FLUAD (Influenza Vaccine, Adjuvanted)
Injectable Emulsion for Intramuscular Use
2024-2025 Formula
Initial U.S. Approval: 2015

INDICATIONS AND USAGE
FLUAD is a vaccine indicated for active immunization for the prevention of influenza
disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD
is approved for use in adults 65 years of age and older. (1)

This indication is approved under accelerated approval based on the immune response
elicited by FLUAD (1).  Continued approval for this indication may be contingent upon
verification and description of clinical benefit in a confirmatory trial.

DOSAGE AND ADMINISTRATION
For intramuscular use
A single 0.5 mL dose for intramuscular injection. (2.1)

DOSAGE FORMS AND STRENGTHS
FLUAD is an injectable emulsion. A single dose is 0.5 mL. (3)

CONTRAINDICATIONS
Do not administer FLUAD to anyone with a history of a severe allergic reaction (e.g.
anaphylaxis) to any component of the vaccine, including egg protein, or to a previous
influenza vaccine. (4, 11)

WARNINGS AND PRECAUTIONS
If Guillain-Barré Syndrome (GBS) has occurred within six weeks of previous influenza
vaccination, the decision to give FLUAD should be based on careful consideration of
the potential benefits and risks. (5.1)

ADVERSE REACTIONS
The most common (≥10%) local and systemic adverse reactions in adults 65 years of age
and older who received FLUAD were injection site pain (25%), injection site tenderness
(21%), myalgia (15%), fatigue (13%) and headache (13%). (6)

To report SUSPECTED ADVERSE REACTIONS, contact Seqirus at 1-855-358-8966
or VAERS at 1-800-822-7967 and www.vaers.hhs.gov.

See 17 for PATIENT COUNSELING INFORMATION

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

1 INDICATIONS AND USAGE
FLUAD is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD is approved for use in adults 65 years of age and older.

This indication is approved under accelerated approval based on the immune response elicited by FLUAD [see Clinical Studies (14)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage and Schedule
Administer FLUAD as a single 0.5 mL intramuscular injection in adults 65 years of age and older.

2.2 Administration
• Gently shake each syringe. FLUAD has a milky-white appearance. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit [see Description (11)]. If either condition exists, FLUAD should not be administered.

• To use a pre-filled syringe fitted with a Luer Lok system, remove the tip cap by unscrewing it in a counter-clockwise direction. Once the tip cap is removed, attach a needle to the syringe by screwing it on in a clockwise direction until it locks. Once the needle is locked in place, remove the needle protector and administer the vaccine.

3 DOSAGE FORMS AND STRENGTHS
FLUAD is an injectable emulsion. A single dose is 0.5 mL.

4 CONTRAINDICATIONS
Do not administer FLUAD to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein [see Description (11)], or to a previous influenza vaccine.

5 WARNINGS AND PRECAUTIONS

5.1 Guillain-Barré Syndrome
If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FLUAD should be based on careful consideration of the potential benefits and risks.

The 1976 swine influenza vaccine was associated with an elevated risk of GBS, [see References (1)] Evidence for a causal relationship 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.

5.2 Preventing and Managing Allergic Reactions
Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of FLUAD.

5.3 Altered Immunocompetence
The immune response to FLUAD in immunocompromised persons, including individuals receiving immunosuppressive therapy, may be lower than in immunocompetent individuals.

5.4 Syncope
Syncope (fainting) may occur in association with administration of injectable vaccines including FLUAD. Procedures should be in place to avoid injury from fainting.

5.5 Limitations of Vaccine Effectiveness
Vaccination with FLUAD may not protect all vaccine recipients against influenza disease.

6 ADVERSE REACTIONS

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

The safety of FLUAD and FLUAD QUADRIVALENT was evaluated in 17 clinical studies in 10,911 adults 65 years of age and older. Data for FLUAD QUADRIVALENT are relevant to FLUAD because both vaccines are manufactured using the same process and have overlapping compositions.

Study 1 (NCT01162122) was a multicenter, observer-blind, randomized controlled study conducted in the United States, Colombia, Panama and the Philippines during the 2010-2011 Northern Hemisphere influenza season. The safety analysis set included 3545 FLUAD recipients and 3537 AGRIFLU (Influenza Vaccine) recipients. The enrolled subject population was 65 to 97 years of age (mean 72 years) and 64% were female. Within each treatment group, 53% were Asian, 28% were Caucasian, 18% were Hispanic, 1% were Black, and fewer than 1% each were Native American/Alaskan, Pacific Islander/Hawaiian, or Other.

Solicited local (injection site) and systemic adverse reactions were collected from subjects who completed a symptom diary card for seven days following vaccination. The reported frequencies of solicited local adverse reactions are presented in Table 1a and systemic adverse reactions are presented in Table 1b.

### Table 1a: Percentages of Subjects ≥ 65 Years of Age With Solicited Local Adverse Reactions in Days 1-7 After Administration of FLUAD or AGRIFLU (a U.S. Licensed Comparator) NCT01162122

<table>
<thead>
<tr>
<th>Solicited Local Adverse Reactions</th>
<th>FLUAD (N=3418-3496) Percentage</th>
<th>AGRIFLU (N=3420-3488) Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site Pain: Any</td>
<td>25.0</td>
<td>12.2</td>
</tr>
<tr>
<td>Injection site Pain: Moderate†</td>
<td>3.9</td>
<td>1.9</td>
</tr>
<tr>
<td>Injection site Pain: Severe†</td>
<td>0.3</td>
<td>0.2</td>
</tr>
<tr>
<td>Tenderness: Any</td>
<td>21.1</td>
<td>11.2</td>
</tr>
<tr>
<td>Tenderness: Moderate</td>
<td>3.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Tenderness: Severe</td>
<td>0.1</td>
<td>0.2</td>
</tr>
<tr>
<td>Erythema: Any</td>
<td>1.2</td>
<td>0.5</td>
</tr>
<tr>
<td>Erythema: 25 to ≤ 50 mm</td>
<td>1.1</td>
<td>0.5</td>
</tr>
<tr>
<td>Erythema: 51 to ≤ 100 mm</td>
<td>0.2</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Erythema: &gt; 100 mm</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Induration: Any</td>
<td>1.3</td>
<td>0.5</td>
</tr>
<tr>
<td>Induration: 25 to ≤ 50 mm</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Induration: 51 to ≤ 100 mm</td>
<td>0.3</td>
<td>0.0</td>
</tr>
<tr>
<td>Induration: &gt; 100 mm</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Swelling: Any</td>
<td>1.2</td>
<td>0.4</td>
</tr>
<tr>
<td>Swelling: 25 to ≤ 50 mm</td>
<td>1.0</td>
<td>0.4</td>
</tr>
<tr>
<td>Swelling: 51 to ≤ 100 mm</td>
<td>0.2</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Swelling: &gt; 100 mm</td>
<td>&lt;0.1</td>
<td>0.0</td>
</tr>
</tbody>
</table>

† N = number of subjects with safety data.
‡ Moderate: pain, tenderness, defined as “some limitation in normal daily activity”
§ Severe: pain, tenderness, defined as “unable to perform normal daily activity”

### Table 1b: Percentages of Subjects ≥ 65 Years of Age With Solicited Systemic Adverse Reactions in Days 1-7 After Administration of FLUAD or AGRIFLU (a U.S. Licensed Comparator) NCT01162122

<table>
<thead>
<tr>
<th>Solicited Systemic Adverse Reactions</th>
<th>FLUAD (N=3418-3496) Percentage</th>
<th>AGRIFLU (N=3420-3488) Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myalgia: Any</td>
<td>14.7</td>
<td>9.7</td>
</tr>
<tr>
<td>Myalgia: Moderate†</td>
<td>2.6</td>
<td>1.8</td>
</tr>
<tr>
<td>Myalgia: Severe†</td>
<td>0.3</td>
<td>0.7</td>
</tr>
<tr>
<td>Fatigue: Any</td>
<td>13.3</td>
<td>10.4</td>
</tr>
<tr>
<td>Fatigue: Moderate</td>
<td>3.1</td>
<td>2.4</td>
</tr>
<tr>
<td>Fatigue: Severe</td>
<td>0.4</td>
<td>0.6</td>
</tr>
<tr>
<td>Fatigue: PLT†</td>
<td>0.0</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Headache: Any</td>
<td>13.2</td>
<td>11.2</td>
</tr>
<tr>
<td>Headache: Moderate</td>
<td>3.0</td>
<td>2.6</td>
</tr>
<tr>
<td>Headache: Severe</td>
<td>0.4</td>
<td>0.6</td>
</tr>
<tr>
<td>Headache: PLT</td>
<td>0.0</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Arthralgia: Any</td>
<td>8.5</td>
<td>7.8</td>
</tr>
<tr>
<td>Arthralgia: Moderate</td>
<td>1.6</td>
<td>1.6</td>
</tr>
<tr>
<td>Arthralgia: Severe</td>
<td>0.2</td>
<td>0.6</td>
</tr>
<tr>
<td>Chills: Any</td>
<td>6.7</td>
<td>4.7</td>
</tr>
<tr>
<td>Chills: Moderate</td>
<td>1.5</td>
<td>1.2</td>
</tr>
<tr>
<td>Chills: Severe</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Chills: PLT</td>
<td>&lt;0.1</td>
<td>0.0</td>
</tr>
<tr>
<td>Diarrhea: Any</td>
<td>4.8</td>
<td>4.5</td>
</tr>
<tr>
<td>Diarrhea: Moderate</td>
<td>1.3</td>
<td>0.9</td>
</tr>
<tr>
<td>Diarrhea: Severe</td>
<td>0.3</td>
<td>0.2</td>
</tr>
<tr>
<td>Diarrhea: PLT</td>
<td>&lt;0.1</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Fever: Any</td>
<td>3.6</td>
<td>3.4</td>
</tr>
<tr>
<td>Fever: ≥38.0°C to ≤ 38.4°C</td>
<td>1.8</td>
<td>1.7</td>
</tr>
</tbody>
</table>
Serious Adverse Events (SAEs) and Deaths: In Study 1, in which subjects were followed for 6 months following vaccination was similar between vaccine groups (16.9% FLUAD vs. 18.0% active comparator).

Serious Adverse Events (SAEs) and Deaths: In Study 2, which was randomized, controlled studies. The total safety population in these studies included 10,952 adults 65 years of age and older, comprising 5,754 who received FLUAD and 5,198 who received other US licensed influenza vaccines. The percentage of subjects with an unsolicited AE within 30 days following vaccination was similar between vaccine groups (16.9% FLUAD vs. 18.0% active comparator).

Unsolicited Adverse Events (AEs): The clinical safety of FLUAD was assessed in fifteen (15) randomized, controlled studies. The total safety population in these trials included 10,952 adults 65 years of age and older, comprising 5,754 who received FLUAD and 5,198 who received other US licensed influenza vaccines. The percentage of subjects with an unsolicited AE within 30 days following vaccination was similar between vaccine groups (16.9% FLUAD vs. 18.0% active comparator).

Serious Adverse Events (SAEs) and Deaths: In Study 3, which was conducted during the 2017-18 Northern Hemisphere influenza season. In this study, 3381 subjects received FLUAD QUADRIVALENT and 3380 subjects received a US-licensed non-influenza comparator vaccine. There were no SAEs, AESIs or deaths in this study that were related to FLUAD QUADRIVALENT. Data for FLUAD QUADRIVALENT are relevant to FLUAD because both vaccines are manufactured using the same process and have overlapping compositions. Because these events were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or to establish, for all events, a causal relationship to vaccine exposure.

Serious Adverse Events (SAEs) and Deaths: In Study 4, which was a multi-center, randomized, observer-blind, non-influenza study conducted during the 2017-18 Northern Hemisphere influenza season. In this study, 3381 subjects received FLUAD QUADRIVALENT and 3380 subjects received a US-licensed non-influenza comparator vaccine. There were no SAEs, AESIs or deaths in this study that were related to FLUAD QUADRIVALENT. Data for FLUAD QUADRIVALENT are relevant to FLUAD because both vaccines are manufactured using the same process and have overlapping compositions. Because these events were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or to establish, for all events, a causal relationship to vaccine exposure.

Serious Adverse Events (SAEs) and Deaths: In Study 5, which was a multi-center, randomized, observer-blind, non-influenza study conducted during the 2017-18 Northern Hemisphere influenza season. In this study, 3381 subjects received FLUAD QUADRIVALENT and 3380 subjects received a US-licensed non-influenza comparator vaccine. There were no SAEs, AESIs or deaths in this study that were related to FLUAD QUADRIVALENT. Data for FLUAD QUADRIVALENT are relevant to FLUAD because both vaccines are manufactured using the same process and have overlapping compositions. Because these events were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or to establish, for all events, a causal relationship to vaccine exposure.
11 DESCRIPTION
FLUAD (Influenza Vaccine, Adjuvanted), a sterile injectable emulsion for intramuscular use, is a trivalent inactivated influenza vaccine prepared from virus propagated in the allantoic cavity of embryonated hens’ eggs inoculated with a specific type of influenza virus.

FLUAD is standardized according to United States Public Health Service requirements and each 0.5 mL dose is formulated to contain 15 mcg of hemagglutinin (HA) from each of the following influenza strains recommended for the 2024-2025 influenza season: A/Victoria/4897/2022 IVR-238 (an A/Victoria/4897/2022 (H1N1)pdm09-like virus), A/Thailand/B/2022 IVR-237 (an A/Thailand/B/2022 (H3N2)-like virus), B/Australia/1359417/2021 BVR-26 (a B/Australia/1359417/2021-like virus). FLUAD also contains MF59C.1 adjuvant (MF59®), a squalene based oil-in-water emulsion. Each of the strains is harvested and clarified separately by centrifugation and filtration prior to inactivation with formaldehyde. The inactivated virus is concentrated and purified by zonal centrifugation. The surface antigens, hemagglutinin and neuraminidase, are obtained from the influenza virus particle by further centrifugation in the presence of cetyltrimethylammonium bromide (CTAB). The antigen preparation is further purified.

FLUAD is prepared by combining the three virus antigens with the MF59C.1 adjuvant. After combining, FLUAD is a sterile, milky-white injectable emulsion supplied in single-dose pre-filled syringes containing 0.5 mL dose. Each 0.5 mL dose contains 15 mcg of hemagglutinin (HA) from each of the three recommended influenza strains and MF59C.1 adjuvant (9.75 mg squalene, 1.175 mg of polysorbate 80, 1.175 mg of sorbitan trioleate, 0.66 mg of sodium citrate dihydrate and 0.04 mg of citric acid monohydrate) at pH 6.9-7.7.

FLUAD may contain trace amounts of neomycin (≤ 0.02 mcg by calculation), kanamycin (≤ 0.03 mcg by calculation) and hydrocortisone (≤ 0.005 ng by calculation) which are used during the initial stages of manufacture, as well as residual egg protein (ovalbumin) (≤ 0.4 mcg), formaldehyde (≤ 10 mcg) or CTAB (≤ 12 mcg).

FLUAD does not contain a preservative. The syringe, syringe plunger stopper and tip caps are not made with natural rubber latex.

12 CLINICAL PHARMACOLOGY
Mechanism of Action
Specific levels of hemagglutination inhibition (HI) antibody titers induced by vaccination with inactivated influenza virus vaccine have not been correlated with protection from influenza illness. In some human studies, HI antibody titers of 1:40 or greater have been associated with protection from influenza illness in up to 50% of subjects. [See References (2,3)]

Antibody against one influenza virus type or subtype confers limited or no protection against another. Furthermore, antibody 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 making with one or more new strains in each year’s influenza vaccine.

13 NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
FLUAD has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals.

14 CLINICAL STUDIES
Study 1 (NCT01162122) evaluated the safety and immunogenicity of FLUAD in comparison to AGRIFLU. A total of 7082 subjects were randomized and vaccinated with FLUAD (N=3541) or AGRIFLU (N=3543). The primary immunogenicity analyses were conducted on all vaccinated subjects with a blood sample collected at Day 22 (N=3225-3227 [91%] and 3,256-3,259 [92%] in the FLUAD and AGRIFLU groups, respectively). Non-inferiority of FLUAD compared with AGRIFLU was demonstrated for all three vaccine strains based on pre-defined thresholds for seroconversion rate differences and GMT ratios (Table 2a & 2b).

15 REFERENCES

16 HOW SUPPLIED/STORAGE AND HANDLING
FLUAD is supplied in the product presentation listed below:

<table>
<thead>
<tr>
<th>Presentation</th>
<th>Carton NDC Number</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Filled Syringe</td>
<td>70461-024-03</td>
<td>0.5 mL dose in a pre-filled syringe (needle not supplied), package of 10 syringes per carton [NDC 70461-024-04]</td>
</tr>
</tbody>
</table>

Store FLUAD refrigerated at 2°C to 8°C (36°F to 46°F). Protect from light. Do not freeze. Discard if the vaccine has been frozen. Do not use after expiration date.

The syringe, syringe plunger stopper and tip cap are not made with natural rubber latex.

17 PATIENT COUNSELING INFORMATION
- Inform vaccine recipients of the potential benefits and risks of immunization with FLUAD.
- Educate vaccine recipients regarding the potential side effects. Clinicians should emphasize that (1) FLUAD contains non-infectious particles and cannot cause influenza and (2) FLUAD is intended to help provide protection against illness due to influenza viruses only.
- Instruct vaccine recipients to report adverse reactions to their healthcare provider and/or to Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 and www.vaers.hhs.gov. Provide vaccine recipients with the Vaccine Information Statements which are required by the National Childhood Vaccine Injury Act of 1986. These materials are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).
- Inform vaccine recipients that annual vaccination is recommended.

FLUAD, FLUAD QUADRIVALENT and MF59 are registered trademarks of Seqirus UK Limited or its affiliates.

Manufactured by: Sequirius Inc., 475 Green Oaks Parkway, Holly Springs, NC 27540, USA
Distributed by: Sequirius USA Inc., 25 Deforest Avenue, Summit, NJ 07901, USA
Tel: 1-855-358-8966
US License No. 2049

USA-FLUD-24-0004

### Table 2a: Immune Responses to Each Antigen 22 Days after Vaccination with FLUAD or AGRIFLU in Adults 65 Years and Older* (Study 1)

<table>
<thead>
<tr>
<th>Vaccine Strains</th>
<th>FLUAD N°=3225-3227 GMT (95% CI)</th>
<th>AGRIFLU N°=3256-3259 GMT (95% CI)</th>
<th>FLUAD and AGRIFLU Difference in Seroconversion Rate* (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/California/7/2009-like (H1N1)</td>
<td>99 (93-106)</td>
<td>70 (66-75)</td>
<td>1.4 (1.32-1.49)</td>
</tr>
<tr>
<td>A/Perth/16/2009-like (H3N2)</td>
<td>272 (257-288)</td>
<td>169 (159-179)</td>
<td>1.61 (1.52-1.7)</td>
</tr>
<tr>
<td>B/Brisbane/60/2008-like</td>
<td>28 (26-29)</td>
<td>24 (23-26)</td>
<td>1.15 (1.08-1.21)</td>
</tr>
</tbody>
</table>

* GMT = Geometric mean antibody titer; CI = Confidence interval
* FLUAD met non-inferiority criteria based on GMT ratios if the lower limit of the 95% CI [FLUAD-AGRIFLU] for each strain was > -10%.

Table 2b: Immune Responses to Each Antigen 22 Days after Vaccination with FLUAD or AGRIFLU in Adults 65 Years and Older* (Study 1)

<table>
<thead>
<tr>
<th>Vaccine Strains</th>
<th>FLUAD N°=3225-3227 % of Subjects (95% CI)</th>
<th>AGRIFLU N°=3256-3259 % of Subjects (95% CI)</th>
<th>FLUAD and AGRIFLU Difference in Seroconversion Rate* (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/California/7/2009-like (H1N1)</td>
<td>69% (67-70%)</td>
<td>58% (57-60%)</td>
<td>9.8% (7.5%-12.1%)</td>
</tr>
<tr>
<td>A/Perth/16/2009-like (H3N2)</td>
<td>73% (71-74%)</td>
<td>58% (56-60%)</td>
<td>13.9% (11.7%-16.1%)</td>
</tr>
<tr>
<td>B/Brisbane/60/2008-like</td>
<td>33% (31-35%)</td>
<td>29% (28-31%)</td>
<td>3.2% (1.1%-5.3%)</td>
</tr>
</tbody>
</table>

* Results obtained following vaccination with influenza vaccine formulated for the 2010-2011 season.
* N is the number of vaccinated participants with available data for the immunologic endpoint listed.
* FLUAD met non-inferiority criteria based on GMT ratios if the lower limit of the 95% CI [FLUAD-AGRIFLU] for each strain was > -10%.