# THE CSL SEQIRUS PORTFOLIO OF INFLUENZA VACCINES—2023-2024 SEASON



CSL Segirus offers a wide range of influenza vaccines for patients 6 months to 65 years of age and older.

PACKAGING		AGES	PRESENTATION	DOSING	CPT CODE	CARTON NDC #	SYRINGE/VIAL LABEL NDC #	PRODUCT DESCRIPTION	CVX CODE <sup>‡</sup>	MVX CODE
FLUAD' QUADRIVALENT influenza vaccine, adjuvanted	Influenza Vaccine, Adjuvanted	65 years and older <sup>1</sup>	10 x 0.5-mL pre-filled syringes*1	1 dose	90694 (covered by Medicare Part B)	70461-123-03	70461-123-04	Quadrivalent influenza vaccine manufactured using <b>adjuvant technology</b> <sup>1</sup>	205	SEQ
Influenza Vaccine PLUCELVAX. QUADRIVALENT	Region Telephone	6 months and older <sup>2</sup>	5-mL multi-dose vial <sup>2</sup>	For children 6 months through 8 years, 1-2 doses depending on vaccination history For persons 9 years of age and older, 1 dose	90756	70461-423-10	70461-423-11	Quadrivalent influenza vaccine manufactured with <b>cell-based technology</b> <sup>2</sup>	186	SEQ
Influenza Vaccine FLU CELVA X GUADRIVALENT	SMANNACAT		10 x 0.5-mL pre-filled syringes* <sup>2</sup>		90674	70461-323-03	70461-323-04		171	SEQ
afluria.	where twice and the state of th	6 months and older <sup>3</sup>	5-mL multi-dose vial <sup>†3</sup>	For children 6 months through 8 years, 1-2 doses depending on vaccination history  For persons 9 years of age and older, 1 dose	90687 (0.25-mL dose)	33332-423-10	33332-423-11	Quadrivalent influenza vaccine manufactured with egg-based technology³	158	SEQ
					90688 (0.5-mL dose)					
MELUENZA VAÇCINE AFÎULITA.	Influence Notice  of Notice Conditionable  of	36 months and older <sup>3</sup>	10 x 0.5-mL pre-filled syringes* <sup>3</sup>		90686	33332-323-03	33332-323-04		150	SEQ

CPT=Current Procedural Terminology; NDC=National Drug Code

Please see Important Safety Information on next page and full US Prescribing Information for FLUAD° QUADRIVALENT, FLUCELVAX° QUADRIVALENT, and AFLURIA° QUADRIVALENT.

**References: 1.** FLUAD QUADRIVALENT. Package insert. Seqirus Inc; 2023. **2.** FLUCELVAX QUADRIVALENT. Package insert. Seqirus USA Inc; 2023. **3.** AFLURIA QUADRIVALENT. Package insert. Seqirus USA Inc; 2023.

Questions?

Visit flu360.com for more information and to place your order.



Call flu360 Customer Service (855) 358-8966, option 2

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**CSL Seqirus** 

<sup>\*</sup>The pre-filled syringes contain no preservative.

<sup>&</sup>lt;sup>†</sup>The number of needle punctures should not exceed 20 per multi-dose vial.

<sup>\*</sup>The CVX, or vaccine administered code, indicates which product was used and is used in combination with the manufacturer (MVX) code.

### FLUAD® QUADRIVALENT (Influenza Vaccine, Adjuvanted), FLUCELVAX® QUADRIVALENT (Influenza Vaccine), and AFLURIA® QUADRIVALENT (Influenza Vaccine)

## INDICATION AND IMPORTANT SAFETY INFORMATION INDICATIONS AND USAGE

<u>FLUAD® QUADRIVALENT</u> (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 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.

FLUCELVAX® QUADRIVALENT (Influenza Vaccine) is an inactivated vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and types B contained in the vaccine. FLUCELVAX QUADRIVALENT is approved for use in persons 6 months of age and older.

<u>AFLURIA® QUADRIVALENT</u> (Influenza Vaccine) is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. AFLURIA QUADRIVALENT is approved for use in persons 6 months of age and older.

#### **IMPORTANT SAFETY INFORMATION**

#### CONTRAINDICATIONS

Do not administer FLUAD QUADRIVALENT or AFLURIA 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.

Do not administer FLUCELVAX QUADRIVALENT to anyone with a history of severe allergic reactions (e.g. anaphylaxis) to any component of the 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 QUADRIVALENT, FLUCELVAX QUADRIVALENT, or AFLURIA 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.

Syncope (fainting) may occur in association with administration of injectable vaccines. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Ensure procedures are in place to avoid falling injury and to restore cerebral perfusion following syncope by maintaining a supine or Trendelenburg position.

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

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

#### **ADVERSE REACTIONS**

#### FLUAD QUADRIVALENT:

The most common ( $\geq$  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%). Other adverse events may occur.

#### FLUCELVAX QUADRIVALENT:

In children 6 months through 3 years of age who received FLUCELVAX QUADRIVALENT, the most commonly reported injection-site adverse reactions were tenderness (27.9%), erythema (25.8%), induration (17.3%) and ecchymosis (10.7%). The most common systemic adverse reactions were irritability (27.9%), sleepiness (26.9%), diarrhea (17.9%) and change of eating habits (17.4%).

In children 2 through 8 years of age who received FLUCELVAX QUADRIVALENT, the most commonly reported injection-site adverse reactions were tenderness (28.7%), pain (27.9%) and erythema (21.3%), induration (14.9%) and ecchymosis (10.0%). The most common systemic adverse reactions were sleepiness (14.9%), headache (13.8%), fatigue (13.8%), irritability (13.8%) and loss of appetite (10.6%).

In children and adolescents 9 through 17 years of age who received FLUCELVAX QUADRIVALENT, the most commonly reported injection-site adverse reactions were injection site pain (21.7%), erythema (17.2%) and induration (10.5%). The most common systemic adverse reactions were headache (18.1%) and fatigue (17.0%).

In adults 18 through 64 years of age who received FLUCELVAX QUADRIVALENT, the most commonly reported injection-site adverse reactions were pain (45.4%), erythema (13.4%) and induration (11.6%). The most common systemic adverse reactions were headache (18.7%), fatique (17.8%) and myalqia (15.4%).

In adults ≥65 years of age who received FLUCELVAX QUADRIVALENT, the most commonly reported injection-site adverse reactions were pain (21.6%) and erythema (11.9%).

Other adverse events may occur.

#### **AFLURIA QUADRIVALENT:**

AFLURIA QUADRIVALENT administered by needle and syringe:

In children 6 months through 35 months of age, the most frequently reported injection site reactions in the clinical study with AFLURIA QUADRIVALENT administered by needle and syringe were pain and redness ( $\geq 20\%$ ). The most common systemic adverse events were irritability ( $\approx 30\%$ ), diarrhea and loss of appetite ( $\approx 20\%$ ).

In children 36 through 59 months of age, the most commonly reported injection site reactions in the clinical study with AFLURIA QUADRIVALENT administered by needle and syringe were pain (\$ 30%) and redness (\$ 20%). The most commonly reported systemic adverse events were malaise and fatigue, and diarrhea (\$ 10%).

In children 5 through 8 years, the most commonly reported injection-site adverse reactions when AFLURIA QUADRIVALENT was administered by needle and syringe were pain ( $\geq 50\%$ ), redness and swelling ( $\geq 10\%$ ). The most common systemic adverse event was headache ( $\geq 10\%$ ).

In adults 18 through 64 years of age, the most commonly reported injection-site adverse reaction observed in clinical studies with AFLURIA QUADRIVALENT administered by needle and syringe was pain ( $\geq$  40%). The most common systemic adverse events observed were myalgia and headache ( $\geq$  20%).

In adults 65 years of age and older, the most commonly reported injection-site adverse reaction observed in clinical studies with AFLURIA QUADRIVALENT administered by needle and syringe was pain (≥ 20%). The most common systemic adverse event observed was myalgia (≥ 10%).

AFLURIA (trivalent formulation) administered by PharmaJet Stratis Needle-Free Injection System:

The safety experience with AFLURIA (trivalent formulation) is relevant to AFLURIA QUADRIVALENT because both vaccines are manufactured using the same process and have overlapping compositions.

In adults 18 through 64 years of age, the most commonly reported injection-site adverse reactions observed in a clinical study with AFLURIA (trivalent formulation) using the PharmaJet Stratis Needle-Free Injection System were tenderness ( $\geq$  80%), swelling, pain, redness ( $\geq$  60%), itching ( $\geq$  20%) and bruising ( $\geq$  10%). The most common systemic adverse events were myalgia, malaise ( $\geq$  30%) and headache ( $\geq$  20%).

Other adverse events may occur.

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

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

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