Fluzone Quadrivalent is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. (1)

Fluzone Quadrivalent is approved for use in persons 6 months of age and older. (1)

INDICATIONS AND USAGE

Initial U.S. Approval (Fluzone Quadrivalent): 2013

2023-2024 Formula Suspension for Intramuscular Injection

*The schedule can be completed as two 0.25-mL doses ≥4 weeks apart, or any combination of 2 doses (either 0.25 mL or 0.5 mL) administered ≥4 weeks apart.

†To determine if 1 or 2 doses are required, refer to Advisory Committee on Immunization Practices annual recommendations on prevention and control of influenza with vaccines.

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5.4 Limitations of Vaccine Effectiveness

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6.2 Post-Marketing Experience

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8.4 Pediatric Use

8.5 Geriatric Use

DOSAGE FORMS AND STRENGTHS

Suspension for injection supplied in 2 presentations: prefilled single-dose syringe (clear plunger rod), 0.5 mL and multi-dose vial, 5 mL. (3)

CONTRAINDICATIONS

Severe allergic reaction (e.g., anaphylaxis) 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 following previous influenza vaccination, the decision to give Fluzone Quadrivalent should be based on careful consideration of the potential benefits and risks. (5.1)

ADVERSE REACTIONS

• In children 6 months through 35 months of age, the most common (≥10%) injection-site reactions were pain (57%) or tenderness (47%–54%), erythema (23%–37%), and swelling (33%–41%), malaise (38%), drowsiness (31%–38%), appetite loss (27%–32%), myalgia (27%), vomiting (10%–15%), and fever (11%–14%). (6.1)

• In children 3 years through 8 years of age, the most common (≥10%) injection-site reactions were pain (67%), erythema (34%), and swelling (25%); the most common solicited systemic adverse reactions were myalgia (39%), malaise (32%), and headache (23%). (6.1)

• In adults 18 years and older, the most common (≥10%) injection-site reaction was pain (47%); the most common solicited systemic adverse reactions were myalgia (24%), headache (16%), and malaise (11%). (6.1)

• In adults 65 years of age and older, the most common (≥10%) injection-site reaction was pain (33%); the most common solicited systemic adverse reactions were myalgia (18%), headache (13%), and malaise (11%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Sanofi Pasteur Inc., at 1-800-822-2463 (1-800-VACCINE) or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

USE IN SPECIFIC POPULATIONS

• Pregnancy: Pregnancy exposure registry available. Call Sanofi Pasteur Inc. at 1-800-822-2463.

• Antibody responses to Fluzone Quadrivalent are lower in persons 75 years of age and older than in younger adults. (8.5)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

Revised: 09/2023
FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Fluzone® Quadrivalent is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. Fluzone Quadrivalent is approved for use in persons 6 months of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular use only

2.1 Dose and Schedule

The dose and schedule for Fluzone Quadrivalent are presented in Table 1. Prior to vaccination, always refer to the current Advisory Committee on Immunization Practices annual recommendations on prevention and control of influenza vaccines.

<table>
<thead>
<tr>
<th>Age</th>
<th>Vaccination Status</th>
<th>Dose</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months through 35 months</td>
<td>Not previously vaccinated with influenza vaccine or unknown vaccination history</td>
<td>Two doses, either 0.25 mL or 0.5 mL</td>
<td>Administer at least 4 weeks apart</td>
</tr>
<tr>
<td>6 months through 35 months</td>
<td>Previously vaccinated with influenza vaccine</td>
<td>One or two doses1, either 0.25 mL or 0.5 mL</td>
<td>If two doses, administer at least 4 weeks apart</td>
</tr>
<tr>
<td>36 months through 8 years</td>
<td>Not previously vaccinated with influenza vaccine or unknown vaccination history</td>
<td>Two 0.5 mL doses</td>
<td>Administer at least 4 weeks apart</td>
</tr>
<tr>
<td>36 months through 8 years</td>
<td>Previously vaccinated with influenza vaccine or unknown vaccination history</td>
<td>One or two 0.5 mL doses1</td>
<td>If two doses, administer at least 4 weeks apart</td>
</tr>
<tr>
<td>9 years and older</td>
<td>-</td>
<td>One 0.5 mL dose</td>
<td>-</td>
</tr>
</tbody>
</table>

1 Assessed in children 24 months through 35 months of age
2 Assessed in children 6 months through 23 months of age

6 ADVERSE REACTIONS

In children 6 months through 35 months of age receiving a 0.25 mL dose of Fluzone Quadrivalent in Study 1 (NCT01240746) the most common (≥10%) injection-site reactions were pain (57%)1,2, tenderness (54%)2,3, erythema (37%), and swelling (22%); the most common solicited systemic adverse reactions were irritability (54%)2, abnormal crying (41%)2, malaise (38%)3, drowsiness (38%)2,2, appetite loss (32%)2, myalgia (27%)2, vomiting (15%)2, and fever (14%). In children 3 years through 8 years of age, the most common (≥10%) injection-site reactions were pain (57%), erythema (34%), and swelling (25%); the most common solicited systemic adverse reactions were myalgia (39%), malaise (32%), and headache (23%). In adults 18 years and older, the most common (≥10%) injection-site reaction was pain (47%); the most common solicited systemic adverse reactions were myalgia (24%), headache (16%), and malaise (11%). In adults 65 years of age and older, the most common (≥10%) injection-site reaction was pain (33%); the most common solicited systemic adverse reactions were myalgia (18%), headache (13%), and malaise (11%).

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(s) of another vaccine and may not reflect the rates observed in practice.

Children 6 Months Through 8 Years of Age

Study 1 (NCT01240746) was a single-blind, randomized, active-controlled multi-center safety and immunogenicity study conducted in the US. In this study, children 6 months through 35 months of age received one or two 0.25 mL doses of either Fluzone Quadrivalent or one of two formulations of a comparator trivalent influenza vaccine (TIV-1 or TIV-2), and children 3 years through 8 years of age received one or two 0.5 mL doses of either Fluzone Quadrivalent, TIV-1, or TIV-2. Each of the trivalent formulations contained an influenza type B virus that corresponded to one of the two type B viruses in Fluzone Quadrivalent (a type B virus of the Victoria lineage or a type B virus of the Yamagata lineage). For participants who received two doses, the doses were administered approximately 4 weeks apart. The safety analysis set included 1841 children 6 months through 35 months of age and 2506 children 3 years through 8 years of age. Among participants 6 months through 8 years of age in the three vaccine groups combined, 49.3% were female (Fluzone Quadrivalent, 49.2%; TIV-1, 49.8%; TIV-2, 49.4%), 58.4% Caucasian (Fluzone Quadrivalent, 58.4%; TIV-1, 59.9%; TIV-2, 57.8%), 20.2% Black (Fluzone Quadrivalent, 20.5%; TIV-1, 19.9%; TIV-2, 19.1%), 14.1% Hispanic (Fluzone Quadrivalent, 14.3%; TIV-1, 13.2%; TIV-2, 14.7%), and 7.3% were of other racial/ethnic groups (Fluzone Quadrivalent, 6.8%; TIV-1, 8.0%; TIV-2, 8.5%). Table 2 and Table 3 summarize solicited injection-site and systemic adverse reactions reported within 7 days post-vaccination via diary cards. Participants were monitored for unsolicited adverse events for 28 days after each dose and serious adverse events (SAEs) during the 6 months following the last dose.

Table 2: Study 1: Percentage of Solicited Injection-site and Systemic Adverse Reactions Within 7 Days After Vaccination in Children 6 Months Through 35 Months of Age (Safety Analysis Set)

<table>
<thead>
<tr>
<th>Fluzone Quadrivalent†,‡ (N=1223)</th>
<th>TIV-1,§ (B Victoria) (N=310)</th>
<th>TIV-2,¶ (B Yamagata) (N=308)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection-site adverse reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain†</td>
<td>57.0</td>
<td>52.3</td>
</tr>
<tr>
<td>Tenderness§</td>
<td>54.1</td>
<td>48.4</td>
</tr>
<tr>
<td>Erythema</td>
<td>37.3</td>
<td>32.9</td>
</tr>
<tr>
<td>Swelling</td>
<td>21.6</td>
<td>19.7</td>
</tr>
<tr>
<td>Systemic adverse reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever (≥100.4°F)#</td>
<td>14.3</td>
<td>16.0</td>
</tr>
<tr>
<td>Malaise#</td>
<td>38.1</td>
<td>35.2</td>
</tr>
<tr>
<td>Myalgia#</td>
<td>26.7</td>
<td>26.6</td>
</tr>
<tr>
<td>Headache#</td>
<td>8.9</td>
<td>9.4</td>
</tr>
<tr>
<td>Irritability#</td>
<td>54.0</td>
<td>52.8</td>
</tr>
<tr>
<td>Crying abnormal#</td>
<td>41.2</td>
<td>36.5</td>
</tr>
<tr>
<td>Drowsiness#</td>
<td>37.7</td>
<td>32.1</td>
</tr>
</tbody>
</table>
Table 2: Study 1: Percentage of Solicited Injection-site and Systemic Adverse Reactions Within 7 Days After Vaccination in Children 3 Years Through 8 Months of Age (Safety Analysis Set) (continued)

<table>
<thead>
<tr>
<th></th>
<th>Fluzone Quadrivalent (N=1223)</th>
<th>TIV-1 (B Victoria) (N=310)</th>
<th>TIV-2 (B Yamagata) (N=308)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any (%)</td>
<td>Grade 2 (%)</td>
<td>Grade 3 (%)</td>
</tr>
<tr>
<td>Appetite loss</td>
<td>32.3</td>
<td>9.1</td>
<td>1.8</td>
</tr>
<tr>
<td>Vomiting</td>
<td>14.8</td>
<td>6.2</td>
<td>1.0</td>
</tr>
</tbody>
</table>

*NCT01240746
†The safety analysis set includes all persons who received at least one dose of study vaccine
‡Fluzone Quadrivalent (0.25 mL) containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria lineage), and B/Florida/04/2006 (Yamagama lineage)
§Participants received 1 or 2 doses according to ACIP recommendations
¶N is the number of participants in the safety analysis set
#2010-2011 Fluzone TIV (0.25 mL) containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Brisbane/60/2008 (Victoria lineage), licensed
¶Investigational TIV (0.25 mL) containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Florida/04/2006 (Yamagama lineage), non-licensed
1Grade 2 - Injection-site pain: sufficiently discomforting to interfere with normal behavior or activities; Injection-site tenderness: cries and protests when injection-site is touched; Injection-site erythema, Injection-site swelling: ≥2.5 cm to <5 cm; Fever: ≥101.3°F to ≤103.1°F (6 months through 23 months); ≥102.1°F to ≤102.0°F (24 months through 35 months); Malaise, Myalgia, and Headache: some interference with activity; Irritability: requiring increased attention; Crying abnormal: 1 to 3 hours; Drowsiness: not interested in surroundings or did not wake up for a feed/meal; Appetite loss: missed 1 or 2 feeds/meals completely; Vomiting: 2 to 5 episodes per 24 hours
2Grade 3 - Injection-site pain: incapacitating, unable to perform usual activities; Injection-site tenderness: cries when injected limb is moved, or the movement of the injected limb is reduced; Injection-site erythema, Injection-site swelling: ≥5 cm; Fever: ≥103.1°F (6 months through 23 months); ≥102.1°F to ≤102.0°F (24 months through 35 months); Malaise, Myalgia, and Headache: significant interference with activity; Irritability: inconsolable; Crying abnormal: ≥3 hours; Drowsiness: sleeping most of the time or difficult to wake up; Appetite loss: refuses ≥3 feeds/meals or refuses most feeds/meals; Vomiting: ≥6 episodes per 24 hours or requiring parenteral hydration
3Assessed in children 24 months through 35 months of age
4Assessed in children 6 months through 23 months of age
5Fever measured by any route

Among children 6 months through 8 years of age, unsolicited non-serious adverse events were reported in 1360 (47.0%) recipients in the Fluzone Quadrivalent group, 352 (48.0%) recipients in the TIV-1 group, and 346 (48.0%) recipients in the TIV-2 group. The most commonly reported unsolicited non-serious adverse events were cough, vomiting, and pyrexia. During the 28 days following vaccination, a total of 16 (0.6%) recipients in the Fluzone Quadrivalent group, 4 (0.5%) recipients in the TIV-1 group, and 4 (0.6%) recipients in the TIV-2 group experienced at least one SAE. Among these SAEs were considered to be possibly related to vaccination: croup in a Fluzone Quadrivalent recipient and 2 episodes of febrile seizure, 1 each in a TIV-1 and a TIV-2 recipient.

Table 3: Study 1: Percentage of Solicited Injection-site and Systemic Adverse Reactions Within 7 Days After Vaccination in Children 3 Years Through 8 Years of Age (Safety Analysis Set) (continued)

<table>
<thead>
<tr>
<th></th>
<th>Fluzone Quadrivalent (N=1669)</th>
<th>TIV-1 (B Victoria) (N=424)</th>
<th>TIV-2 (B Yamagata) (N=413)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any (%)</td>
<td>Grade 2 (%)</td>
<td>Grade 3 (%)</td>
</tr>
<tr>
<td>Malaise</td>
<td>31.9</td>
<td>11.2</td>
<td>5.5</td>
</tr>
<tr>
<td>Myalgia</td>
<td>38.6</td>
<td>12.2</td>
<td>3.3</td>
</tr>
</tbody>
</table>

*NCT01240746
†The safety analysis set includes all persons who received at least one dose of study vaccine
‡Fluzone Quadrivalent containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria lineage), and B/Florida/04/2006 (Yamagama lineage)
§N is the number of participants in the safety analysis set
†Fluzone Quadrivalent (0.25 mL) containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Brisbane/60/2008 (Victoria lineage), licensed
¶Investigational TIV (0.25 mL) containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Florida/04/2006 (Yamagama lineage), non-licensed
1Grade 2 - Injection-site pain: sufficiently discomforting to interfere with normal behavior or activities; Injection-site tenderness: cries and protests when injection-site is touched; Injection-site erythema, Injection-site swelling: ≥2.5 cm to <5 cm; Fever: ≥101.2°F to ≤102.0°F; Headache, Malaise, and Myalgia: some interference with activity; Irritability: requiring increased attention; Crying abnormal: 1 to 3 hours; Drowsiness: not interested in surroundings or did not wake up for a feed/meal; Appetite loss: misses 1 or 2 feeds/meals completely; Vomiting: 2 to 5 episodes per 24 hours
2Grade 3 - Injection-site pain: incapacitating, unable to perform usual activities; Injection-site tenderness: cries when injected limb is moved, or the movement of the injected limb is reduced; Injection-site erythema, Injection-site swelling: ≥5 cm; Fever: ≥103.1°F (6 months through 23 months); ≥102.1°F to ≤102.0°F (24 months through 35 months); Malaise, Myalgia, and Headache: significant interference with activity; Irritability: inconsolable; Crying abnormal: ≥3 hours; Drowsiness: sleeping most of the time or difficult to wake up; Appetite loss: refuses ≥3 feeds/meals or refuses most feeds/meals; Vomiting: ≥6 episodes per 24 hours or requiring parenteral hydration
0.5mL Dose of Fluzone Quadrivalent in Children 6 Months Through 35 Months of Age

Study 2 (NCT02915302) was a randomized, observer-blinded, 2-arm, multi-center safety and immunogenicity study conducted in the US. In this study, 1950 children 6 months through 35 months of age were randomly assigned to receive Fluzone Quadrivalent administered in either a volume of 0.25 mL (Group 1) or 0.5 mL (Group 2). For participants recommended to receive two doses of influenza vaccine as per Advisory Committee on Immunization Practices guidance, the same dose was administered 4 weeks after the first.

Table 4: Study 2: Percentage of Solicited Injection-site and Systemic Adverse Reactions Within 7 Days After Vaccination in Children 6 Months Through 35 Months of Age (Safety Analysis Set)

<table>
<thead>
<tr>
<th></th>
<th>Fluzone Quadrivalent (N=589)</th>
<th>Fluzone Quadrivalent (N=589)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any (%)</td>
<td>Grade 3 (%)</td>
</tr>
<tr>
<td>Tenderness</td>
<td>47.3</td>
<td>1.7</td>
</tr>
<tr>
<td>Redness</td>
<td>23.1</td>
<td>0.0</td>
</tr>
<tr>
<td>Swelling</td>
<td>12.9</td>
<td>0.1</td>
</tr>
</tbody>
</table>
| Systemic adverse reactions
| Irritability   | 47.4                           | 3.6                            | 48.6                           |
| Abnormal Crying| 33.3                           | 3.1                            | 34.1                           |
| Drowsiness     | 31.9                           | 2.1                            | 31.3                           |
| Loss of Appetite| 27.3                           | 1.4                            | 28.3                           |

Table 3: Study 2: Percentage of Solicited Injection-site and Systemic Adverse Reactions Within 7 Days After Vaccination in Children 3 Years Through 8 Years of Age (Safety Analysis Set)

<table>
<thead>
<tr>
<th></th>
<th>Fluzone Quadrivalent (N=1223)</th>
<th>TIV-1 (B Victoria) (N=310)</th>
<th>TIV-2 (B Yamagata) (N=308)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any (%)</td>
<td>Grade 2 (%)</td>
<td>Grade 3 (%)</td>
</tr>
<tr>
<td>Fever (≥100.4°F)</td>
<td>7.0</td>
<td>2.1</td>
<td>2.1</td>
</tr>
<tr>
<td>Headache</td>
<td>23.1</td>
<td>6.8</td>
<td>2.2</td>
</tr>
</tbody>
</table>
Table 4: Study 2: Percentage of Solicited Injection-site and Systemic Adverse Reactions Within 7 Days After Vaccination in Children 6 Months Through 35 Months of Age (Safety Analysis Set) (continued)

<table>
<thead>
<tr>
<th></th>
<th>Fluzone Quadrivalent (N=949)</th>
<th>Fluzone Quadrivalent (N=992)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any (%)  Grade 3(^a)</td>
<td>Any (%)  Grade 3(^a)</td>
</tr>
<tr>
<td>Fever ((\geq 100.4°F))</td>
<td>11.3 0.6</td>
<td>12.2 1.2</td>
</tr>
<tr>
<td>Vomiting</td>
<td>10.0 0.4</td>
<td>10.2 0.5</td>
</tr>
</tbody>
</table>

\(^{a}\)NCT02915302
\(^{†}\)The safety analysis set includes all persons who received at least one dose of study vaccine

\(^{‡}\)Participants received 1 or 2 doses according to ACIP recommendations

\(^{§}\)N is the number of participants in the safety analysis set

\(^{¶}\)Participants received 1 or 2 doses according to ACIP recommendations

\(^{¶}\)NCT02915302

\(^{†}\)The safety analysis set includes all persons who received study vaccine

Table 5: Study 3: Percentage of Solicited Injection-site and Systemic Adverse Reactions Within 3 Days After Vaccination in Adults 18 Years of Age and Older (Safety Analysis Set) (continued)

<table>
<thead>
<tr>
<th></th>
<th>Fluzone Quadrivalent (N=190)</th>
<th>TIV-1(^b) (B Victoria) (N=190)</th>
<th>TIV-2(^b) (B Yamagata) (N=190)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any (%)  Grade 3(^a)</td>
<td>Any (%)  Grade 3(^a)</td>
<td>Any (%)  Grade 3(^a)</td>
</tr>
<tr>
<td>Shivering</td>
<td>2.6 0.0 0.0</td>
<td>5.3 1.1 0.0</td>
<td>3.2 0.5 0.0</td>
</tr>
<tr>
<td>Fever ((\geq 100.4°F))</td>
<td>0.0 0.0 0.0</td>
<td>0.5 0.5 0.0</td>
<td>0.5 0.5 0.0</td>
</tr>
</tbody>
</table>

\(^{†}\)The safety analysis set includes all persons who received study vaccine

\(^{‡}\)Fluzone Quadrivalent containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria lineage), and B/Florida/04/2006 (Yamagata lineage)

\(^{§}\)N is the number of participants in the safety analysis set

\(^{†}\)Fluzone Quadrivalent containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria lineage), and B/Florida/04/2006 (Yamagata lineage)

Table 6: Study 4: Percentage of Solicited Injection-site and Systemic Adverse Reactions Within 7 Days After Vaccination in Adults 65 Years of Age and Older (Safety Analysis Set)

<table>
<thead>
<tr>
<th></th>
<th>Fluzone Quadrivalent (N=225)</th>
<th>TIV-1(^b) (B Victoria) (N=225)</th>
<th>TIV-2(^b) (B Yamagata) (N=225)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any (%)  Grade 3(^a)</td>
<td>Any (%)  Grade 3(^a)</td>
<td>Any (%)  Grade 3(^a)</td>
</tr>
<tr>
<td>Pain</td>
<td>32.6 1.3 0.9</td>
<td>28.6 2.7 0.0</td>
<td>23.1 0.9 0.0</td>
</tr>
<tr>
<td>Erythema</td>
<td>2.7 0.9 0.0</td>
<td>1.3 0.0 0.0</td>
<td>1.3 0.4 0.0</td>
</tr>
<tr>
<td>Swelling</td>
<td>1.8 0.4 0.0</td>
<td>1.3 0.0 0.0</td>
<td>0.0 0.0 0.0</td>
</tr>
</tbody>
</table>

\(^{†}\)The safety analysis set includes all persons who received study vaccine

\(^{‡}\)Fluzone Quadrivalent containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria lineage), and B/Florida/04/2006 (Yamagata lineage)

\(^{§}\)N is the number of participants in the safety analysis set

\(^{†}\)Fluzone Quadrivalent containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria lineage), and B/Florida/04/2006 (Yamagata lineage)
Table 6: Study 4: Percentage of Solicited Injection-site and Systemic Adverse Reactions Within 7 Days After Vaccination in Adults 65 Years of Age and Older (Safety Analysis Set) (continued)

<table>
<thead>
<tr>
<th></th>
<th>Fluzone Quadrivalent† (N=225)</th>
<th>TIV-1† (B Victoria) (N=225)</th>
<th>TIV-2† (B Yamagata) (N=225)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any (%)</td>
<td>Grade 2 (%)</td>
<td>Grade 3 (%)</td>
<td>Grade 2 (%)</td>
</tr>
<tr>
<td>Malaise</td>
<td>10.7</td>
<td>4.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Fever (≥100.4°F)*</td>
<td>1.3</td>
<td>0.0</td>
<td>0.4</td>
</tr>
</tbody>
</table>

*NCT01218646
†The safety analysis set includes all persons who received study vaccine
‡Fluzone Quadrivalent containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Brisbane/60/2008 (Victoria lineage), and B/Florida/04/2006 (Yamagata lineage).
§N is the number of participants in the safety analysis set.
¶2010-2011 TIV Flu containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Brisbane/60/2008 (Victoria lineage), licensed investigational TIV containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Florida/04/2006 (Yamagata lineage), licensed.
∫Grade 2 - Injection-site pain: some interference with activity; Injection-site erythema and Injection-site swelling: ≥10 cm; Fever: ≥101.2°F to ≤102.0°F; Myalgia, Headache, and Malaise: some interference with activity.
∫∫Grade 3 - Injection-site pain: Significant; prevents daily activity; Injection-site erythema and Injection-site swelling: ≥10 cm; Fever: ≥102.1°F; Myalgia, Headache, and Malaise: Significant; prevents daily activity.
∫∫∫Fever measured by any route

Unsolicited non-serious adverse events were reported in 28 (12.4%) recipients in the Fluzone Quadrivalent group; 22 (9.8%) recipients in the TIV-1 group, and 22 (9.8%) recipients in the TIV-2 group. The most commonly reported adverse events were oropharyngeal pain, rhinorrhea, injection-site induration, and headache. Three SAEs were reported during the follow-up period, 2 (0.9%) in the TIV-1 group and 1 (0.4%) in the TIV-2 group.

6.2 Post-Marketing Experience

The following events have been spontaneously reported during the post-approval use of Fluzone (trivalent) or Fluzone Quadrivalent. 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 (trivalent) or Fluzone Quadrivalent:

- Blood and Lymphatic System Disorders: Thrombocytopenia, lymphopenopathy
- 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, myalgia (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/flooding
- Respiratory, Thoracic and Mediastinal Disorders: Dyspnea, cough, wheezing, throat tightness, oropharyngeal pain, rhinorrhea
- Skin and Subcutaneous Tissue Disorders: Rash, pruritus, and Stevens-Johnson syndrome
- General Disorders and Administration Site Conditions: Asthenia/fatigue, pain in extremities, chest pain
- Gastrointestinal Disorders: Vomiting

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

Sanofi Pasteur Inc. is maintaining a prospective pregnancy exposure registry to collect data on pregnancy outcomes following vaccination with Fluzone Quadrivalent during pregnancy. Healthcare providers are encouraged to enroll women who receive Fluzone Quadrivalent during pregnancy in Sanofi Pasteur Inc.’s vaccination pregnancy registry by calling 1-800-822-2463.

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data with Fluzone Quadrivalent use in pregnant women are insufficient to inform vaccine-associated risk of adverse developmental outcomes.

A developmental and reproductive toxicity study was performed in female rabbits given a 0.5 mL dose of Fluzone Quadrivalent prior to mating and during gestation (a single human dose is 0.5 mL). This study revealed no adverse effects to the fetus or pre-weaning development due to Fluzone Quadrivalent [see Animal Data (8.1)].

Data

Animal Data: In a developmental and reproductive toxicity study female rabbits were administered a 0.5 mL dose of Fluzone Quadrivalent by intramuscular injection 24 and 10 days before insemination, and on Days 6, 12, and 27 of gestation (a single human dose is 0.5 mL). There were no adverse effects on pre-weaning development or vaccine-related fetal malformations noted in this study.

Clinical Considerations

Disease-associated Maternal and/or Embryo/Fetal Risk

Pregnant women are at increased risk of complications associated with influenza infection compared to non-pregnant women. Pregnant women who contract influenza may be at increased risk for adverse pregnancy outcomes, including preterm labor and delivery. 8.2 Lactation

Risk Summary

It is not known whether Fluzone Quadrivalent is excreted in human milk. Data are not available to assess the effects of Fluzone Quadrivalent on the breastfed infant or on milk production/excretion.

The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for Fluzone Quadrivalent and any potential adverse effects on the breastfed child from Fluzone Quadrivalent or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptible to the disease prevented by the vaccine.

8.4 Pediatric Use

Safety and effectiveness of Fluzone Quadrivalent in children below the age of 6 months have not been established.

8.5 Geriatric Use

Safety and immunogenicity of Fluzone Quadrivalent were evaluated in adults 65 years of age and older. [See Clinical Studies (14.6)] Antibody responses to Fluzone Quadrivalent are lower in persons 65 years of age than in younger adults.

11 DESCRIPTION

Fluzone Quadrivalent (Influenza Vaccine) for intramuscular injection is an inactivated influenza 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 an non-ionic surfactant, octylphenol ethoxylate (Triton® X-100), producing a “split” virus. The split virus is further purified as a fum phosphate-buffered isotonic sodium chloride solution. The Fluzone Quadrivalent process uses an additional concentration factor after the ultrafiltration step in order to obtain a higher hemagglutinin (HA) antigen concentration. Antigens from the four strains included in the vaccine are produced separately and then combined to make the quadrivalent formulation.

Fluzone Quadrivalent suspension for injection is clear and slightly opalescent in color. Antigens not used in the manufacture of Fluzone Quadrivalent are sterilized by filtration, lyophilized, and then reconstituted with sterile water for injection with a stability-enhancing excipient. Fluzone Quadrivalent is standardized according to United States Public Health Service requirements and is formulated to contain HA of each of the following four influenza strains recommended for the 2023-2024 influenza season: A/Victoria/4897/2022 IVR-238 (H1N1), A/Darwin/8/2021 SAN-010 (H3N2), B/Puhek/0307/2013 (B Yamagata lineage), and B/Michigan/01/2021 (a B/Austria/135947/2021-like virus, B Victoria lineage). The amounts of HA and other ingredients per dose of vaccine are listed in Table 7. The single-dose, pre-filled syringes (0.5 mL) is manufactured and formulated without thimerosal or any other preservative. The 5 mL multi-dose vial presentation contains thimerosal, a mercury derivative, added as a preservative. Each 0.5 mL dose from the multi-dose vial contains 25 mcg mercury. Each 0.25 mL dose from the multi-dose vial contains 12.5 mcg mercury.

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. Since 1977, antigenic variants
of influenza A (H1N1) and H3N2) viruses and influenza B viruses have been in global circulation. Since 2001, two distinct lineages of influenza B (Victoria and Yamagata lineages) have co-circulated worldwide. Protection from influenza virus infection has not been correlated with a specific level of hemagglutination inhibition (HI) antibody titer post-vaccination. However, in some human studies, antibody titers ≥1:40 have been associated with protection from influenza illness in up to 50% of subjects. (See ref. 2) (See ref. 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 representing the influenza viruses likely to be circulating in the US during the influenza season. Annual vaccination with the influenza 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 Quadrivalent has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. Vaccination of female rabbits with Fluzone Quadrivalent revealed no evidence of impaired female fertility [see Animal Data (8.1)].

14 CLINICAL STUDIES

the effectiveness of Fluzone Quadrivalent was demonstrated based on clinical endpoint efficacy data for Fluzone (trivalent influenza vaccine) and on an evaluation of serum HI antibody responses to Fluzone Quadrivalent. Fluzone Quadrivalent, an inactivated influenza vaccine that contains the hemagglutinins of two influenza A subtype viruses and two influenza type B viruses, is manufactured according to the same process as Fluzone.

14.1 Efficacy of Fluzone (Trivalent Influenza Vaccine) in Children 6 through 24 Months of Age

A randomized, double-blind, placebo-controlled study was conducted at a single US center during the 1999-2000 (Year 1) and 2000-2001 (Year 2) influenza seasons. The intent-to-treat analysis set included a total of 786 children 6 through 24 months of age.

Table 1: Study 1

<table>
<thead>
<tr>
<th>Antigen Strain</th>
<th>Antigen Type</th>
<th>Pooled TIV*</th>
<th>Fluzone Quadrivalent N=2339</th>
<th>GMT Ratio (95% CI)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (H1N1)</td>
<td>A/Beijing/262/95 (H1N1), A/Sydney/15/97 (H3N2), and B/Yamanashi/166/98 (Yamagata lineage) and A/Beijing/262/95 (H1N1), A/Sydney/15/97 (H3N2), and B/Yamanashi/166/98 (Yamagata lineage)</td>
<td>1096</td>
<td>1124</td>
<td>1.03 (0.93; 1.14)</td>
</tr>
<tr>
<td>A (H3N2)</td>
<td>A/Beijing/262/95 (H1N1), A/Sydney/15/97 (H3N2), and B/Yamanashi/166/98 (Yamagata lineage)</td>
<td>828</td>
<td>822</td>
<td>0.99 (0.91; 1.08)</td>
</tr>
</tbody>
</table>

14.2 Efficacy of Fluzone (Trivalent Influenza Vaccine) in Adults

A randomized, double-blind, placebo-controlled study was conducted in a single US center during the 2007-2008 influenza season. Participants received one dose of either Fluzone vaccine (N = 813), an active comparator (N = 814), or placebo (N = 325). The intent-to-treat analysis set included 1138 healthy adults who received Fluzone or placebo. Participants were 18 through 49 years of age (mean age was 23.3 years); 63.3% were female, 83.1% were Caucasian, and 16.9% were of other racial/ethnic groups. Cases of influenza were identified through active and passive surveillance and confirmed by cell culture and/or real-time polymerase chain reaction (PCR). Influenza-like illness was defined as an illness with at least 1 respiratory symptom (cough or nasal congestion) and at least 1 constitutional symptom (fever or feverishness, chills, or body aches). Vaccine efficacy of Fluzone against all influenza viral types and subtypes is presented in Table 9.

Table 9: Estimated Efficacy of Fluzone (Trivalent Influenza Vaccine) Against Influenza in Adults Aged 18 through 49 Years during the 2007-2008 Influenza Season – Intent-to-Treat Analysis Set.1

<table>
<thead>
<tr>
<th>Laboratory-Confirmed Symptomatic Influenza</th>
<th>Fluzone† (N=813)</th>
<th>Placebo† (N=325)</th>
<th>Fluzone vs. Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate (%)§</td>
<td>(95% CI)</td>
<td>Rate (%)§</td>
<td>(95% CI)</td>
</tr>
<tr>
<td>Positive culture</td>
<td>21</td>
<td>2.6</td>
<td>(1.6; 3.9)</td>
</tr>
<tr>
<td>Positive PCR</td>
<td>28</td>
<td>3.4</td>
<td>(2.3; 4.9)</td>
</tr>
</tbody>
</table>

1NCT00538512

1The intent-to-treat analysis set includes all enrolled participants who were randomly assigned to receive Fluzone or placebo and vaccinated

†Fluzone: 2007-2008 formulation containing A/Solomon Islands/3/2006 (H1N1), A/Wisconsin/67/2005 (H3N2), and B/Malaysia/2506/2004 (Victoria lineage)

§n is the number of participants with culture-confirmed influenza for the given year of study as listed in the first column

¶Relative reduction in vaccine efficacy was defined as (1 - relative risk) x 100
In this study, children 6 months through 35 months of age received one or two doses of either 0.25 mL or 0.5 mL of Fluzone Quadrivalent. Non-inferiority of the 0.5 mL dose(s) relative to the 0.25 mL dose(s) of Fluzone Quadrivalent was demonstrated for all four strains based on pre-specified criteria (lower limit of the 2-sided 95% CI of the ratio of GMTs between groups > 0.667; lower limit of the 2-sided 95% CI of the difference in seroconversion rates > -10%). GMT ratios (GMTs0.5 mL dose divided by GMTs0.25 mL dose) for the A/H1N1, A/H3N2, B Victoria lineage, and B Yamagata lineage strains were 1.42 (95% CI: 1.16; 1.74), 1.48 (95% CI: 1.21; 1.82), 1.33 (95% CI: 1.09; 1.62), and 1.41 (95% CI: 1.17; 1.70), respectively. Seroconversion rate (SCR) differences (SCR0.5 mL dose minus SCR0.25 mL dose) for the A/H1N1, A/H3N2, B Victoria lineage, and B Yamagata lineage strains were 4.6% (95% CI: -0.4%; 9.6%), 5.1% (95% CI: 0.4%; 9.8%), 1.3% (95% CI: -2.9%; 5.6%), and 2.6% (95% CI: -1.4%; 6.5%).

14.5 Immunogenicity of Fluzone Quadrivalent in Adults ≥18 Years of Age

In Study 3 (NCT00988143) [see Adverse Reactions (6.1)], 565 adults 18 years of age and older who had received one dose of Fluzone Quadrivalent, TV1-1, or TV-2 were included in the per-protocol immunogenicity analysis. The distribution of demographic characteristics was similar to that of the safety analysis set [see Adverse Reactions (6.1)]. HI antibody GMTs 21 days following vaccination with Fluzone Quadrivalent were non-inferior to those following each TV for all four strains, based on pre-specified criteria (see Table 12).

<table>
<thead>
<tr>
<th>Antigen Strain</th>
<th>Fluzone Quadrivalent†</th>
<th>Pooled TVV =375</th>
<th>GMT Ratio (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (H1N1)</td>
<td>161</td>
<td>151</td>
<td>1.06 (0.87; 1.31)</td>
</tr>
<tr>
<td>A (H3N2)</td>
<td>304</td>
<td>339</td>
<td>0.90 (0.70; 1.15)</td>
</tr>
</tbody>
</table>

*NCT00988143
†Per-protocol analysis set included all persons who had no study protocol deviations
‡Fluzone Quadrivalent containing A/Brisbane/59/2007 (H1N1), A/Uruguay/716/2007 (H3N2), B/Brisbane/80/2008 (Victoria lineage), and B/Florida/04/2008 (Yamagata lineage)
§N is the number of participants in the per-protocol analysis set
¶Pooled TVV group includes participants vaccinated with either TVV-1 or TVV-2
Non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI of the ratio of GMTs (Fluzone Quadrivalent divided by pooled TV for the A strain, or the TV containing the corresponding B strain) was >2.10
12008-2010 Fluzone TVV containing A/Brisbane/59/2007 (H1N1), A/Uruguay/716/2007 (H3N2), and B/Brisbane/60/2008 (Victoria lineage), licensed
§Seroconversion: Paired samples with pre-vaccination HI titer <1:10 and post-vaccination titer ≥1:40 or a minimum 4-fold increase for participants with pre-vaccination titer ≥1:10
*Non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI of the difference in seroconversion rates (Fluzone Quadrivalent minus pooled TV for the A strain, or the TV containing the corresponding B strain) was >10%
§Per-protocol analysis set included all persons who had no study protocol deviations
¶Fluzone Quadrivalent containing A/Caifornia/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria lineage), and B/Florida/04/2008 (Yamagata lineage)
<table>
<thead>
<tr>
<th>Antigen Strain</th>
<th>Fluzone Quadrivalent†</th>
<th>Pooled TVV =375</th>
<th>GMT Ratio (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>B (Victoria)</td>
<td>101</td>
<td>114</td>
<td>0.89 (0.70; 1.12)</td>
</tr>
<tr>
<td>B (Yamagata)</td>
<td>155</td>
<td>135</td>
<td>1.15 (0.93; 1.42)</td>
</tr>
</tbody>
</table>

*NCT00988143
†Non-inferiority immunogenicity criteria based on HI antibody GMTs and seroconversion rates were also met when age subgroups (6 months to <36 months and 3 years to <9 years) were examined. In addition, HI antibody GMTs and seroconversion rates following Fluzone Quadrivalent were higher than those following TVV for the B strain not contained in each respective TVV based on pre-specified criteria (the lower limit of the 2-sided 95% CI of the ratio of the GMTs [Fluzone Quadrivalent divided by TVV] >1.5 for each B strain in Fluzone Quadrivalent compared with the corresponding B strain not contained in each TVV and the lower limit of the 2-sided 95% CI of the difference of the seroconversion rates [Fluzone Quadrivalent minus TVV] >10% for each B strain in Fluzone Quadrivalent compared with the corresponding B strain not contained in each TVV).

14.4 Immunogenicity of the 0.5 mL Dose of Fluzone Quadrivalent in Children 6 Months through 35 Months of Age

In Study 2 (NCT02915302) [see Adverse Reactions (6.1)], 1027 children, 6 months through 35 months of age, were included in the per-protocol immunogenicity analysis. The distribution of demographic characteristics was similar to that of the safety analysis set [see Adverse Reactions (6.1)].
Table 13: Study 4: Non-inferiority of Fluzone Quadrivalent Relative to TIV for Each Strain by HI Antibody GMTs at 21 Days Post-Vaccination, Adults 65 Years of Age and Older (Per-protocol Analysis Set)†

<table>
<thead>
<tr>
<th>Antigen Strain</th>
<th>Fluzone Quadrivalent† N=220</th>
<th>Pooled TIV‡ N=440</th>
<th>GMT Ratio (95% CI)§</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (H1N1)</td>
<td>231</td>
<td>270</td>
<td>0.85 (0.67; 1.09)</td>
</tr>
<tr>
<td>A (H3N2)</td>
<td>501</td>
<td>324</td>
<td>1.55 (1.25; 1.92)</td>
</tr>
</tbody>
</table>

Table 14: Study 4: Non-inferiority of Fluzone Quadrivalent Relative to TIV for Each Strain by Seroconversion Rates at 21 Days Post-Vaccination, Adults 65 Years of Age and Older (Per-protocol Analysis Set)†

<table>
<thead>
<tr>
<th>Antigen Strain</th>
<th>Fluzone Quadrivalent‡ N=220</th>
<th>Pooled TIV§ N=440</th>
<th>Seroconversion%(Fluzone Quadrivalent minus Fluzone TIV) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluzone Quadrivalent† N=220</td>
<td>65.91</td>
<td>69.77</td>
<td>-3.86 (-11.50; 3.56)</td>
</tr>
<tr>
<td>A (H1N1)</td>
<td>69.09</td>
<td>59.32</td>
<td>9.77 (1.96; 17.20)</td>
</tr>
<tr>
<td>A (H3N2)</td>
<td>69.09</td>
<td>59.32</td>
<td>9.77 (1.96; 17.20)</td>
</tr>
</tbody>
</table>

1) Per-protocol analysis set included all persons who had no study protocol deviations
2) Fluzone Quadrivalent containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria lineage), and B/Florida/04/2009 (Yamagata lineage) were licensed.
3) N is the number of participants in the per-protocol analysis set
4) Pooled TIV group includes participants vaccinated with either TIV-1 or TIV-2
5) Non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI of the ratio of GMTs (Fluzone Quadrivalent divided by pooled TIV for the A strain, or the TIV containing the corresponding B strain) was >0.60
6) 2009-2010 Flu Vaccine Fluzone Quadrivalent contained A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Brisbane/60/2008 (Victoria lineage). Licensed investigational TIV containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Florida/04/2006 (Yamagata lineage), non-licensed
7) ATIV-2 did not contain B/Florida/04/2006
8) ATIV-1 did not contain B/Florida/04/2006

15 REFERENCES

16 HOW SUPPLIED/STORAGE AND HANDLING
1. Single-dose, prefilled syringe (clear plunger rod), without needle, 0.5 mL (NDC 42981-423-88) (not made with natural rubber latex). Supplied as package of 10 (NDC 42981-423-50).

17 PATIENT COUNSELING INFORMATION
See FDA-approved patient labeling (Patient Information). Inform the vaccine recipient or guardian:
- Fluzone Quadrivalent contains killed viruses and cannot cause influenza.
- Fluzone Quadrivalent stimulates the immune system to protect against influenza, but does not prevent other respiratory infections.
- Annual influenza vaccination is recommended.
- Report adverse reactions to their healthcare provider and/or to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967.
- Sanofi Pasteur Inc. is maintaining a prospective pregnancy exposure registry to collect data on pregnancy outcomes and newborn health status following vaccination with Fluzone Quadrivalent during pregnancy. Women who receive Fluzone Quadrivalent during pregnancy are encouraged to contact Sanofi Pasteur Inc. directly or have their healthcare provider contact Sanofi Pasteur Inc. at 1-800-822-2463.
- Vaccine Information Statements must be provided to vaccine recipients or their guardians, as required by the National Childhood Vaccine Injury Act of 1986 prior to immunization. These materials are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).
- Fluzone is a registered trademark of Sanofi Pasteur Inc.
headache
• fever

These are not all of the possible side effects of Fluzone Quadrivalent. 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.

Sanofi Pasteur Inc. is collecting information on pregnancy outcomes and the health of newborns following vaccination with Fluzone Quadrivalent during pregnancy. Women who receive Fluzone Quadrivalent during pregnancy are encouraged to contact Sanofi Pasteur Inc. directly or have their healthcare provider contact Sanofi Pasteur Inc. at 1-800-822-2463.

What are the ingredients in Fluzone Quadrivalent?

Fluzone Quadrivalent contains 4 killed flu virus strains. Inactive ingredients include formaldehyde and octylphenol ethoxylate. The preservative thimerosal is only in the multi-dose vial of Fluzone Quadrivalent.

Manufactured by:
Sanofi Pasteur Inc.
Swiftwater, PA 18370 USA

INFZ4-FPLR-SL-SEP23 Rx Only