HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Fluzone Intradermal safely and effectively. See full prescribing information for Fluzone Intradermal.

Fluzone Intradermal (Influenza Virus Vaccine)
Suspension for Intradermal Injection
2012-2013 Formula
Initial US Approval: 2011

----------RECENT MAJOR CHANGES----------

Indications and Usage (1) **[05/2011]**
Dosage and Administration (2) **[05/2011]**

----------INDICATIONS AND USAGE----------

Fluzone Intradermal is indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. (1)
Fluzone Intradermal is approved for use in persons 18 through 64 years of age. (1)

----------DOSAGE AND ADMINISTRATION----------

- **For intradermal use only**

A single 0.1 mL dose for intradermal injection in adults 18 through 64 years of age (2.1).

----------DOSAGE FORMS AND STRENGTHS----------

Suspension for injection in a prefilled microinjection system, 0.1 mL. (3)

----------CONTRAINDICATIONS----------

Severe allergic reaction to any component of the vaccine, including egg protein, or after previous dose 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 Intradermal should be based on careful consideration of the potential benefits and risks. (5.1)

----------ADVERSE REACTIONS----------

The most common injection-site reactions were erythema (>75%), induration (>50%), swelling (>50%), pain (>50%), and pruritus (>40%). Erythema, induration, swelling and pruritus occurred more frequently following Fluzone Intradermal than Fluzone. The most common solicited systemic adverse events were headache, myalgia, and malaise (>20%). (6.1)
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 www.vaers.hhs.gov.

----------USE IN SPECIFIC POPULATIONS----------

Safety and effectiveness of Fluzone Intradermal have not been established in pregnant women. (8.1) Pregnancy registry available for Fluzone Intradermal. Contact Sanofi Pasteur Inc. at 1-800-822-2463.

See **17 PATIENT COUNSELING INFORMATION and FDA-approved patient labeling**.

Revised: May 2012

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

FULL PRESCRIBING INFORMATION:

1 INDICATIONS AND USAGE

Fluzone® Intradermal is an inactivated influenza virus vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

Fluzone Intradermal is approved for use in persons 18 through 64 years of age.

2 DOSAGE AND ADMINISTRATION

- **For intradermal use only**

2.1 Dose and Schedule

Fluzone Intradermal should be administered as a single 0.1 mL injection by the intradermal route in adults 18 through 64 years of age.

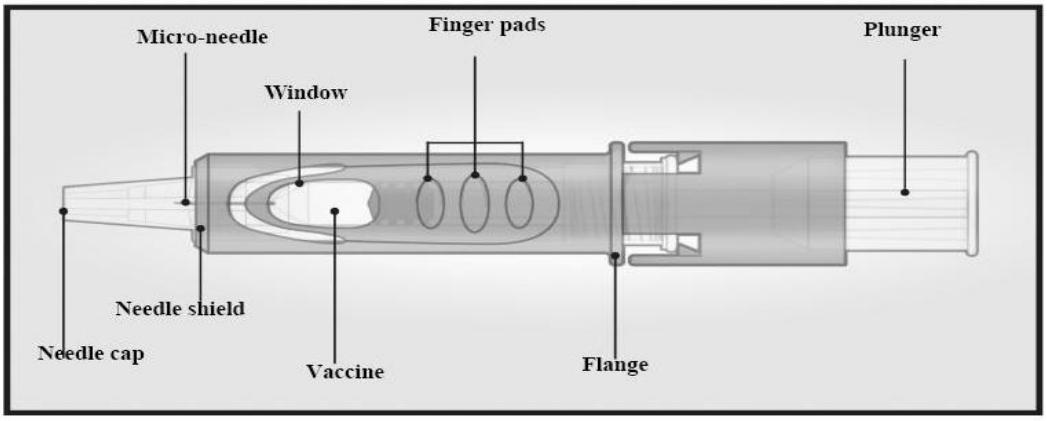
2.2 Administration

Inspect Fluzone Intradermal microinjection system visually for particulate matter and/or discoloration prior to administration. If either of these conditions exist, the vaccine should not be administered.

The preferred site of injection is the skin in the region of the deltoid.

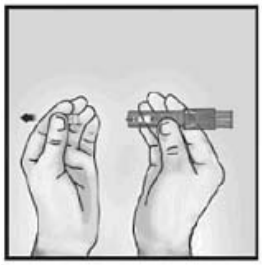
Fluzone Intradermal vaccine should not be combined through reconstitution or mixed with any other vaccine.

Gently shake the microinjection system before administering the vaccine.



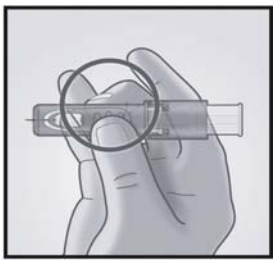
1. Remove Needle Cap

Remove the needle cap from the microinjection system.



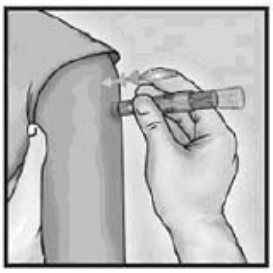
2. Hold Microinjection System Between Thumb and Middle Finger

Hold the system by placing the thumb and middle finger only on the finger pads, the index finger remains free. Do not place fingers on the windows.



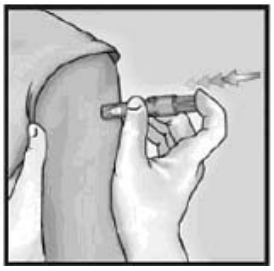
3. Insert Needle Rapidly and Perpendicular to the Skin

Insert the needle perpendicular to the skin, in the region of the deltoid, in a short, quick movement.



4. Inject Using the Index Finger

Once the needle has been inserted, maintain light pressure on the surface of the skin and inject using the index finger to push on the plunger. Do not aspirate. Once the intradermal vaccine has been administered, a wheal may be visible at the injection site.



5. Remove Needle from Skin and Activate Needle Shield by Pushing Firmly on Plunger

Remove the needle from the skin. Direct the needle away from you and others. With the same hand, push very firmly with the thumb on the plunger to activate the needle shield. You will hear a click when the shield extends to cover the needle.

3 DOSAGE FORMS AND STRENGTHS

Fluzone Intradermal is a suspension for injection.

Fluzone Intradermal is supplied in a single-dose prefilled microinjection system, 0.1 mL, for adults 18 through 64 years of age.

4 CONTRAINDICATIONS

A severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine [see *Description (11)*], including egg protein, or to a previous dose of any influenza vaccine is a contraindication to administration of Fluzone Intradermal.

5 WARNINGS AND PRECAUTIONS

5.1 Guillain-Barré Syndrome

The 1976 swine influenza vaccine was associated with an elevated risk of Guillain-Barré syndrome (GBS). Evidence for a causal relation of GBS with other influenza vaccines is inconclusive; if an excess risk exists, it is probably slightly more than 1 additional case per 1 million persons vaccinated (1). If GBS has occurred within 6 weeks of previous influenza vaccination, the decision to give Fluzone Intradermal should be based on careful consideration of the potential benefits and risks.

5.2 Preventing and Managing Allergic Reactions

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

5.3 Altered Immunocompetence

If Fluzone Intradermal is administered to an immunocompromised person, including those receiving immunosuppressive therapy, the expected immune response may not be obtained.

5.4 Limitations of Vaccine Effectiveness

Vaccination with Fluzone Intradermal may not protect all recipients.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse event rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trial of another vaccine, and may not reflect the rates observed in practice.

Adults 18 through 64 years of age were randomized to receive Fluzone Intradermal or Fluzone (year 2008-2009 formulation) in a multi-center trial conducted in the US. The trial was open-label for administration route. The safety analysis set included 2855 Fluzone Intradermal recipients and 1421 Fluzone recipients. Table 1 summarizes solicited injection-site reactions and systemic adverse events reported within 7 days post-vaccination via diary cards. With the exception of pain, solicited injection-site reactions were more frequent after vaccination with Fluzone Intradermal compared to Fluzone. Nine percent of Fluzone recipients and 49% of Fluzone Intradermal recipients had an injection-site reaction present beyond Day 3 post-vaccination. Approximately 20% of subjects in both groups had a solicited systemic adverse event present beyond Day 3 post-vaccination.

Table 1: Frequency of Solicited Injection-Site Reactions and Systemic Adverse Events Within 7 Days After Vaccine Injection, Adults 18 Through 64 Years of Age

	Fluzone Intradermal (N[a]=2798-2802) Percentage			Fluzone (N[a]=1392-1394) Percentage		
	Any	**Grade 2[b]**	**Grade 3[c]**	**Any**	**Grade 2[b]**	**Grade 3[c]**
Injection-Site Erythema	76.4	28.8	13.0	13.2	2.1	0.9
Injection-Site Induration	58.4	13.0	3.4	10.0	2.3	0.5
Injection-Site Swelling	56.8	13.4	5.4	8.4	2.1	0.9
Injection-Site Pain	51.0	4.4	0.6	53.7	5.8	0.8
Injection-Site Pruritus	46.9	4.1	1.1	9.3	0.4	0.0
Injection-Site Ecchymosis	9.3	1.4	0.4	6.2	1.1	0.4
Headache	31.2	6.4	1.5	30.3	6.5	1.6
Myalgia	26.5	4.6	1.5	30.8	5.5	1.4
Malaise	23.3	5.5	2.2	22.2	5.5	1.8
Shivering	7.3	1.5	0.7	6.2	1.1	0.6
Fever[d]	3.9	0.6	0.1	2.6	0.4	0.2

[a]N is the number of vaccinated subjects with available data for the events listed.

[b] Grade 2 - Injection-site erythema, Injection-site induration, Injection-site swelling, and Injection-site ecchymosis: ≥2.5 cm to <5 cm; Injection-site pain and Injection-site pruritus: sufficiently discomforting to interfere with normal behavior or activities; Fever: >100.4 ºF to ≤102.2ºF; Headache, Myalgia, Malaise, and Shivering: interferes with daily activities

[c] Grade 3 - Injection-site erythema, Injection-site induration, Injection-site swelling, and Injection-site ecchymosis: ≥5 cm; Injection-site pain: incapacitating, unable to perform usual activities; Injection-site pruritus: incapacitating, unable to perform usual activities, may have/or required medical care or absenteeism; Fever: >102.2ºF; Headache, Myalgia, Malaise, and Shivering: prevents daily activities

[d] Fever - Any Fever indicates ≥99.5ºF. The percentage of temperature measurements that were taken by oral or axillary routes, or not recorded were 99.9%, <0.1%, and 0.1%, respectively for Fluzone Intradermal; and 99.6%, 0.0%, and 0.4%, respectively for Fluzone

Within 28 days post-vaccination, a serious adverse event was reported by 10 (0.4%) Fluzone Intradermal recipients and 5 (0.4%) Fluzone recipients. Within 6 months post-vaccination, a serious adverse event was reported by 47 (1.6%) Fluzone Intradermal recipients and 20 (1.4%) Fluzone recipients. No deaths were reported during the 6 months post-vaccination. Throughout the study, one reported serious adverse event was considered to be caused by vaccination: a pruritic rash on the extremities and torso that began 48 hours after receipt of Fluzone Intradermal and resulted in hospitalization and treatment with an antihistamine and steroids.

6.2 Post-Marketing Experience

Currently, there are no post-marketing data available for Fluzone Intradermal vaccine.

The following events have been spontaneously reported during the post-approval use of Fluzone. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Adverse events were included based on one or more of the following factors: severity, frequency of reporting, or strength of evidence for a causal relationship to Fluzone.

Events Reported During Post-Approval Use of Fluzone.

- *Blood and Lymphatic System Disorders*: Thrombocytopenia, lymphadenopathy
- *Immune System Disorders*: Anaphylaxis, other allergic/hypersensitivity reactions (including urticaria, angioedema)
- *Eye disorders:* Ocular hyperemia

- *Nervous System Disorders*: Guillain-Barré syndrome (GBS), convulsions, febrile convulsions, myelitis (including encephalomyelitis and transverse myelitis), facial palsy (Bell's palsy), optic neuritis/neuropathy, brachial neuritis, syncope (shortly after vaccination), dizziness, paresthesia
- *Vascular Disorders*: Vasculitis, vasodilatation/flushing
- *Respiratory, Thoracic and Mediastinal Disorders*: Dyspnea, pharyngitis, rhinitis, cough, wheezing, throat tightness
- *Skin and Subcutaneous Tissue Disorders*: Stevens-Johnson syndrome
- *General Disorders and Administration Site Conditions*: Pruritus, asthenia/fatigue, pain in extremities, chest pain
- *Gastrointestinal Disorders*: Vomiting

7 DRUG INTERACTIONS

Data evaluating the concomitant administration of Fluzone Intradermal with other vaccines are not available.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B: A developmental and reproductive toxicity study has been performed in female rabbits at a dose approximately 20 times the human dose (on a mg/kg basis) and has revealed no evidence of impaired female fertility or harm to the fetus due to Fluzone Intradermal. There are, however, no adequate and well-controlled studies in pregnant women. Because animal

reproduction studies are not always predictive of human response, Fluzone Intradermal should be used during pregnancy only if clearly needed.

Healthcare providers are encouraged to register women who receive Fluzone Intradermal during pregnancy in Sanofi Pasteur Inc.'s vaccination pregnancy registry by calling 1-800-822-2463.

8.3 Nursing Mothers

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

8.4 Pediatric Use

Safety and effectiveness of Fluzone Intradermal in persons <18 years of age have not been established. In a clinical trial, 97 infants and toddlers 6 months through 35 months of age and 160 children 3 years through 8 years of age were enrolled to receive two injections of Fluzone Intradermal. Infants and children in a control group received two injections of Fluzone. Fluzone Intradermal was associated with increased local reactogenicity relative to Fluzone. The size of the study was not adequate to reliably evaluate serious adverse events or the immune response elicited by Fluzone Intradermal relative to Fluzone.

8.5 Geriatric Use

Safety and effectiveness of Fluzone Intradermal in persons 65 years of age and older have not been established.

11 DESCRIPTION

Fluzone Intradermal (Influenza Virus Vaccine) for intradermal injection is an inactivated influenza virus vaccine, prepared from influenza viruses propagated in embryonated chicken eggs. The virus-containing allantoic fluid is harvested and inactivated with formaldehyde. Influenza virus is concentrated and purified in a linear sucrose density gradient solution using a continuous flow centrifuge. The virus is then chemically disrupted using a non-ionic surfactant, Octylphenol Ethoxylate (Triton® X-100), producing a "split virus". The split virus is further purified and then suspended in sodium phosphate-buffered isotonic sodium chloride solution. The Fluzone Intradermal process uses an additional concentration factor after the ultrafiltration step in order to obtain a higher hemagglutinin (HA) antigen concentration.

Fluzone Intradermal is a clear, slightly opalescent suspension for injection.

Neither antibiotics nor preservative are used in the manufacture of Fluzone Intradermal.

Fluzone Intradermal is standardized according to United States Public Health Service requirements and is formulated to contain HA of each of the following three influenza strains recommended for the 2012-2013 influenza season: A/California/07/2009 NYMC X-179A (H1N1), A/Victoria/361/2011 IVR-165 (H3N2) and B/Texas/6/2011 (a B/Wisconsin/1/2010-like virus). The amounts of HA and other ingredients per dose of vaccine are listed in Table 2.

Table 2: Fluzone Intradermal Ingredients

	Quantity (per dose)
Ingredient	**Fluzone Intradermal 0.1 mL Dose**
Active Substance: Split influenza virus, inactivated strains[a]:	27 mcg HA total
A (H1N1)	9 mcg HA
A (H3N2)	9 mcg HA
B	9 mcg HA
Other:	
Sodium phosphate-buffered isotonic sodium chloride solution	QS[b] to appropriate volume
Formaldehyde	≤20 mcg
Octylphenol Ethoxylate	≤50 mcg
Gelatin	None
Preservative	None

[a]per United States Public Health Service (USPHS) requirement.

[b]Quantity Sufficient.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Influenza illness and its complications follow infection with influenza viruses. Global surveillance of influenza identifies yearly antigenic variants. For example, since 1977, antigenic variants of influenza A (H1N1 and H3N2) viruses and influenza B viruses have been in global circulation. Specific levels of hemagglutination inhibition (HI) antibody titer post-vaccination with inactivated influenza virus vaccines have not been correlated with protection from influenza virus

infection. In some human studies, antibody titers ≥1:40 have been associated with protection from influenza illness in up to 50% of subjects. (2) (3)

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

Annual vaccination with the current vaccine is recommended because immunity during the year after vaccination declines, and because circulating strains of influenza virus change from year to year.

13 NON-CLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Fluzone Intradermal has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.

14 CLINICAL STUDIES

14.1 Immunogenicity of Fluzone Intradermal in Adults

Adults 18 through 64 years of age were randomized to receive Fluzone Intradermal or Fluzone (year 2008-2009 formulation) in a multi-center trial conducted in the US. The trial was open-label for administration route. For immunogenicity analyses, there were 2581 participants who received Fluzone Intradermal and 1287 participants who received Fluzone in the per protocol analysis set. There were fewer males than females (36.1% and 35.8% males in the Fluzone Intradermal and Fluzone groups, respectively). In the Fluzone Intradermal group, the mean age was 42.7 years (ranged from 18.1 through 65.0 years), and in the Fluzone group, the mean age was 42.6 years (ranged from 18.2 through 65.0 years). Most participants in the Fluzone Intradermal and Fluzone groups, respectively, were Caucasian (79.6% and 80.0%), followed by Hispanic (10.2% and 11.0%), and Black (7.7% and 6.3%). HI antibody geometric mean titers (GMTs) following Fluzone Intradermal were non-inferior to those following Fluzone for all three strains. (See Table 3) Seroconversion rates following Fluzone Intradermal were non-inferior to those following Fluzone for strains A (H1N1) and A (H3N2), but not for strain B. (See Table 4) At 28 days following vaccination with either Fluzone or Fluzone Intradermal, the percentages of subjects with a serum HI antibody titer of at least 1:40 ranged from 87% to 92%, depending on the influenza strain.

Table 3: Non-inferiority of Fluzone Intradermal Relative to Fluzone by HI Antibody GMTs at 28 Days Post Vaccination, Adults 18 through 64 Years of Age

Influenza Strain	GMT		GMT Ratio (95% CI)	Non-inferior[a]
	Fluzone Intradermal N=2575-2579	Fluzone N=1283-1285	Fluzone GMT divided by Fluzone Intradermal GMT	
A (H1N1)	193.2	178.3	0.92 (0.85; 1.01)	Yes
A (H3N2)	246.7	230.7	0.94 (0.85; 1.03)	Yes
B	102.5	126.9	1.24 (1.15; 1.33)	Yes

[a]Pre-defined criterion for non-inferiority: The upper bound of the two sided 95% CI of the ratio of GMTs (Fluzone divided by Fluzone Intradermal) is <1.5.

Table 4: Non-inferiority of Fluzone Intradermal Relative to Fluzone by HI Antibody Seroconversion at 28 Days Post Vaccination, Adults 18 through 64 Years of Age

Influenza Strain	Seroconversion[a] %		Difference (95% CI)	Non-inferior[b]
	Fluzone Intradermal N=2573-2578	Fluzone N=1283-1285	Fluzone minus Fluzone Intradermal	
A (H1N1)	61.2	60.5	-0.69 (-3.97; 2.56)	Yes
A (H3N2)	75.3	74.8	-0.55 (-3.49; 2.31)	Yes
B	46.2	54.2	7.99 (4.64; 11.31)	No

[a] Serocoversion: Paired samples with pre-vaccination HI titer <1:10 and post-vaccination (day 28) titer ≥ 1:40 or a minimum 4-fold increase for participants with pre-vaccination titer ≥1:10.

[b] Pre-defined criterion for non-inferiority: The upper bound of the two sided 95% CI of the difference in seroconversion rates (Fluzone minus Fluzone Intradermal) is <10%.

15 REFERENCES

1 Lasky T, Terracciano GJ, Magder L, et al. The Guillain-Barre´ syndrome and the 1992-1993 and 1993-1994 influenza vaccines. N Engl J Med 1998;339(25):1797-802.

2 Hannoun C, Megas F, Piercy J. Immunogenicity and protective efficacy of influenza vaccination. Virus Res 2004;103:133-138.

3 Hobson D, Curry RL, Beare AS, Ward-Gardner A. The role of serum haemagglutination-inhibiting antibody in protection against challenge infection with influenza A2 and B viruses. J Hyg Camb 1972;767-777.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Fluzone Intradermal microinjection system does not contain latex.

Single-dose prefilled microinjection system, 0.1 mL, package of 10 – NDC 49281-705-55.

16.2 Storage and Handling

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

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

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patient Information).

- Inform the patient that Fluzone Intradermal contains killed viruses and cannot cause influenza.
- Fluzone Intradermal stimulates the immune system to produce antibodies that help protect against influenza, but do not prevent other respiratory infections.
- Annual influenza vaccination is recommended.
- Instruct vaccine recipients to report adverse reactions to their healthcare provider and/or to the Vaccine Adverse Event Reporting System (VAERS). Inform the patient about the Sanofi Pasteur Inc. pregnancy registry for Fluzone Intradermal as appropriate.

Manufactured by:

Sanofi Pasteur Inc.

Swiftwater PA 18370 USA 6221

Patient Information Sheet
Fluzone® Intradermal
Influenza Virus Vaccine

Please read this information sheet before getting Fluzone Intradermal vaccine. This summary is not intended to take the place of talking with your healthcare provider. If you have questions or would like more information, please talk with your healthcare provider.

What is Fluzone Intradermal vaccine?

Fluzone Intradermal is a vaccine that helps protect against influenza illness (flu).

Fluzone Intradermal vaccine is for people 18 through 64 years of age.

Vaccination with Fluzone Intradermal vaccine may not protect all people who receive the vaccine.

Who should not get Fluzone Intradermal vaccine?

You should not get Fluzone Intradermal vaccine if you:

- ever had a severe allergic reaction to eggs or egg products.
- ever had a severe allergic reaction after getting any flu shot.
- are younger than 18 years of age.
- are 65 years of age or older.

Tell your healthcare provider if you have or have had:

- Guillain-Barré syndrome (severe muscle weakness) after getting a flu shot.
- problems with your immune system as the immune response may be diminished.

How is Fluzone Intradermal vaccine given?

Fluzone Intradermal vaccine is a shot given into the skin of the arm.

What are the possible side effects of Fluzone Intradermal vaccine?

The most common side effects of Fluzone Intradermal vaccine are:

- pain, redness, swelling, hardness, and itching where you got the shot
- muscle ache
- tiredness
- headache

These are not all of the possible side effects of Fluzone Intradermal vaccine. You can ask your healthcare provider for a list of other side effects that is available to healthcare professionals.

Call your healthcare provider for advice about any side effects that concern you. You may report side effects to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or *http://vaers.hhs.gov*. A pregnancy registry is available for Fluzone Intradermal by contacting Sanofi Pasteur Inc. at 1-800-822-2463.

What are the ingredients in Fluzone Intradermal vaccine?

Fluzone Intradermal vaccine contains 3 killed flu virus strains.

Inactive ingredients include formaldehyde, and octylphenol ethoxylate.

Manufactured by: Sanofi Pasteur Inc.

Swiftwater, PA 18370 USA