

FLUCELVAX QUADRIVALENT- influenza a virus a/georgia/12/2022 cvr-167 (h1n1) antigen (mdck cell derived, propiolactone inactivated), influenza a virus a/darwin/11/2021 (h3n2) antigen (mdck cell derived, propiolactone inactivated), influenza b virus b/singapore/wuh4618/2021 antigen (mdck cell derived, propiolactone inactivated), influenza b virus b/singapore/inftt-16-0610/2016 antigen (mdck cell derived, propiolactone inactivated) injection, suspension

Bamboo US BidCo LLC

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

**FLUCELVAX QUADRIVALENT (Influenza Vaccine)
Suspension for Intramuscular Injection
2023-2024 Formula
Initial U.S. Approval: 2016**

Principal Display Panel - 0.5 mL Carton Label

For use in persons 6 months of age and older

For Intramuscular Injection Only

Ten 0.5 mL, single-dose, pre-filled syringes

Rx Only

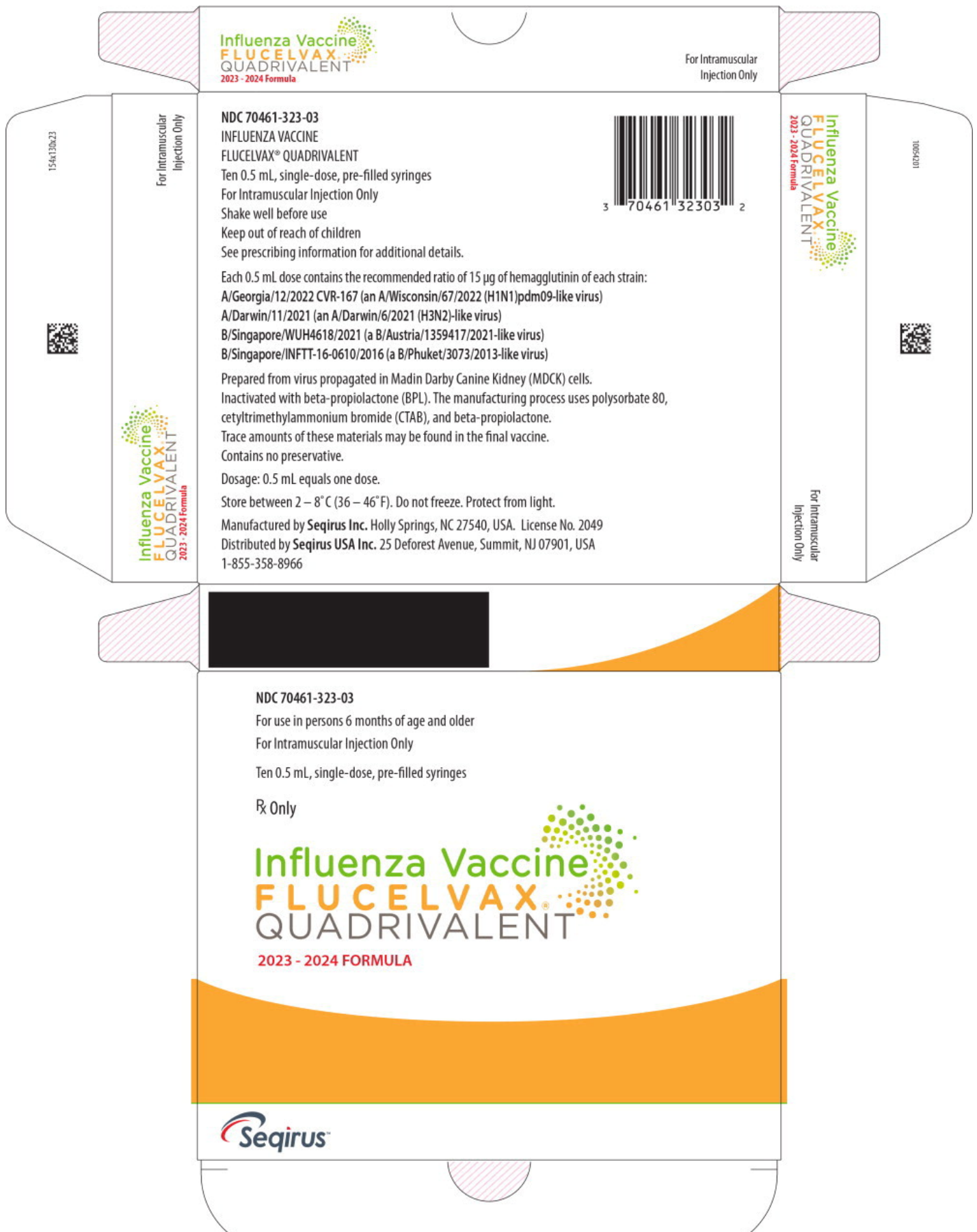
Influenza Vaccine

FLUCELVAX®

QUADRIVALENT

2023 - 2024 Formula

Seqirus™



Principal Display Panel - 0.5 mL Syringe Label
Influenza Vaccine

FLUCELVAX®

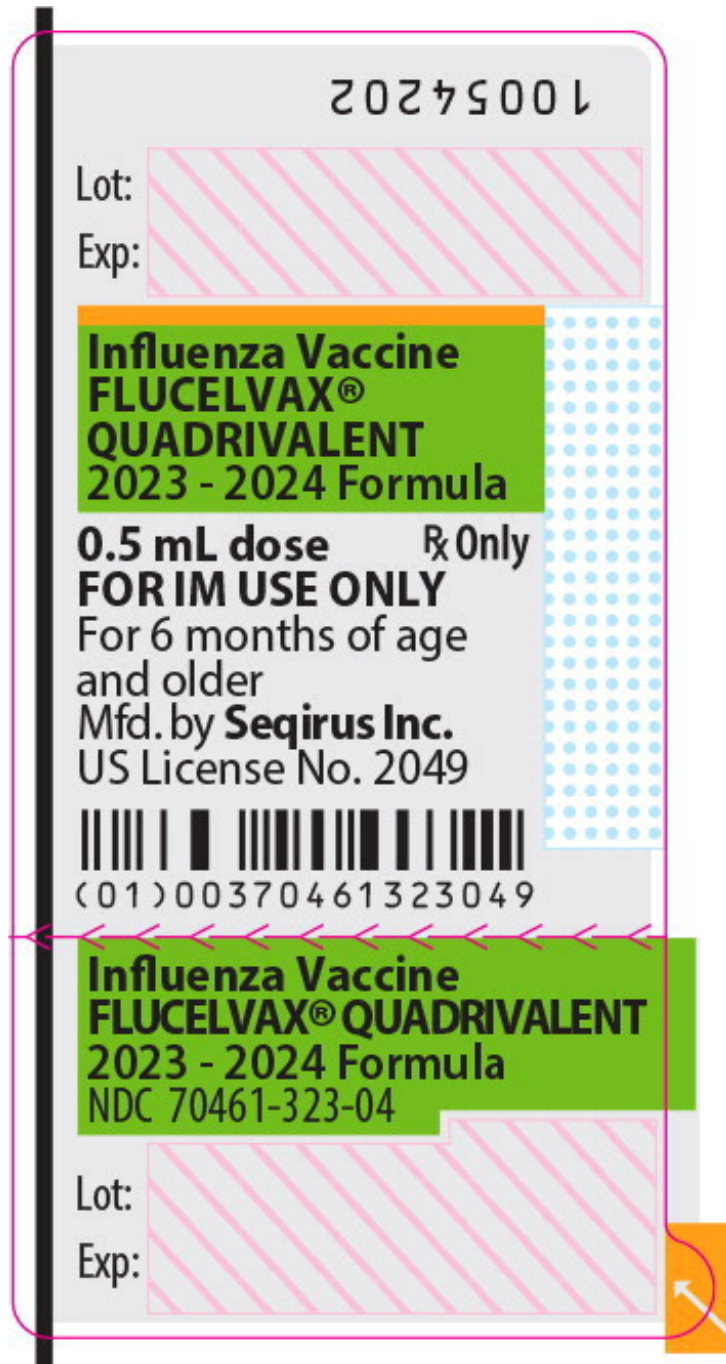
QUADRIVALENT

2023 - 2024 Formula

0.5 mL dose

Rx Only

FOR IM USE ONLY



FLUCELVAX QUADRIVALENT

influenza a virus a/georgia/12/2022 cvr-167 (h1n1) antigen (mdck cell derived, propiolactone

inactivated), influenza a virus a/darwin/11/2021 (h3n2) antigen (mdck cell derived, propiolactone inactivated), influenza b virus b/singapore/wuh4618/2021 antigen (mdck cell derived, propiolactone inactivated), influenza b virus b/singapore/inftt-16-0610/2016 antigen (mdck cell derived, propiolactone inactivated) injection, suspension

Product Information

Product Type	VACCINE	Item Code (Source)	NDC:83703-037
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
INFLUENZA A VIRUS A/GEORGIA/12/2022 CVR-167 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) (UNII: B8P3XN76W4) (INFLUENZA A VIRUS A/GEORGIA/12/2022 CVR-167 (H1N1) HEMAGGLUTININ ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) - UNII:N8JKS3VK2A)	INFLUENZA A VIRUS A/GEORGIA/12/2022 CVR-167 (H1N1) HEMAGGLUTININ ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)	15 ug in 0.5 mL
INFLUENZA A VIRUS A/DARWIN/11/2021 (H3N2) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) (UNII: PV9K2R8HRM) (INFLUENZA A VIRUS A/DARWIN/11/2021 (H3N2) HEMAGGLUTININ ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) - UNII:C6PM4NXJ33)	INFLUENZA A VIRUS A/DARWIN/11/2021 (H3N2) HEMAGGLUTININ ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)	15 ug in 0.5 mL
INFLUENZA B VIRUS B/SINGAPORE/WUH4618/2021 ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) (UNII: TUE3AGP9ME) (INFLUENZA B VIRUS B/SINGAPORE/WUH4618/2021 HEMAGGLUTININ ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) - UNII:C76JLA4DM6)	INFLUENZA B VIRUS B/SINGAPORE/WUH4618/2021 HEMAGGLUTININ ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)	15 ug in 0.5 mL
INFLUENZA B VIRUS B/SINGAPORE/INFTT-16-0610/2016 ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) (UNII: G4VX46P9M6) (INFLUENZA B VIRUS B/SINGAPORE/INFTT-16-0610/2016 HEMAGGLUTININ ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) - UNII:0JXM8X6ZW8)	INFLUENZA B VIRUS B/SINGAPORE/INFTT-16-0610/2016 HEMAGGLUTININ ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)	15 ug in 0.5 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83703-037-03	10 in 1 CARTON		
1	NDC:83703-037-04	0.5 mL in 1 SYRINGE, GLASS; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125408	07/01/2023	07/31/2024

Labeler - Bamboo US BidCo LLC (119087615)

Establishment

Name	Address	ID/FEI	Business Operations
Seqirus Inc.		080102141	manufacture, label, pack, analysis

Revised: 6/2024

Bamboo US BidCo LLC