FLUAD® (influenza vaccine, adjuvanted) generates a strong immune response in adults 65+ to help protect them against the flu

INDICATIONS AND USAGE: FLUAD® is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD® is approved for use in persons aged 65 years and older. FLUAD® should not be used in persons aged 65 years and older with a history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine, including egg protein, or to a previous influenza vaccine.

IMMUNOGENICITY: FLUAD® may not be 100% effective in all who receive it.\(^1\) Immunogenicity was assessed in adults aged 65 years and older who received FLUAD® (N = 7189) or AGRIFLU (influenza vaccine) (N = 7189). The primary immunogenicity analysis was performed on all vaccinated groups, respectively. A determination of noninferiority was made on the basis of predefined thresholds for seroconversion rate differences and GMT ratios. The study was supported by INFLUENZASKILLS (FLUAD®) and FLUAD® vaccine development safety update report. Additional safety data were derived from 15 randomized controlled studies involving 10,952 adults aged 65 years and older who received FLUAD® (N = 7189) or other US-licensed vaccines (N = 3940).

Please see Important Safety Information in opposite side and accompanying US full Prescribing Information.

**FLUAD® (influenza vaccine, adjuvanted)**

**INDICATIONS AND USAGE:** FLUAD® is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD® is approved for use in persons aged 65 years and older. FLUAD® should not be used in persons aged 65 years and older with a history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine, including egg protein, or to a previous influenza vaccine.

**IMMUNOGENICITY:** FLUAD® may not be 100% effective in all who receive it.\(^1\) Immunogenicity was assessed in adults aged 65 years and older who received FLUAD® (N = 7189) or AGRIFLU (influenza vaccine) (N = 7189). The primary immunogenicity analysis was performed on all vaccinated groups, respectively. A determination of noninferiority was made on the basis of predefined thresholds for seroconversion rate differences and GMT ratios. The study was supported by INFLUENZASKILLS (FLUAD®) and FLUAD® vaccine development safety update report. Additional safety data were derived from 15 randomized controlled studies involving 10,952 adults aged 65 years and older who received FLUAD® (N = 7189) or other US-licensed vaccines (N = 3940).

Please see Important Safety Information in opposite side and accompanying US full Prescribing Information.

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

**WARNINGS AND PRECAUTIONS:**

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

**ADVERSE REACTIONS:**

- FLUAD® may not be 100% effective in all who receive it.\(^1\) Immunogenicity was assessed in adults aged 65 years and older who received FLUAD® (N = 7189) or AGRIFLU (influenza vaccine) (N = 7189). The primary immunogenicity analysis was performed on all vaccinated groups, respectively. A determination of noninferiority was made on the basis of predefined thresholds for seroconversion rate differences and GMT ratios. The study was supported by INFLUENZASKILLS (FLUAD®) and FLUAD® vaccine development safety update report. Additional safety data were derived from 15 randomized controlled studies involving 10,952 adults aged 65 years and older who received FLUAD® (N = 7189) or other US-licensed vaccines (N = 3940).

Please see Important Safety Information in opposite side and accompanying US full Prescribing Information.

**FLUAD® (influenza vaccine, adjuvanted)**

**INDICATIONS AND USAGE:** FLUAD® is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD® is approved for use in persons aged 65 years and older. FLUAD® should not be used in persons aged 65 years and older with a history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine, including egg protein, or to a previous influenza vaccine.

**IMMUNOGENICITY:** FLUAD® may not be 100% effective in all who receive it.\(^1\) Immunogenicity was assessed in adults aged 65 years and older who received FLUAD® (N = 7189) or AGRIFLU (influenza vaccine) (N = 7189). The primary immunogenicity analysis was performed on all vaccinated groups, respectively. A determination of noninferiority was made on the basis of predefined thresholds for seroconversion rate differences and GMT ratios. The study was supported by INFLUENZASKILLS (FLUAD®) and FLUAD® vaccine development safety update report. Additional safety data were derived from 15 randomized controlled studies involving 10,952 adults aged 65 years and older who received FLUAD® (N = 7189) or other US-licensed vaccines (N = 3940).

Please see Important Safety Information in opposite side and accompanying US full Prescribing Information.
FLUAD: Safety Results From the Pivotal Trial

INDICATIONS AND USAGE
FLUAD is a licensed influenza vaccine indicated for active immunization against influenza viruses causing respiratory illness in adults. FLUAD has been approved in over 30 countries worldwide.

ADVERSE REACTIONS

FLUAD: Solicited Systemic Adverse Reactions

- pH: 7.0-7.3
- Relative density: 1.085-1.095
- Squalene: 0.45-0.55

FLUAD: Solicited Local Adverse Reactions

- Pain: 18%
- Tenderness: 17%
- Myalgia: 13%
- Fatigue: 13%
- Headache: 13%
- Arthralgia: 11%

FLUAD: How Supplied

- The package contains ten 0.5 mL prefilled, needleless syringes per vial (NDC number: 61773-011-01)

FLUAD: Accepted Use Worldwide

- Over 81 million doses distributed worldwide since 1997
- Approved for use in persons 65 years and older

ADVERSE REACTIONS

• Pain, tenderness, myalgia, fatigue, headache, arthralgia, chills, nausea, vomiting defined as "some limitation in normal daily activity," diarrhea defined as "4 to 5 stools a day.

b N = number of subjects with safety data.

c Moderate: pain, tenderness, myalgia, fatigue, headache, arthralgia, chills, nausea, vomiting defined as "some limitation in normal daily activity," diarrhea defined as "4 to 5 stools a day.

b N = number of subjects with safety data.

v vs AGRIFLU at day 221

Immunogenicity: In a large pivotal trial (N = 7082), FLUAD was shown to elicit a strong immune response vs AGRIFLU (influenza vaccine). A total of 7082 subjects aged 65 years and older were randomized and vaccinated with FLUAD (N = 3541) or AGRIFLU (N = 3541). The primary immunogenicity analysis was performed on all vaccinated subjects aged 65 years and older.

Immunogenicity: FLUAD met noninferiority criteria based on GMT ratios if the lower limit of the 95% CI [FLUAD: AGRIFLU] for each strain was >0.67.

Immunogenicity: FLUAD met noninferiority criteria based on GMT ratios if the lower limit of the 95% CI [FLUAD – AGRIFLU] for each strain was >-10%.

Please see Important Safety Information on opposite side and accompanying US full Prescribing Information.

Important Safety Information

INDICATIONS AND USAGE
FLUAD is an inactivated influenza vaccine indicated for active immunization against influenza viruses causing respiratory illness in adults. FLUAD has been approved in over 30 countries worldwide.

ADVERSE REACTIONS

• Pain, tenderness, myalgia, fatigue, headache, arthralgia, chills, nausea, vomiting defined as "some limitation in normal daily activity," diarrhea defined as "4 to 5 stools a day.

b N = number of subjects with safety data.

c Moderate: pain, tenderness, myalgia, fatigue, headache, arthralgia, chills, nausea, vomiting defined as "some limitation in normal daily activity," diarrhea defined as "4 to 5 stools a day.

b N = number of subjects with safety data.

v vs AGRIFLU at day 221

Immunogenicity: In a large pivotal trial (N = 7082), FLUAD was shown to elicit a strong immune response vs AGRIFLU (influenza vaccine). A total of 7082 subjects aged 65 years and older were randomized and vaccinated with FLUAD (N = 3541) or AGRIFLU (N = 3541). The primary immunogenicity analysis was performed on all vaccinated subjects aged 65 years and older.

Immunogenicity: FLUAD met noninferiority criteria based on GMT ratios if the lower limit of the 95% CI [FLUAD: AGRIFLU] for each strain was >0.67.

Immunogenicity: FLUAD met noninferiority criteria based on GMT ratios if the lower limit of the 95% CI [FLUAD – AGRIFLU] for each strain was >-10%.

Please see accompanying US full Prescribing Information.