

# FLUAD<sup>®</sup> QUADRIVALENT

**FLUAD<sup>®</sup>**  
QUADRIVALENT  
influenza vaccine,  
adjuvanted

The first-and-only adjuvanted  
quadrivalent seasonal influenza  
vaccine approved for adults

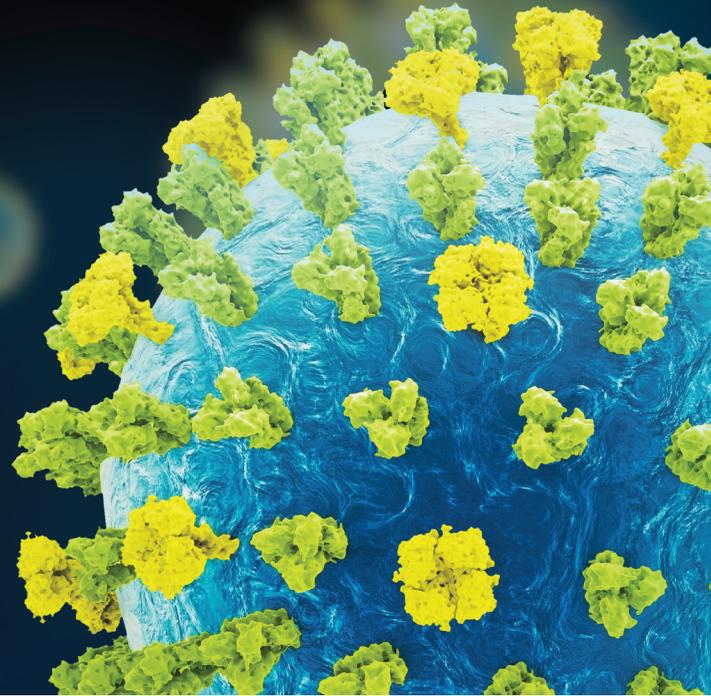
**65 YEARS  
AND OLDER<sup>1</sup>**

FLUAD QUADRIVALENT is formulated with **MF59<sup>®</sup>**  
adjuvant to boost the immune response to all  
**4 influenza strains** represented in the vaccine.<sup>1</sup>

**REIMBURSED BY MEDICARE PART B  
CPT CODE 90694**

For more information, please see Brief Summary  
on adjacent page.

Learn more at [flu.seqirus.com](http://flu.seqirus.com)



## Important Safety Information

### INDICATIONS AND USAGE

FLUAD QUADRIVALENT 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 QUADRIVALENT is approved for use in persons 65 years of age and older.

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

### CONTRAINDICATIONS

Severe allergic reaction 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 six weeks of previous influenza vaccination, the decision to give 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 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 QUADRIVALENT. Ensure procedures are in place to avoid injury from falling associated with syncope.

### ADVERSE REACTIONS

- The most common ( $\geq 10\%$ ) local and systemic reactions in elderly subjects 65 years of age and older were injection site pain (16.3%), headache (10.8%) and fatigue (10.5%).

Other adverse events may occur. For a comprehensive list of local and systemic adverse reactions, please see full Prescribing Information.

**To report SUSPECTED ADVERSE REACTIONS, contact Seqirus at 1-855-358-8966 or VAERS at 1-800-822-7967 and [www.vaers.hhs.gov](http://www.vaers.hhs.gov).**

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

FLUAD<sup>®</sup> QUADRIVALENT is a registered trademark of Seqirus UK Limited or its affiliates.

**REFERENCE: 1.** FLUAD QUADRIVALENT [package insert]. Holly Springs, NC: Seqirus Inc; 2020.

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A CSL COMPANY

**FLUAD QUADRIVALENT (Influenza Vaccine, Adjuvanted)**  
**Injectable Emulsion for Intramuscular Use**  
**2020-2021 Formula**  
**Initial U.S. Approval: 2020**

**BRIEF SUMMARY**

These highlights do not include all the information needed to use FLUAD® QUADRIVALENT safely and effectively. See full prescribing information for FLUAD QUADRIVALENT.

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

FLUAD QUADRIVALENT 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 QUADRIVALENT is approved for use in persons 65 years of age and older. (1)

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

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

A single 0.5 mL dose for intramuscular injection. (2.1)

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

Injectable emulsion supplied in 0.5 mL single-dose pre-filled syringes. (3)

**-----CONTRAINDICATIONS-----**

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

**-----ADVERSE REACTIONS-----**

The most common ( $\geq 10\%$ ) local and systemic reactions in elderly subjects 65 years of age and older were injection site pain (16.3%), headache (10.8%) and fatigue (10.5%). (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](http://www.vaers.hhs.gov).**



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