

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Influenza A (H1N1) 2009 Monovalent Vaccine safely and effectively. See full prescribing information for Influenza A (H1N1) 2009 Monovalent Vaccine.

Influenza A (H1N1) 2009 Monovalent Vaccine
Manufactured by Sanofi Pasteur Inc.
Suspension for Intramuscular Injection
Initial US Approval: 1980

RECENT MAJOR CHANGES

Indications and Usage (1) [9/2009]
Dosage and Administration (2.2) [9/2009]

INDICATIONS AND USAGE

Influenza A (H1N1) 2009 Monovalent Vaccine is an inactivated influenza virus vaccine indicated for active immunization of persons 6 months of age and older against influenza disease caused by pandemic (H1N1) 2009 virus. (1)

DOSAGE AND ADMINISTRATION

Based on currently available information the vaccination regimen is as follows:

Children

- 6 through 35 months of age (0.25 mL dose, intramuscular injection):
 - Two 0.25 mL doses approximately one month apart. (2.2)
- 36 months through 9 years of age (0.5 mL dose, intramuscular injection):
 - Two 0.5 mL doses approximately one month apart. (2.2)
- 10 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

Influenza A (H1N1) 2009 Monovalent Vaccine, a sterile suspension for intramuscular injection, is supplied in four presentations:

- Prefilled syringe, 0.25 mL, no preservative; 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, 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, 11)

WARNINGS AND PRECAUTIONS

- If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of previous influenza vaccination, the decision to give Influenza A (H1N1) 2009 Monovalent Vaccine should be based on careful consideration of the potential benefits and risks. (5.1)
- Immunocompromised persons may have a reduced immune response to Influenza A (H1N1) 2009 Monovalent Vaccine. (5.2)

ADVERSE REACTIONS

Adverse reaction information is based on studies conducted with seasonal trivalent Influenza Virus Vaccine.

- 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 Influenza A (H1N1) 2009 Monovalent Vaccine. (7.2)

USE IN SPECIFIC POPULATIONS

Information in this section is based on seasonal trivalent Influenza Virus Vaccine manufactured by Sanofi Pasteur Inc. (Fluzone vaccine).

- Safety and effectiveness of Influenza A (H1N1) 2009 Monovalent Vaccine have not been established in pregnant women or nursing mothers or children <6 months of age. (8.1, 8.3, 8.4)
- Antibody responses to Fluzone vaccine were lower in the geriatric population than in younger adults. (8.5)

See 17 PATIENT_COUNSELING_INFORMATION.

Revised: September 2009

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1 **FULL PRESCRIBING INFORMATION:**

2 **1. INDICATIONS AND USAGE**

3 Influenza A (H1N1) 2009 Monovalent Vaccine is an inactivated influenza virus vaccine
4 indicated for active immunization of persons 6 months of age and older against influenza disease
5 caused by pandemic (H1N1) 2009 virus.

6
7 **2. DOSAGE AND ADMINISTRATION**

8 **2.1. Preparation for Administration**

9 Inspect Influenza A (H1N1) 2009 Monovalent Vaccine syringes and vials visually for particulate
10 matter and/or discoloration prior to administration. If either of these conditions exist, the vaccine
11 should not be 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 Clinical studies are ongoing with Influenza A (H1N1) 2009 Monovalent Vaccine to determine
18 the optimal dosage, number of doses and schedule.

19

20 Available data show that children 9 years of age and younger are largely serologically naive to
21 the pandemic (H1N1) 2009 virus. (1) Based upon these data Influenza A (H1N1) 2009

22 Monovalent Vaccine should be administered as follows:

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Children

Children 6 through 35 months of age should receive two 0.25 mL intramuscular doses approximately 1 month apart. (1)

Children 36 months through 9 years of age should receive two 0.5 mL intramuscular doses approximately 1 month apart. (1)

Children 10 years of age and older should receive a single 0.5 mL intramuscular dose. (1)

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

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

Adults

Persons 18 years of age and older should receive a single 0.5 mL intramuscular dose.

In adults, the preferred site for intramuscular injection is the deltoid muscle.

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

3

4 **3. DOSAGE FORMS AND STRENGTHS**

5 Influenza A (H1N1) 2009 Monovalent Vaccine is a sterile suspension for intramuscular
6 injection. [See *Description (11)*]

7

8 Influenza A (H1N1) 2009 Monovalent Vaccine is supplied in 4 presentations:

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

16

17 **4. CONTRAINDICATIONS**

18 Do not administer Influenza A (H1N1) 2009 Monovalent Vaccine to anyone with a known
19 severe hypersensitivity to egg proteins or any component of the vaccine or life-threatening
20 reactions after previous administration of any influenza vaccine. [See *Warnings and Precautions*
21 *(5)* and *Description (11)*]

22

23 **5. WARNINGS AND PRECAUTIONS**

1 **5.1. Guillain-Barré Syndrome**

2 Recurrence of Guillain-Barré syndrome (GBS) has been temporally associated with the
3 administration of influenza vaccine. The decision to give Influenza A (H1N1) 2009 Monovalent
4 Vaccine to individuals who have a prior history of Guillain-Barré syndrome should be based on
5 careful consideration of the potential benefits and risks.

6

7 **5.2. Altered Immunocompetence**

8 If Influenza A (H1N1) 2009 Monovalent Vaccine is administered to immunocompromised
9 persons, including those receiving immunosuppressive therapy, the immune response may be
10 diminished.

11

12 **5.3. Preventing and Managing Allergic Reaction**

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

15

16 **5.4. Limitations of Vaccine Effectiveness**

17 Vaccination with Influenza A (H1N1) 2009 Monovalent Vaccine may not protect all recipients.

18

19 **6. ADVERSE REACTIONS**

20 Sanofi Pasteur's Influenza A (H1N1) 2009 Monovalent Vaccine and seasonal trivalent Influenza
21 Virus Vaccine (Fluzone[®]) are manufactured by the same process. The following sub-sections

1 summarize safety data from clinical experience with seasonal trivalent inactivated influenza
2 vaccines, including Fluzone vaccine.

3 **6.1. Clinical Trial Experience**

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

9 10 *Adults and Geriatrics*

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

20

1 **Children**

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

8

9 **6.2. Post-Marketing Experience**

10 The following additional events have been reported during post-approval use of Fluzone vaccine.
11 Because these events are reported voluntarily from a population of uncertain size, it is not always
12 possible to reliably estimate their frequency or establish a causal relationship to vaccine
13 exposure.

14

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

16

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

19

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

1

2 *Vascular Disorders:* Vasculitis, vasodilation/flushing

3

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

5

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

7

8 *General Disorders and Administration Site Conditions:* Fever, pain, pruritis, asthenia/fatigue,
9 pain in extremities, chest pain

10

11 **6.3. Other Adverse Events Associated with Influenza Vaccines**

12 Anaphylaxis has been reported after administration of influenza vaccines. Although Influenza A
13 (H1N1) 2009 Monovalent Vaccine contains only a limited quantity of egg protein, this protein
14 can induce immediate hypersensitivity reactions among persons who have severe egg allergy.

15 Allergic reactions include hives, angioedema, allergic asthma, and systemic anaphylaxis. [See
16 *Contraindications (4)*]

17

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

22

1 Neurological disorders temporally associated with influenza vaccination such as encephalopathy,
2 optic neuritis/neuropathy, partial facial paralysis, and brachial plexus neuropathy have been
3 reported.

4

5 Microscopic polyangitis (vasculitis) has been reported temporally associated with influenza
6 vaccination.

7

8 **7. DRUG INTERACTIONS**

9 **7.1. Concomitant Administration with Other Vaccines**

10 There are no data on the concomitant administration of Influenza A (H1N1) 2009 Monovalent
11 Vaccine with seasonal trivalent influenza vaccines.

12

13 Influenza A (H1N1) 2009 Monovalent Vaccine should not be mixed with any other vaccine in
14 the same syringe or vial.

15

16 If Influenza A (H1N1) 2009 Monovalent Vaccine is to be given at the same time as another
17 injectable vaccine(s), the vaccine(s) should always be administered at different injection sites.

18

19 **7.2. Immunosuppressive Therapies**

20 If Influenza A (H1N1) 2009 Monovalent Vaccine is administered to immunosuppressed persons
21 or persons receiving immunosuppressive therapy, immunologic response may be diminished.

22

1 **8. USE IN SPECIFIC POPULATIONS**

2 Sanofi Pasteur's Influenza A (H1N1) 2009 Monovalent Vaccine and seasonal trivalent Influenza
3 Virus Vaccine (Fluzone vaccine) are manufactured by the same process. Available information
4 for Fluzone vaccine is provided in this section.

5 **8.1. Pregnancy**

6 Pregnancy Category C: Animal reproduction studies have not been conducted with Influenza A
7 (H1N1) 2009 Monovalent Vaccine or Fluzone vaccine. It is also not known whether these
8 vaccines can cause fetal harm when administered to a pregnant woman or can affect reproduction
9 capacity. Influenza A (H1N1) 2009 Monovalent Vaccine should be given to a pregnant woman
10 only if clearly needed.

11
12 **8.3. Nursing Mothers**

13 It is not known whether Influenza A (H1N1) 2009 Monovalent Vaccine or Fluzone vaccine is
14 excreted in human milk. Because many drugs are excreted in human milk, caution should be
15 exercised when this vaccine is administered to a nursing woman.

16
17 **8.4. Pediatric Use**

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

21
22 **8.5. Geriatric Use**

1 Immune response to Fluzone vaccine in subjects older than 61 years of age were lower when
2 compared to immune responses in adults 19-59 years of age. [See *Clinical Studies (14)*]
3

4 **11. DESCRIPTION**

5

6 Influenza A (H1N1) 2009 Monovalent Vaccine, an inactivated influenza virus vaccine, for
7 intramuscular use, is prepared from influenza viruses propagated in embryonated chicken eggs.
8 The virus-containing allantoic fluid is harvested and inactivated with formaldehyde. Influenza
9 virus is concentrated and purified in a linear sucrose density gradient solution using a continuous
10 flow centrifuge. The virus is then chemically disrupted using a non-ionic surfactant, polyethylene
11 glycol p-isooctylphenyl ether (Triton[®] X-100), producing a “split virus”. The split virus is further
12 purified and then suspended in sodium phosphate-buffered isotonic sodium chloride solution.
13

14 Influenza A (H1N1) 2009 Monovalent Vaccine is formulated to contain 15 mcg hemagglutinin
15 (HA) of influenza A/California/07/2009 (H1N1) v-like virus per 0.5 mL dose. Gelatin 0.05% is
16 added as a stabilizer. Each 0.5 mL dose may contain residual amounts of formaldehyde (not
17 more than 100 mcg), polyethylene glycol p-isooctylphenyl ether (not more than 0.02%), and
18 sucrose (not more than 2.0%).
19

20 There is no thimerosal used in the manufacturing process of the single-dose presentations of
21 Influenza A (H1N1) 2009 Monovalent Vaccine. The multi-dose presentation of Influenza A
22 (H1N1) 2009 Monovalent Vaccine contains thimerosal, a mercury derivative, added as a
23 preservative. Each 0.5 mL dose of the multidose presentation contains 25 mcg mercury.

1

2 Influenza A (H1N1) 2009 Monovalent Vaccine is a sterile clear to a slightly opalescent
3 suspension.

4

5 Antibiotics are not used in the manufacture of Influenza A (H1N1) 2009 Monovalent Vaccine.

6

7 All presentations of Influenza A (H1N1) 2009 Monovalent Vaccine do not contain latex.

8

9 **12. CLINICAL PHARMACOLOGY**

10 **12.1. Mechanism of Action**

11 Influenza illness and its complications follow infection with influenza viruses. Global
12 surveillance of influenza identifies yearly antigenic variants. For example, since 1977, antigenic
13 variants of influenza A (H1N1 and H3N2) viruses and influenza B viruses have been in global
14 circulation. Specific levels of hemagglutinin inhibition (HI) antibody titer post-vaccination with
15 inactivated influenza virus vaccines have not been correlated with protection from influenza
16 virus infection. In some human studies, antibody titer of $\geq 1:40$ have been associated with
17 protection from influenza illness in up to 50% of subjects. (4) (5)

18

19 Antibodies against one influenza virus type or subtype confer limited or no protection against
20 another. Furthermore, antibodies to one antigenic variant of influenza virus might not protect
21 against a new antigenic variant of the same type or subtype. Frequent development of antigenic

1 variants through antigenic drift is the virologic basis for seasonal epidemics and the reason for
2 the usual change of one or more new strains in each year's influenza vaccine.

3

4 **13. NON-CLINICAL TOXICOLOGY**

5 **13.1. Carcinogenesis, Mutagenesis, Impairment of Fertility**

6 Neither Fluzone vaccine nor Influenza A (H1N1) 2009 Monovalent Vaccine have been evaluated
7 for carcinogenic or mutagenic potential, or for impairment of fertility.

8

9 **14. CLINICAL STUDIES**

10 Sanofi Pasteur's Influenza A (H1N1) 2009 Monovalent Vaccine and seasonal trivalent Influenza
11 Virus Vaccine (Fluzone vaccine) are manufactured by the same process. Data in this section
12 were obtained in clinical studies conducted with Fluzone vaccine.

13

14 **14.1. Immunogenicity in the Adult and Geriatric Population**

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

21 (4)

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

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)
	Cohort 2000	Young (N = 58)	9.4	21.5 (38)
		Elderly (N = 62)	7.4	9.9 (11)

3 N = Number of participants

4

5 **14.2. Immunogenicity in Children**

6 In a study using 2 doses of Fluzone vaccine (2003-2004) in 31 healthy children 6–36 months of
7 age (3 Black, 23 Caucasian, 2 Hispanic, and 3 other; 15 were male and 16 were female), the
8 following immunogenicity results were obtained on day 0 before vaccination and approximately
9 14 days after dose number 2. (See [Table 2.](#))

10

- 1 **Table 2: Geometric Mean Titer (GMT) and Percentage (%) Achieving an HI Titer of \geq**
2 **1:40 in Children (after vaccination with Fluzone vaccine)**

ANTIGEN	PRE-VACCINE GMT	POST-DOSE 2 GMT (% TITER \geq40)
A (H3N2)	7.7	52.9 (77.4)
A (H1N1)	6.5	52.9 (77.4)
B	5.2	27.3 (48.4)

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5

1 **15. REFERENCES**

2

3

4 1 Centers for Disease Control and Prevention. Serum Cross-Reactive Antibody Response to a
5 Novel Influenza A (H1N1) Virus After Vaccination with Seasonal Influenza Vaccine.
6 MMWR 2009;58(19):521-524.

7 2 Centers for Disease Control and Prevention. Prevention and Control of Influenza:
8 Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR
9 2009;58(RR08):1-52.

10 3 Sanofi Pasteur Inc. Data on file, 071107.

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

13 5 Hobson D, et al. The role of serum hemagglutinin-inhibiting antibody in protection against
14 challenge infection with influenza A2 and B viruses J Hyg Camb 1972;70:767-777.

15

16

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

2 **16.1. How Supplied**

3 Single-dose prefilled syringe, without needle, 0.25 mL, package of 10 prefilled syringes per
4 carton – Product No. NDC 49281-650-25.

5
6 Single-dose prefilled syringe, without needle, 0.25 mL, package of 25 prefilled syringes per
7 carton – Product No. NDC 49281-650-70.

8
9 Single-dose prefilled syringe, without needle, 0.5 mL, package of 10 prefilled syringes per carton
10 – Product No. NDC 49281-650-50.

11
12 Single-dose prefilled syringe, without needle, 0.5 mL, package of 25 prefilled syringes per carton
13 – Product No. NDC 49281-650-90.

14
15 Single-dose vial, 0.5 mL, package of 10 vials per carton – Product No. NDC 49281-650-10.

16
17 Multi-dose vial, 5 mL, one vial per carton. The vial contains ten 0.5 mL doses – Product No. NDC
18 49281-640-15.

19
20 Vial stoppers and syringe plungers do not contain latex.

21
22 **16.2. Storage and Handling**

1 Store all Influenza A (H1N1) 2009 Monovalent Vaccine presentations refrigerated at 2° to 8°C
2 (35° to 46°F). DO NOT FREEZE. Discard if vaccine has been frozen.

3

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

6

7 Do not use after the expiration date shown on the label.

8

9 **17. PATIENT COUNSELING INFORMATION**

- 10 • Inform vaccine recipients or guardians that Influenza A (H1N1) 2009 Monovalent Vaccine
11 contains killed viruses and cannot cause influenza.
- 12 • Inform vaccine recipients or guardians that there are two influenza vaccine formulations for
13 this influenza season, the monovalent vaccine against influenza disease caused by pandemic
14 (H1N1) 2009 virus and seasonal trivalent influenza vaccine.
- 15 • Instruct vaccine recipients or guardians to report any severe or unusual adverse reactions to
16 their health care provider.

17

18

19

20

21

22

23 Manufactured by:

Product information
as of September 2009.

1 **Sanofi Pasteur Inc.**

2 Swiftwater PA 18370 USA

3

5860-5862

4

sanofi pasteur

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