive only one 0.25 mL dose. (1)

1
2 Children 36 months through 8 years of age not previously vaccinated with an influenza vaccine
3 or vaccinated for the first time last season with only one dose should receive two 0.5 mL doses,
4 one on day 1 followed by another 0.5 mL dose at least 1 month later. Children 36 months
5 through 8 years of age given two doses last season or at least one dose two or more years ago
6 should receive only one 0.5 mL dose. (1)

7
8 Children 9 years of age and older should receive a single 0.5 mL intramuscular dose. (1)

9
10 Refer to current Advisory Committee on Immunization Practices (ACIP) recommendations for
11 needle length and site of injection. (2)

12
13 The preferred sites for intramuscular injections are the anterolateral aspect of the thigh in infants
14 or the deltoid muscle of the upper arm in toddlers and young children.

15
16 ***Adults***

17 Fluzone vaccine should be administered as a single 0.5 mL intramuscular dose preferably in the
18 deltoid muscle.

19
20 The vaccine should not be injected into the gluteal region or into areas where there may be a
21 major nerve trunk.

22

3. DOSAGE FORMS AND STRENGTHS

Fluzone vaccine is a sterile suspension for intramuscular injection. Each 0.25 mL dose of Fluzone vaccine contains 7.5 micrograms (mcg) of influenza virus hemagglutinin (HA) and each 0.5 mL dose contains 15 mcg HA from each of the following 3 viruses: A/Brisbane/59/2007, IVR-148 (H1N1), A/Uruguay/716/2007, NYMC X-175C (H3N2) (an A/Brisbane/10/2007-like virus), and B/Brisbane/60/2008. [See *Description (11)*]

Fluzone vaccine is supplied in 4 presentations:

- 1) Prefilled syringe, 0.25 mL, no preservative, pediatric dose, for 6 through 35 months of age, distinguished by a pink syringe plunger rod;
- 2) Prefilled syringe, 0.5 mL, no preservative, for 36 months of age and older;
- 3) Single-dose vial, 0.5 mL, no preservative, for 36 months of age and older;
- 4) Multi-dose vial, 5 mL, for 6 months of age and older, contains thimerosal, a mercury derivative, added as a preservative. Each 0.5 mL dose contains 25 mcg mercury.

4. CONTRAINDICATIONS

Do not administer Fluzone vaccine to anyone with a known severe hypersensitivity to egg proteins or any component of the vaccine or life-threatening reactions after previous administration of any influenza vaccine. [See *Warnings and Precautions (5)* and *Description (11)*]

5. WARNINGS AND PRECAUTIONS

5.1. Guillain-Barré Syndrome

1 Recurrence of Guillain-Barré syndrome (GBS) has been temporally associated with the
2 administration of influenza vaccine. Fluzone vaccine should be administered to individuals who
3 have a prior history of Guillain-Barré syndrome only based on careful consideration of the
4 potential benefits and risks.

5

6 **5.2. Altered Immunocompetence**

7 If Fluzone vaccine is administered to immunocompromised persons, including those receiving
8 immunosuppressive therapy, the immune response may be diminished.

9

10 **5.3. Preventing and Managing Allergic Reaction**

11 Appropriate medical treatment and supervision must be available to manage possible
12 anaphylactic reactions following administration of the vaccine.

13

14 **5.4. Limitations of Vaccine Effectiveness**

15 Vaccination with Fluzone vaccine may not protect all recipients.

16

17 **6. ADVERSE REACTIONS**

18 Adverse event information from clinical trials provides the basis for identifying adverse events
19 that appear to be related to vaccine use and for approximating the rates of these events. However,
20 because clinical trials are conducted under widely varying conditions, adverse event rates
21 observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trial
22 of another vaccine, and may not reflect the rates observed in practice.

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6.1. Clinical Trial Experience

Adults and Geriatrics

In placebo-controlled studies among adults, the most frequent side effect of vaccination is soreness at the vaccination site (affecting 10%–64% of patients) that lasts <2 days, local pain and swelling. These local reactions typically are mild. Fever, malaise, myalgia, and other systemic symptoms can occur following vaccination and most often affect persons who have had no prior exposure to the influenza virus antigens in the vaccine (e.g., young children). These reactions begin 6–12 hours after vaccination and can persist for 1–2 days. Placebo-controlled trials demonstrate that among older persons and healthy young adults, administration of split-virus influenza vaccine is not associated with higher rates of systemic symptoms (e.g., fever, malaise, myalgia, and headache) when compared with placebo injections. (1)

Children

The 2003-2004 formulation of Fluzone vaccine was studied in 19 children 6 to 23 months of age and in 12 children 24 to 36 months of age, given in 2 doses one month apart. Local reactions and systemic events were solicited for 3 days after each dose. Most local and systemic reactions were mild. The proportions of local and systemic reactions in children were similar to the proportions in adults. No reported local or systemic reaction required a therapeutic intervention other than analgesics. (3)

6.2. Post-Marketing Experience

1 The following additional events have been reported during post-approval use of Fluzone vaccine.

2

3 Because these events are reported voluntarily from a population of uncertain size, it is not always
4 possible to reliably estimate their frequency or establish a causal relationship to vaccine
5 exposure.

6

7 *Blood and Lymphatic System Disorders:* Thrombocytopenia, lymphadenopathy

8

9 *Immune System Disorders:* Anaphylaxis, other allergic/hypersensitivity reactions (including
10 urticaria, angioedema)

11

12 *Nervous System Disorders:* GBS, convulsions, myelitis (including encephalomyelitis and
13 transverse myelitis), facial palsy (Bell's palsy), optic neuritis/neuropathy, brachial neuritis,
14 syncope (shortly after vaccination), dizziness, paresthesia

15

16 *Vascular Disorders:* Vasculitis, vasodilation/flushing

17

18 *Respiratory, Thoracic and Mediastinal Disorders:* Dyspnea, pharyngitis, rhinitis

19

20 *Skin and Subcutaneous Tissue Disorders:* Stevens-Johnson syndrome

21

1 *General Disorders and Administration Site Conditions:* Fever, pain, pruritis, asthenia/fatigue,
2 pain in extremities, chest pain
3

3

4 **6.3. Other Adverse Events Associated with Influenza Vaccines**

5 Anaphylaxis has been reported after administration of influenza vaccines. Although Fluzone
6 vaccine contains only a limited quantity of egg protein, this protein can induce immediate
7 hypersensitivity reactions among persons who have severe egg allergy. Allergic reactions include
8 hives, angioedema, allergic asthma, and systemic anaphylaxis. [See *Contraindications* (4)]
9

9

10 The 1976 swine influenza vaccine was associated with an increased frequency of Guillain-Barré
11 syndrome (GBS). Evidence for a causal relation of GBS with subsequent vaccines prepared from
12 other influenza viruses is unclear. If influenza vaccine does pose a risk, it is probably slightly
13 more than 1 additional case/1 million persons vaccinated.
14

14

15 Neurological disorders temporally associated with influenza vaccination such as encephalopathy,
16 optic neuritis/neuropathy, partial facial paralysis, and brachial plexus neuropathy have been
17 reported.
18

18

19 Microscopic polyangitis (vasculitis) has been reported temporally associated with influenza
20 vaccination.
21

21

22 **7. DRUG INTERACTIONS**

1 **7.1. Concomitant Administration with Other Vaccines**

2 Fluzone vaccine should not be mixed with any other vaccine in the same syringe or vial.

3

4 If Fluzone vaccine is to be given at the same time as another injectable vaccine(s), the vaccine(s)
5 should always be administered at different injection sites.

6

7 **7.2. Immunosuppressive Therapies**

8 If Fluzone vaccine is administered to immunosuppressed persons or persons receiving
9 immunosuppressive therapy, immunologic response may be diminished.

10

11 **8. USE IN SPECIFIC POPULATIONS**

12 **8.1. Pregnancy**

13 Pregnancy Category C: Animal reproduction studies have not been conducted with Fluzone
14 vaccine. It is also not known whether Fluzone vaccine can cause fetal harm when administered to
15 a pregnant woman or can affect reproduction capacity. Fluzone vaccine should be given to a
16 pregnant woman only if clearly needed.

17

18 **8.3. Nursing Mothers**

19 It is not known whether Fluzone vaccine is excreted in human milk. Because many drugs are
20 excreted in human milk, caution should be exercised when Fluzone vaccine is administered to a
21 nursing woman.

22

1 **8.4. Pediatric Use**

2 Safety and effectiveness of Fluzone vaccine in children below the age of 6 months have not been
3 established. The immune response and safety of Fluzone vaccine was evaluated in 31 children
4 between the ages of 6-26 months. [See *Adverse Reactions (6.1)*, *Clinical Studies (14)*]

5
6 **8.5. Geriatric Use**

7 Immune response to Fluzone vaccine in subjects older than 65 years of age may be lower when
8 compared to immune responses in younger subjects. [See *Clinical Studies (14)*]

9
10 **11. DESCRIPTION**

11
12 Fluzone vaccine (Influenza Virus Vaccine), an inactivated influenza virus vaccine, for
13 intramuscular use, is prepared from influenza viruses propagated in embryonated chicken eggs.
14 The virus-containing allantoic fluid is harvested and inactivated with formaldehyde. Influenza
15 virus is concentrated and purified in a linear sucrose density gradient solution using a continuous
16 flow centrifuge. The virus is then chemically disrupted using a non-ionic surfactant, polyethylene
17 glycol p-isooctylphenyl ether, (Triton® X-100) producing a “split virus”. The split virus is further
18 purified and then suspended in sodium phosphate-buffered isotonic sodium chloride solution.

19
20 Fluzone vaccine has been standardized according to the US Public Health Service (USPHS)
21 requirements for the 2009-2010 influenza season and is formulated to contain 45 micrograms
22 (mcg) hemagglutinin per 0.5 mL dose. Each 0.5 mL dose contains 15 mcg influenza virus

1 hemagglutinin (HA) of each of the following 3 viruses: A/Brisbane/59/2007, IVR-148 (H1N1),
2 A/Uruguay/716/2007, NYMC X-175C (an A/Brisbane/10/2007-like virus) (H3N2), and
3 B/Brisbane/60/2008. Gelatin 0.05% is added as a stabilizer. Each 0.5 mL dose may contain
4 residual amounts of formaldehyde (not more than 100 mcg), polyethylene glycol p-
5 isooctylphenyl ether (not more than 0.02%), and sucrose (not more than 2.0%).

6

7 There is no thimerosal used in the manufacturing process of the No Preservative single-dose
8 presentations of Fluzone vaccine. The multi-dose presentation of Fluzone vaccine contains
9 thimerosal, a mercury derivative, added as a preservative. Each 0.5 mL dose contains 25 mcg
10 mercury.

11

12 Fluzone vaccine is a clear to a slightly opalescent suspension.

13

14 Antibiotics are not used in the manufacture of Fluzone vaccine.

15

16 All presentations of Fluzone vaccine are latex-free.

17

18 **12. CLINICAL PHARMACOLOGY**

19 **12.1. Mechanism of Action**

20 Influenza illness and its complications follow infection with influenza viruses. Global
21 surveillance of influenza identifies yearly antigenic variants. For example, since 1977, antigenic
22 variants of influenza A (H1N1 and H3N2) viruses and influenza B viruses have been in global

1 circulation. Specific levels of hemagglutinin inhibition (HI) antibody titer post-vaccination with
2 inactivated influenza virus vaccines have not been correlated with protection from influenza
3 virus infection. In some human studies, antibody titer of $\geq 1:40$ have been associated with
4 protection from influenza illness in up to 50% of subjects. (4) (5)

5
6 Antibodies against one influenza virus type or subtype confer limited or no protection against
7 another. Furthermore, antibodies to one antigenic variant of influenza virus might not protect
8 against a new antigenic variant of the same type or subtype. Frequent development of antigenic
9 variants through antigenic drift is the virologic basis for seasonal epidemics and the reason for
10 the usual change of one or more new strains in each year's influenza vaccine. Therefore,
11 influenza vaccines are standardized to contain the hemagglutinins of influenza virus strains (ie,
12 typically two type A and one type B), representing the influenza viruses likely to be circulating
13 in the US in the upcoming winter.

14
15 Annual vaccination with the current vaccine is recommended because immunity during the year
16 after vaccination declines, and because circulating strains of influenza virus change from year to
17 year. (1)

18

19 **13. NON-CLINICAL TOXICOLOGY**

20 **13.1. Carcinogenesis, Mutagenesis, Impairment of Fertility**

21 Fluzone vaccine has not been evaluated for carcinogenic or mutagenic potential, or for
22 impairment of fertility.

14. CLINICAL STUDIES

14.1. Immunogenicity in the Adult and Geriatric Population

In an observational study of the immunogenicity of Fluzone vaccine in a geriatric population (median age: 72.0 range: 61 to 86 years of age) compared with younger adults (median age: 38.0 range: 19 to 59 years of age; racial distribution was 2 Asian, 11 Black, 106 Caucasian, and 2 other; no gender data were available), the following results were obtained using a single-dose of the year 1999–2000 formulation of Fluzone vaccine. (See [Table 1.](#)) Antibody levels were obtained on the day of and just prior to vaccination and approximately 21 days after vaccination.

(4)

Table 1: Geometric Mean Titer (GMT) and Percentage (%) Achieving an HI Titer $\geq 1:40$ (N = 58-62) in Adults and the Elderly

| ANTIGEN | | | PRE-VACCINE GMT | POST-VACCINE GMT (% TITER ≥ 40) |
|----------|-------------|------------------|-----------------|---------------------------------------|
| A (H3N2) | Cohort 1999 | Young (N = 60) | 16.6 | 53.1 (72) |
| | | Elderly (N = 61) | 20.1 | 58.2 (70) |
| | Cohort 2000 | Young (N = 58) | 18.6 | 72.7 (79) |
| | | Elderly (N = 62) | 18.1 | 49.7 (68) |
| A (H1N1) | Cohort 1999 | Young (N = 60) | 11.1 | 35.6 (49) |
| | | Elderly (N = 61) | 12.2 | 26.5 (38) |
| | Cohort 2000 | Young (N = 58) | 8.9 | 35.9 (54) |
| | | Elderly (N = 62) | 6.7 | 16.0 (23) |
| B | Cohort 1999 | Young (N = 60) | 14.4 | 41.4 (38) |
| | | Elderly (N = 61) | 9.9 | 19.4 (10) |

| ANTIGEN | | PRE-VACCINE GMT | POST-VACCINE GMT (% TITER ≥40) |
|-------------|------------------|-----------------|--------------------------------|
| Cohort 2000 | Young (N = 58) | 9.4 | 21.5 (38) |
| | Elderly (N = 62) | 7.4 | 9.9 (11) |

1 N = Number of participants

2

3

14.2. Immunogenicity in Children

4 In a study using 2 doses of Fluzone vaccine (2003-2004) in 31 healthy children 6–36 months of
5 age (3 Black, 23 Caucasian, 2 Hispanic, and 3 other; 15 were male and 16 were female), the
6 following immunogenicity results were obtained on day 0 before vaccination and approximately
7 14 days after dose number 2. (See [Table 2.](#))

8

9 **Table 2: Geometric Mean Titer (GMT) and Percentage (%) Achieving an HI Titer of ≥**

10 **1:40 in Children**

| ANTIGEN | PRE-VACCINE GMT | POST-DOSE 2 GMT (% TITER ≥40) |
|----------|-----------------|-------------------------------|
| A (H3N2) | 7.7 | 52.9 (77.4) |
| A (H1N1) | 6.5 | 52.9 (77.4) |
| B | 5.2 | 27.3 (48.4) |

11

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1 **15. REFERENCES**

2

3

4 1 Centers for Disease Control and Prevention. Prevention and Control of Influenza:
5 Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR
6 2008;57(RR07):1-60.

7 2 CDC. General recommendations on immunization: Recommendations of the ACIP and the
8 American Academy of Family Physicians (AAFP). MMWR 2006;55(RR15):1-48.

9 3 Sanofi Pasteur Inc. Data on file, 071107.

10 4 Hannoun C et al. Immunogenicity and protective efficacy of influenza vaccination. Virus
11 Res 2004;103:133-138

12 5 Hobson D, et al. The role of serum hemagglutinin-inhibiting antibody in protection against
13 challenge infection with influenza A2 and B viruses J Hyg Camb 1972;767-777.

14

15

1 **16. HOW SUPPLIED/STORAGE AND HANDLING**

2 **16.1. How Supplied**

3 Latex-free prefilled syringe, without needle, 0.25 mL, package of 10 prefilled syringes per carton
4 – Product No. NDC 49281-009-25.

5
6 Latex-free prefilled syringe, without needle, 0.5 mL, package of 10 prefilled syringes per carton –
7 Product No. NDC 49281-009-50.

8
9 Latex-free single-dose vial, 0.5 mL, package of 10 vials per carton – Product No. NDC 49281-
10 009-10.

11
12 Latex-free multi-dose vial, 5 mL, one vial per carton. The vial contains ten 0.5 mL doses –
13 Product No. NDC 49281-384-15.

14
15 **16.2. Storage and Handling**

16 Store all Fluzone vaccine presentations refrigerated at 2° to 8°C (35° to 46°F). DO NOT
17 FREEZE. Discard if vaccine has been frozen.

18
19 Between uses, return the multi-dose vial to the recommended storage conditions at 2° to 8°C (35°
20 to 46°F).

21
22 Do not use after the expiration date shown on the label.

1

2 **17. PATIENT COUNSELING INFORMATION**

3 • Inform the patient or guardian that Fluzone vaccine contains killed viruses and cannot cause
4 influenza. Fluzone vaccine stimulates the immune system to produce antibodies that protect
5 against influenza, but not against other respiratory diseases. Annual vaccination is
6 recommended.

7

8 • Vaccine recipients and guardians should be instructed to report any severe or unusual adverse
9 reactions to their health care provider.

10

11 Fluzone vaccine is a registered trademark of Sanofi Pasteur Inc.

12

13

14

Product information

15

as of May 2009.

16

17 Manufactured by:

18 **Sanofi Pasteur Inc.**

19 Swiftwater PA 18370 USA

20

21

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