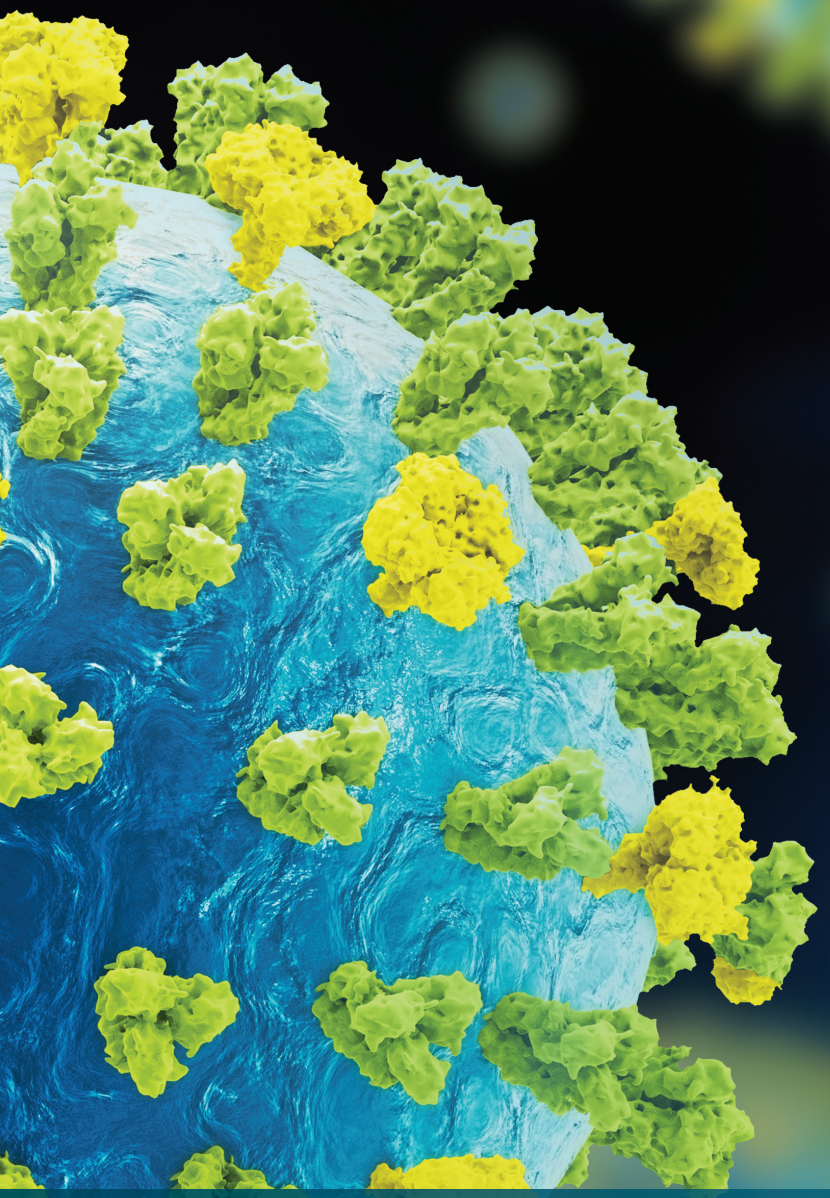


FLUAD® QUADRIVALENT
influenza vaccine, adjuvanted

Adding an adjuvant makes a difference[1]

FLUAD® QUADRIVALENT is the first-and-only MF59® adjuvanted quadrivalent seasonal influenza vaccine approved for adults

65 YEARS AND OLDER[2]

185+ MILLION DOSES
DISTRIBUTED OVER 20+ YEARS[a,3]

[a]Doses distributed globally as of June 2021 and includes both FLUAD and FLUAD QUADRIVALENT

INDICATION AND USAGE

FLUAD® (Influenza Vaccine, Adjuvanted) 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® QUADRIVALENT (Influenza Vaccine, Adjuvanted) is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and types B contained in the vaccine. FLUAD and FLUAD QUADRIVALENT are approved for use in persons 65 years of age and older.

These indications are approved under accelerated approval based on the immune response elicited by FLUAD and FLUAD QUADRIVALENT.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Do not administer FLUAD or FLUAD QUADRIVALENT 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.

Please see Important Safety Information throughout and the accompanying full US Prescribing Information for FLUAD and FLUAD QUADRIVALENT.

For US Healthcare Professional Use Only

Seqirus™
A CSL COMPANY

Influenza has a devastating impact on adults 65+

In the US, influenza impacts adults 65+ with high hospitalization and death rates.[4]

The Centers for Disease Control and Prevention (CDC) estimates that in recent years, adults 65+ account for approximately:

70%-85% of influenza-related deaths[4]

50%-70% of influenza-related hospitalizations[4]

Approximately **two-thirds of adults 65-84 years old** and **up to 80% of adults 85 years and older** have been diagnosed with multiple chronic health conditions, putting them at high risk for influenza-related complications.[5]

In the first weeks after influenza infection, adults 65+ have an increased risk of:

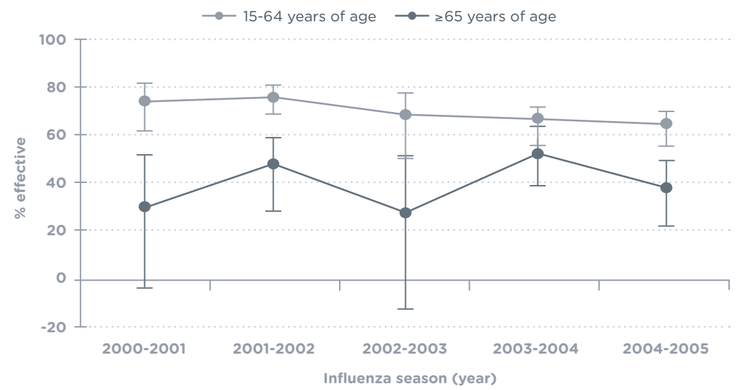
A first or subsequent heart attack: **up to 3-5 times more likely**[6]

A first or subsequent stroke: **up to 2-3 times more likely**[6]

Developing pneumonia and bronchitis, the most common complications of influenza[6,7]

Influenza vaccine effectiveness continues to be challenging in adults 65+

IN ADULTS 65+, VACCINE EFFECTIVENESS HAS BEEN SUBOPTIMAL COMPARED TO YOUNGER ADULTS[a,8]



[a]Vaccine effectiveness against influenza-like illness for adults 15-64 years of age and adults 65 years of age and older, France, 1995-2005.

INFLUENZA VACCINE EFFECTIVENESS IN THE US

2019-2020 SEASON[b,9]	
37%	for 18-64 yrs[c]
39%	for 65+
2018-2019 SEASON[b,10]	
20%	for 18-64 yrs[c]
12%	for 65+
2017-2018 SEASON[b,11]	
32%	for 18-64 yrs[c]
17%	for 65+

[b]Data estimates from the Centers for Disease Control and Prevention

[c]Average of vaccine effectiveness from 18-49 years and 50-64 years.

Influenza vaccine effectiveness in adults 65+ is largely driven by two factors:

Weakened Immune System

Aging reduces the body's ability to produce a sufficient protective immune response to the vaccine, leaving them more vulnerable to influenza infection and its complications.[4,8]

Strain Mismatch

This occurs when circulating influenza strains do not match the strains contained in the seasonal influenza vaccine.[12,13]

IN THE INFLUENZA SEASONS IN THE US BETWEEN 2010-2011 AND 2019-2020, STRAIN MISMATCHES HAVE OCCURRED 6 OF 10 TIMES.[13-22]

Use an adjuvanted influenza vaccine to help address challenges in adults 65 years and older

An adjuvant is a substance added to a vaccine to boost the immune response.[23]

Adjuvants have been used in vaccines for decades.[23] Adjuvanted vaccines have been approved to help prevent diseases such as seasonal influenza, shingles, pneumococcal pneumonia, hepatitis A and B, and diphtheria, tetanus, and pertussis (DTaP).[24]

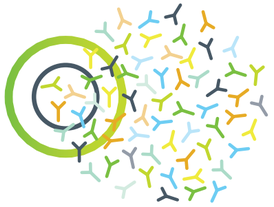
Adding MF59® Adjuvant to an influenza vaccine is designed to strengthen, broaden, and lengthen the duration of the immune response[1,25,26]

Adding MF59® Adjuvant to an influenza vaccine does more than an antigen alone[1,25,26]

MF59® ADJUVANTED INFLUENZA VACCINE[1,25,26]

Antigen + MF59® Adjuvant

Strengthens the immune response by **stimulating more immune cells** to **create more antibodies**



Broadens the immune response by creating **more diverse, cross-reactive antibodies**

This may be important if there is a mismatch between the influenza virus strains in the vaccine and the circulating influenza strains.

NON-ADJUVANTED, STANDARD-DOSE INFLUENZA VACCINE[1,25,26]

Antigen only

Stimulates immune cells

Creates fewer antibodies

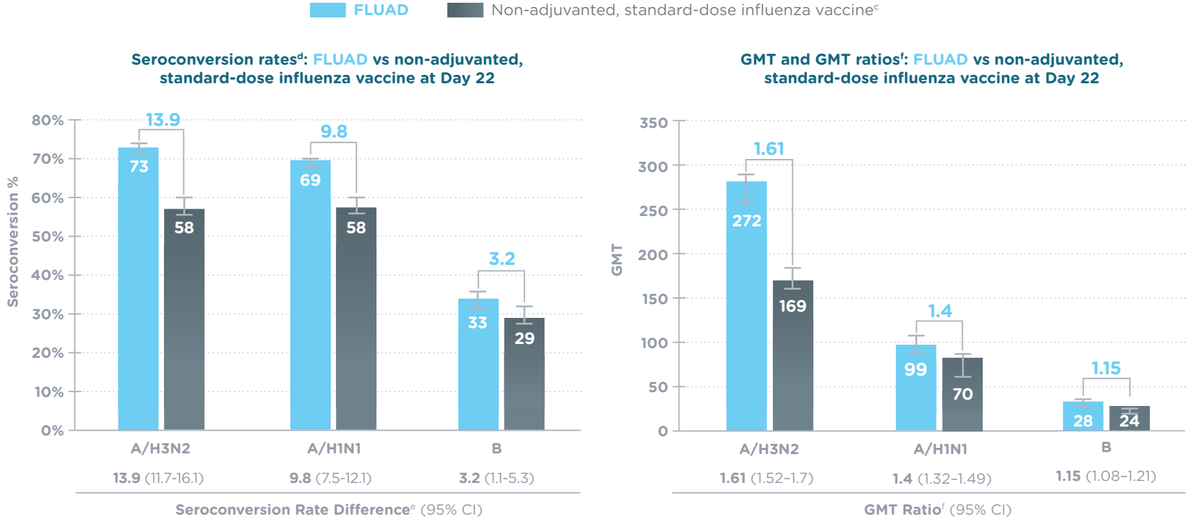
This is a conceptualization of the mechanism of action of an MF59® adjuvanted influenza vaccine and a non-adjuvanted, standard-dose influenza vaccine.

Made with MF59® Adjuvant...

FLUAD® QUADRIVALENT (Influenza Vaccine, Adjuvanted) builds upon the original trivalent formulation (FLUAD), which produced a strong immune response in adults 65+

FLUAD QUADRIVALENT is manufactured using the same process and has overlapping composition to FLUAD.[a,2,27]

FLUAD met non-inferiority criteria for the two influenza A strains and the influenza B strain represented in the vaccine, compared to a non-adjuvanted, standard-dose influenza vaccine.[b,27,28]



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=3541). The primary immunogenicity analyses were conducted on all vaccinated subjects with a blood sample collected at Day 22 (N=3225-3227 [91%] and 3256-3259 [92%] in the FLUAD and AGRIFLU groups, respectively).

CI=confidence interval; GMT=geometric mean antibody titer; HI=hemagglutinin inhibition; N=the number of vaccinated participants with available data from the immunologic endpoint listed.

[a]Only FLUAD QUADRIVALENT is available for the 2021-2022 US influenza season. FLUAD is no longer being manufactured for distribution in the US. [b]Results obtained following vaccination with influenza vaccine formulated for the 2010-2011 season. [c]AGRIFLU. [d]Seroconversion was defined as prevaccination HI titer <10 and postvaccination HI titer ≥40 or at least a 4-fold increase in HI from prevaccination HI titer ≥10. [e]FLUAD met non-inferiority criteria based on seroconversion rate differences if the lower limit of the 95% CI [FLUAD–AGRIFLU] for each strain was >-10%. [f]FLUAD met non-inferiority criteria based on GMT ratios if the lower limit of the 95% CI [FLUAD–AGRIFLU] for each strain was >0.67.

WARNINGS AND PRECAUTIONS

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

FLUAD® has a demonstrated safety profile

FLUAD has a similar safety profile to that of a non-adjuvanted, standard-dose influenza vaccine.

Most common (≥10%) local and systemic adverse reactions observed within 7 days of vaccination with FLUAD or non-adjuvanted, standard-dose influenza vaccine.[27]

While more frequent injection-site–related events were reported for FLUAD, most were mild to moderate.[27]

		FLUAD Percentage (N=3418–3496)				Non-adjuvanted, standard-dose influenza vaccine Percentage (N=3420–3488)			
		Any	Moderate[a]	Severe[b]	PLT[c]	Any	Moderate[a]	Severe[b]	PLT[c]
Systemic	Myalgia	14.7	2.6	0.3	NA	9.7	1.8	0.7	NA
Systemic	Fatigue	13.3	3.1	0.4	0.0	10.4	2.4	0.6	<0.1
Systemic	Headache	13.2	3.0	0.4	0.0	11.2	2.6	0.6	<0.1
Local	Injection-site pain	25.0	3.9	0.3	NA	12.2	1.9	0.2	NA
Local	Tenderness	21.1	3.0	0.1	NA	11.2	1.0	0.2	NA

N=the number of subjects with safety data.

[a]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]Severe: pain, tenderness, myalgia, fatigue, headache, arthralgia, chills, nausea, vomiting defined as "unable to perform normal daily activity," diarrhea defined as "6 or more watery stools a day." [c]Potentially life-threatening (PLT) reaction defined as requiring emergency room visit or hospitalization.

WARNINGS AND PRECAUTIONS (continued)

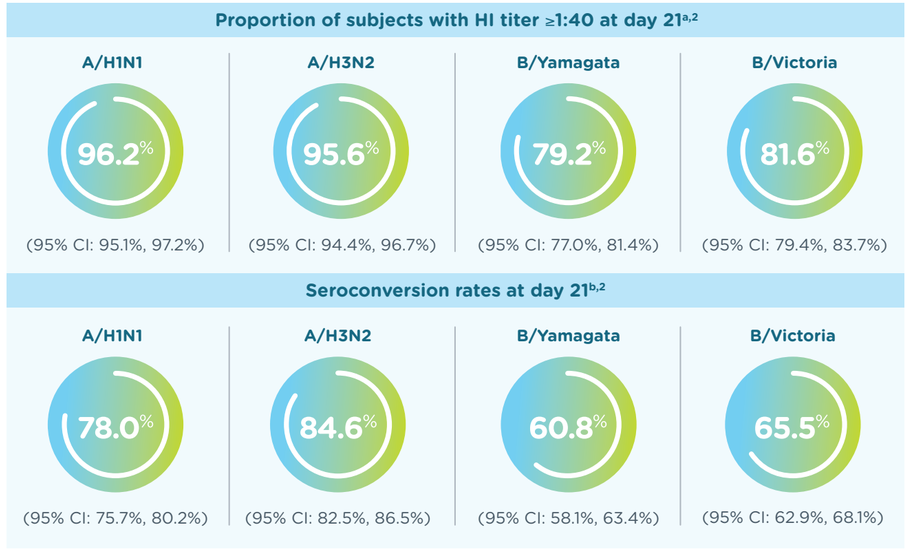
Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

Please see Important Safety Information throughout and the accompanying full US Prescribing Information for FLUAD and FLUAD QUADRIVALENT.

Made with MF59® Adjuvant...

FLUAD® QUADRIVALENT (Influenza Vaccine, Adjuvanted) produces robust immune responses

Compared to FLUAD, FLUAD QUADRIVALENT includes an additional B strain to help prevent disease caused by all 4 influenza strains represented in the vaccine.[2]



For the non-influenza comparator vaccine, the proportion of subjects with HI titers greater than or equal to 1:40 at Day 21 were 46.7% for the A/H1N1 strain, 41.7% for A/H3N2, 21.5% for B/Yamagata, and 18.4% for B/Victoria. The seroconversion rates for the non-influenza comparator vaccine were 2.1% for A/H1N1, 3.9% for A/H3N2, 3.6% for B/Yamagata, and 2.1% for B/Victoria.

Study 1 evaluated the immunogenicity of FLUAD QUADRIVALENT in a randomized, observer-blind, non-influenza comparator-controlled, multicenter efficacy study. Adult subjects 65 years of age and older received 1 dose of either FLUAD QUADRIVALENT (N=3379) or a US-licensed non-influenza comparator vaccine (N=3382).[c]

[a]Success criterion: lower bound of the 95% CI for the % of subjects with HI titer ≥1:40 must be ≥60%. [b]Seroconversion is defined as a prevaccination HI titer <1:10 and postvaccination HI titer ≥1:40 or at least a 4-fold increase in HI from prevaccination HI titer ≥1:10. Success criterion: lower bound of the 95% CI for the seroconversion rate must be ≥30%. [c]Non-influenza comparator vaccine=combined tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine, Boostrix® (GlaxoSmithKline Biologicals).

WARNINGS AND PRECAUTIONS (continued)

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

FLUAD® QUADRIVALENT has a demonstrated safety profile

The safety of FLUAD QUADRIVALENT was evaluated in 2 multicenter, randomized controlled trials in 4269 adults 65 years and older.[2]

In Study 1, most common (≥10%) local and systemic adverse reactions observed within 7 days of vaccination with FLUAD QUADRIVALENT or a non-influenza comparator vaccine.[2]

		FLUAD QUADRIVALENT Percentage (N[a]=595-659)	Non-influenza comparator vaccine Percentage (N[a]=607-664)
		Any[b]	Any[b]
Systemic	Headache	10.8	8.3
Systemic	Fatigue	10.5	8.8
Local	Injection-site pain	16.3	11.2

N=number of subjects with solicited safety data.

[a]Solicited safety population: all subjects in the exposed population who received a study vaccine and provided postvaccination solicited safety data. [b]Severe reactions of each type were reported in 1.1% or fewer subjects receiving FLUAD QUADRIVALENT; severe reactions of each type were also reported in the comparator group at similar percentages. Severe definitions: erythema, induration, and ecchymosis=>100 mm diameter; injection-site pain, nausea, fatigue, myalgia, arthralgia, headache, and chills=prevents daily activity; loss of appetite=not eating at all; vomiting=6 or more times in 24 hours or requires intravenous hydration; diarrhea=6 or more loose stools in 24 hours or requires intravenous hydration; fever=≥102.2 °F (39 °C)

In Study 2, FLUAD QUADRIVALENT demonstrated a similar safety profile to that of FLUAD.[2]

Solicited local and systemic adverse reactions reported were similar to those reported for Study 1.

WARNINGS AND PRECAUTIONS (continued)

Syncope (fainting) may occur in association with administration of injectable vaccines including FLUAD or FLUAD QUADRIVALENT. Ensure procedures are in place to avoid injury from falling associated with syncope.

Vaccination with FLUAD or FLUAD QUADRIVALENT may not protect all vaccine recipients against influenza disease.

Please see Important Safety Information throughout and the accompanying full US Prescribing Information for FLUAD and FLUAD QUADRIVALENT.

FLUAD® QUADRIVALENT influenza vaccine, adjuvanted

FLUAD® (Influenza Vaccine, Adjuvanted) and FLUAD® QUADRIVALENT (Influenza Vaccine, Adjuvanted) INDICATION and IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

FLUAD® (Influenza Vaccine, Adjuvanted) 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® QUADRIVALENT (Influenza Vaccine, Adjuvanted) is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and types B contained in the vaccine. FLUAD and FLUAD QUADRIVALENT are approved for use in persons 65 years of age and older. These indications are approved under accelerated approval based on the immune response elicited by FLUAD and FLUAD QUADRIVALENT.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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

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

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

Syncope (fainting) may occur in association with administration of injectable vaccines including FLUAD or FLUAD QUADRIVALENT. Ensure procedures are in place to avoid injury from falling associated with syncope.

Vaccination with FLUAD or FLUAD QUADRIVALENT may not protect all vaccine recipients against influenza disease.

ADVERSE REACTIONS

The most common (≥ 10%) local (injection site) adverse reactions observed in clinical studies with FLUAD were injection site pain (25%) and tenderness (21%). The most common (≥ 10%) systemic adverse reactions observed in clinical studies with FLUAD were myalgia (15%), headache (13%) and fatigue (13%).

The most common (≥10%) local and systemic reactions with FLUAD QUADRIVALENT in elderly subjects 65 years of age and older were injection site pain (16.3%), headache (10.8%) and fatigue (10.5%).

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

Before administration, please see the full US Prescribing Information for FLUAD and FLUAD QUADRIVALENT.

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FLUAD®
QUADRIVALENT
influenza vaccine, adjuvanted

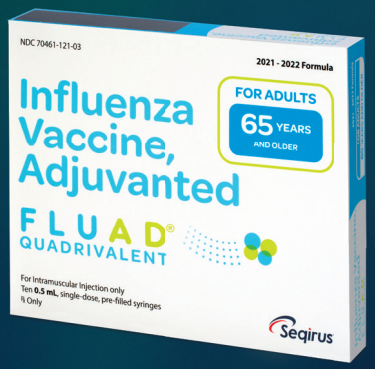
185+ MILLION DOSES
DISTRIBUTED OVER 20+ YEARS[a,3]

FLUAD® QUADRIVALENT is the first-and-only MF59® adjuvanted quadrivalent seasonal influenza vaccine approved for adults **65 years and older.**[b,2]

Covered by Medicare Part B and by most Medicare Advantage Plans with no copay*,[29]

CPT CODE 90694

- Contains no preservative
- For intramuscular injection
- 0.5 mL pre-filled syringe
- 10 syringes per carton
- Syringe, plunger, and tip cap are not made from natural rubber latex



*This information does not constitute a guarantee or warranty of coverage benefits or reimbursement

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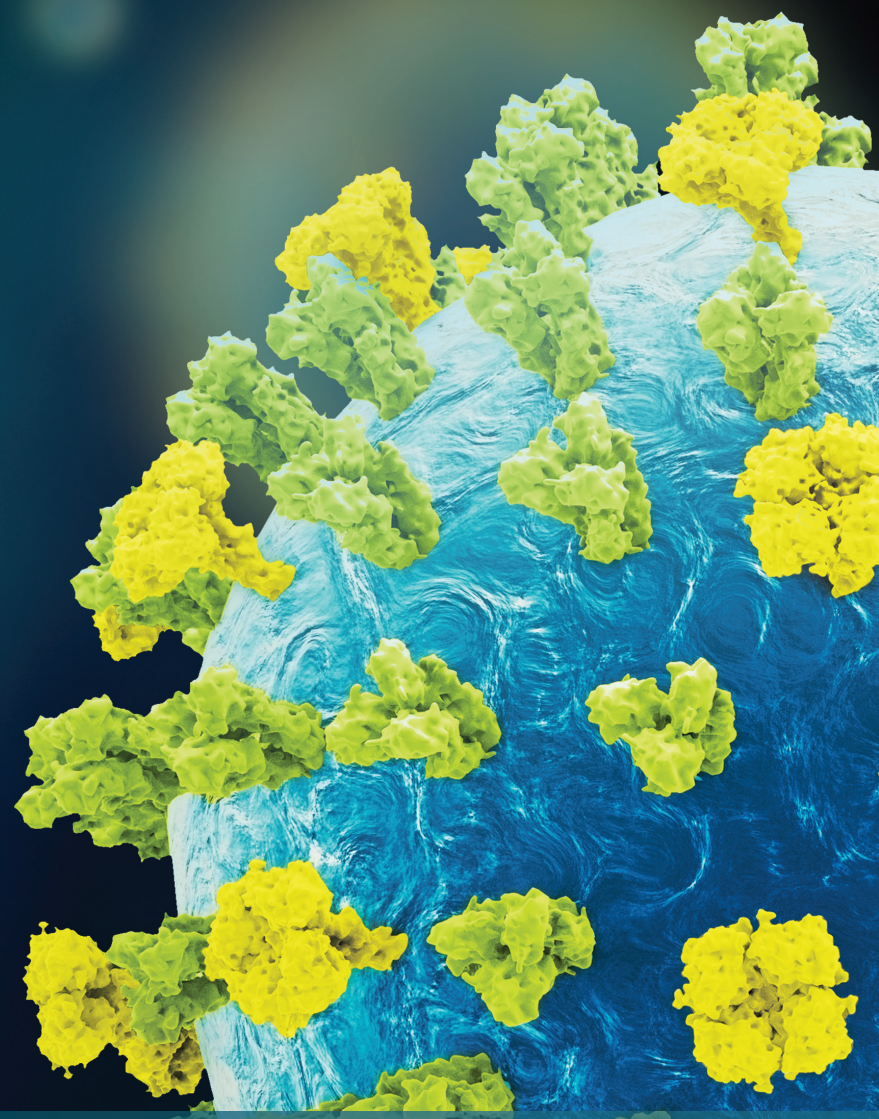

[a]Doses distributed globally as of June 2021 and includes both FLUAD and FLUAD QUADRIVALENT.
[b]Only FLUAD QUADRIVALENT will be available to order for the 2022-2023 flu season.

CONTRAINDICATIONS

Do not administer FLUAD or FLUAD QUADRIVALENT 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.

Please see Important Safety Information throughout and the accompanying full US Prescribing Information for FLUAD and FLUAD QUADRIVALENT.

For US Healthcare Professional Use Only

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