THE SEQIRUS PORTFOLIO OF INFLUENZA VACCINES 2020-2021 SEASON

flu360 WE'VE GOT FLU COVERED™

Seqirus 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§
FLUAD influenza vaccine, adjuvanted 	65 years and older[1]	10 x 0.5 mL pre-filled syringes*[1]	1 dose[1]	90653 (covered by Medicare Part B)	70461-020-03	70461-020-04	Trivalent influenza vaccine manufactured using **adjuvant technology**[1]	168
FLUAD QUADRIVALENT influenza vaccine, adjuvanted 	65 years and older[2]	10 x 0.5 mL pre-filled syringes*[2]	1 dose[2]	90694 (covered by Medicare Part B)	70461-120-03	70461-120-04	Quadrivalent influenza vaccine manufactured using **adjuvant technology**[2]	205
Influenza Vaccine FLUCELVAX QUADRIVALENT 	4 years and older[3]	5 mL multi-dose vial†[3]	1 or 2 doses (depends on vaccination history as per Advisory Committee on Immunization Practices annual recommendations on prevention and control of influenza with vaccines)[3]	90756	70461-420-10	70461-420-11	Quadrivalent influenza vaccine manufactured with **cell-based technology**[3]	186
Influenza Vaccine FLUCELVAX QUADRIVALENT 		10 x 0.5 mL pre-filled syringes*[3]		90674	70461-320-03	70461-320-04		171
INFLUENZA VACCINE afluria QUADRIVALENT 	6 months and older[4]	5 mL multi-dose vial‡[4]	1 or 2 doses (depends on vaccination history as per Advisory Committee on Immunization Practices annual recommendations on prevention and control of influenza with vaccines)[4]	90687 (0.25 mL dose)	33332-420-10	33332-420-11	Quadrivalent influenza vaccine manufactured with egg-based technology[4]	158
				90688 (0.5 mL dose)				
INFLUENZA VACCINE afluria QUADRIVALENT 	36 months and older[4]	10 x 0.5 mL pre-filled syringes*[4]		90686	33332-320-01	33332-320-02		150
INFLUENZA VACCINE afluria QUADRIVALENT 	6 months through 35 months[4]	10 x 0.25 mL pre-filled syringes*[4]		90685	33332-220-20	33332-220-21		161

*The pre-filled syringes contain no preservative.
†No more than 10 doses (0.5 mL) should be withdrawn from the FLUCELVAX QUADRIVALENT multi-dose vial.
‡No more than 10 doses (0.25 mL or 0.5 mL) should be withdrawn from the AFLURIA QUADRIVALENT multi-dose vial.
§The CVX, or vaccine administered code, indicates which product was used and is used in combination with the manufacturer (MVX) code. The MVX code for Seqirus is SEQ.
CPT=Current Procedural Terminology; NDC=National Drug Code

Visit flu.seqirus.com for more information and to place your order.

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

References: 1. FLUAD [package insert]. Summit, NJ: Seqirus USA Inc; 2020. **2.** FLUAD QUADRIVALENT [package insert]. Holly Springs, NC: Seqirus Inc; 2020. **3.** FLUCELVAX QUADRIVALENT [package insert]. Summit, NJ: Seqirus USA Inc; 2020. **4.** AFLURIA QUADRIVALENT [package insert]. Summit, NJ: Seqirus USA Inc; 2020.

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

INDICATION and IMPORTANT SAFETY INFORMATION

INDICATIONS 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 QUADRIVALENT.

AFLURIA® QUADRIVALENT (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.

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 type B contained in the vaccine. FLUCELVAX QUADRIVALENT is approved for use in persons 4 years of age and older. For children and adolescents 4 through 17 years of age, approval is based on the immune response elicited by FLUCELVAX QUADRIVALENT. Data demonstrating a decrease in influenza disease after vaccination of this age group with FLUCELVAX QUADRIVALENT are not available.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Do not administer FLUAD, 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 reaction (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, FLUAD QUADRIVALENT, AFLURIA QUADRIVALENT or FLUCELVAX 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, FLUAD QUADRIVALENT, AFLURIA QUADRIVALENT and FLUCELVAX 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, FLUAD QUADRIVALENT, and FLUCELVAX QUADRIVALENT. Ensure procedures are in place to avoid injury from falling associated with syncope.

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

ADVERSE REACTIONS

FLUAD:

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%).

FLUAD QUADRIVALENT:

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%).

AFLURIA QUADRIVALENT:

AFLURIA QUADRIVALENT administered by needle and syringe:
In adults 18 through 64 years, the most commonly reported injection-site adverse reaction was pain (≥ 40%). The most common systemic adverse events were myalgia and headache (≥ 20%).

In adults 65 years of age and older, the most commonly reported injection-site adverse reaction was pain (≥ 20%). The most common systemic adverse event was myalgia (≥ 10%). In children 5 through 8 years, the most commonly reported injection-site adverse reactions were pain (≥ 50%), redness and swelling (≥ 10%). The most common systemic adverse event was headache (≥ 10%).

In children 9 through 17 years, the most commonly reported injection-site adverse reactions were pain (≥ 50%), redness and swelling (≥ 10%). The most common systemic adverse events were headache, myalgia, and malaise and fatigue (≥ 10%).

In children 6 months through 35 months of age, the most commonly reported injection-site reactions were pain and redness (≥ 20%). The most common systemic adverse events were irritability (≥ 30%), diarrhea and loss of appetite (≥ 20%).

In children 36 through 59 months of age, the most commonly reported injection site reactions were pain (≥ 30%) and redness (≥ 20%). The most commonly reported systemic adverse events were malaise and fatigue, and diarrhea (≥ 10%).

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 with AFLURIA (trivalent formulation) when administered by the PharmaJet Stratis Needle-Free Injection System were tenderness (≥80%), swelling, pain, redness (≥60%), itching (≥20%) and bruising (≥10%). The most common systemic adverse events were myalgia, malaise (≥30%), and headache (≥20%).

FLUCELVAX QUADRIVALENT:

The most common (≥10%) local and systemic reactions in adults 18 through 64 years of age were injection site pain (45.4%), headache (18.7%), fatigue (17.8%) and myalgia (15.4%), injection site erythema (13.4%), and induration (11.6%).

The most common (≥10%) local and systemic reactions in adults ≥65 years of age were injection site pain (21.6%) and injection site erythema (11.9%).

The most common (≥10%) local and systemic reactions in children 4 through 5 years of age after first dose of vaccine were tenderness at the injection site (46%), injection site erythema (18%), sleepiness (19%), irritability (16%), injection site induration (13%) and change in eating habits (10%).

The most common (≥10%) local and systemic reactions in children 6 through 8 years of age after first dose of vaccine were pain at the injection site (54%), injection site erythema (22%), injection site induration (16%), headache (14%), fatigue (13%) and myalgia (12%).

The most common (≥10%) local and systemic reactions in children and adolescents 9 through 17 years of age were pain at the injection site (58%), headache (22%), injection site erythema (19%), fatigue (18%) and myalgia (16%), and injection site induration (15%).

To report SUSPECTED ADVERSE REACTIONS, contact Seqirus USA Inc. 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, FLUAD QUADRIVALENT, AFLURIA QUADRIVALENT and FLUCELVAX QUADRIVALENT.

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