

FLUCELVAX- influenza a virus a/georgia/12/2022 cvr-167 (h1n1) antigen (mdck cell derived, propiolactone inactivated), influenza a virus a/victoria/800/2024 cvr-289 (h3n2) antigen (mdck cell derived, propiolactone inactivated), influenza b virus b/singapore/wuh4618/2021 antigen (mdck cell derived, propiolactone inactivated) injection, suspension
Bamboo US BidCo LLC

FLUCELVAX (Influenza Vaccine)
Injectable Suspension, for Intramuscular Use
2025-2026 Formula
Initial U.S. Approval: 2012

Principal Display Panel - 0.5 mL Carton Label

For use in persons 6 months of age and older

For Intramuscular Use

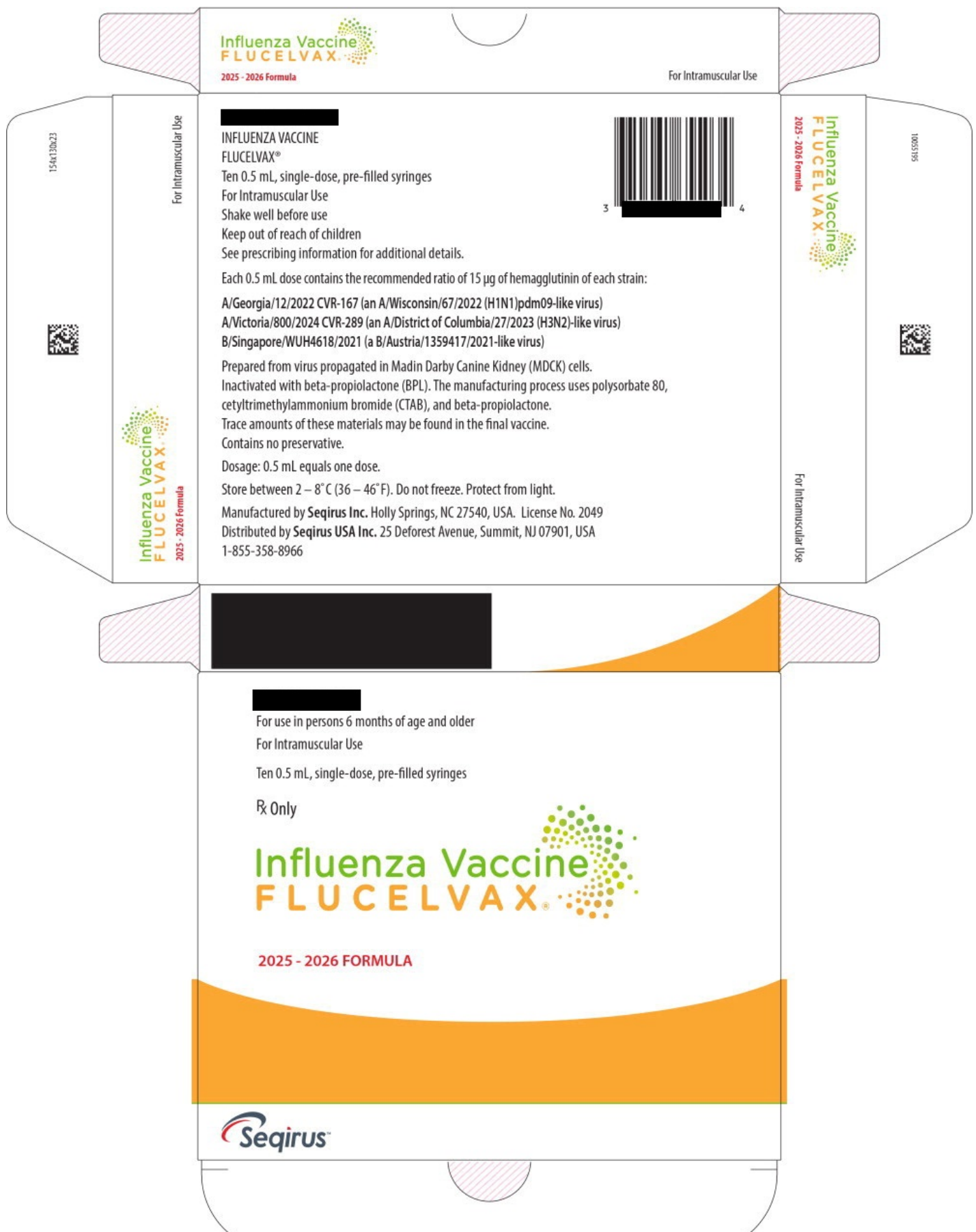
Ten 0.5 mL, single-dose, pre-filled syringes

Rx Only

Influenza Vaccine
FLUCELVAX[®]

2025 - 2026 FORMULA

Seqirus[™]



Principal Display Panel - 0.5 mL Syringe Label

**Influenza Vaccine
FLUCELVAX®**

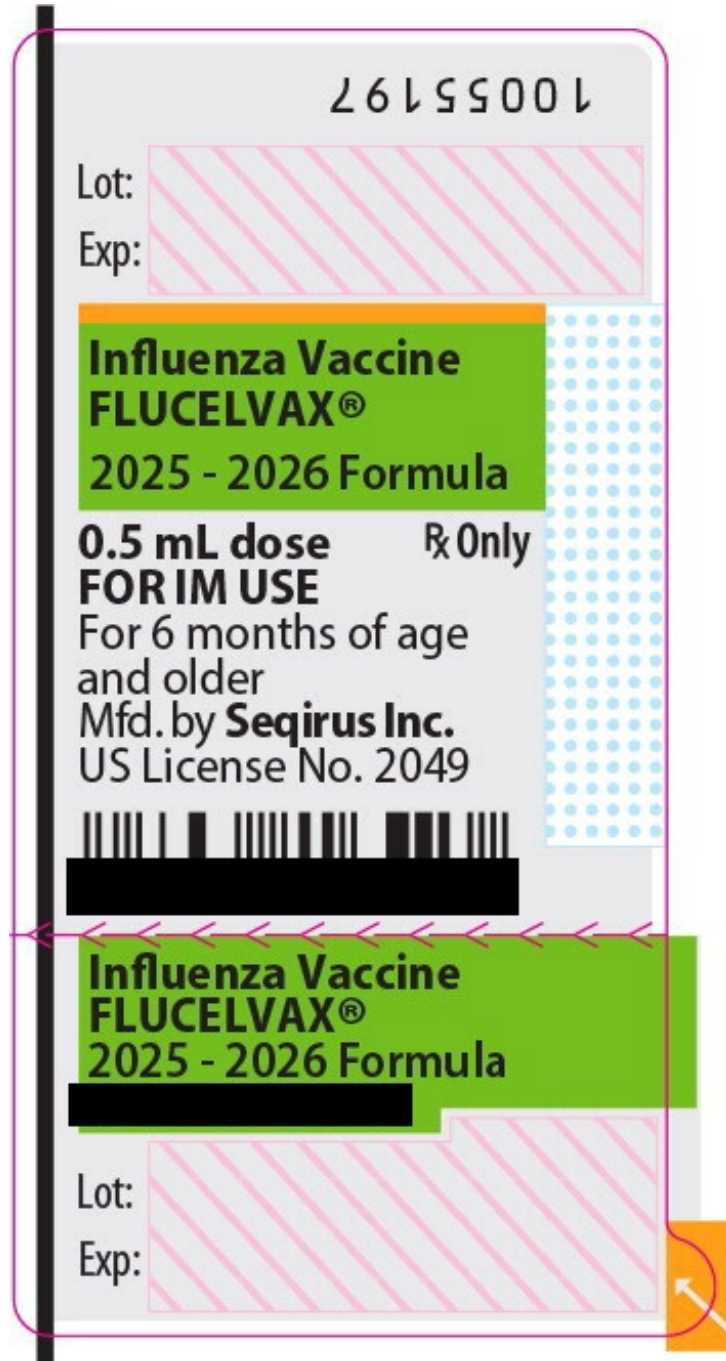
2025 - 2026 Formula

0.5 mL dose

Rx Only

FOR IM USE

For 6 months of age and older



FLUCELVAX

influenza a virus a/georgia/12/2022 cvr-167 (h1n1) antigen (mdck cell derived, propiolactone inactivated), influenza a virus a/victoria/800/2024 cvr-289 (h3n2) antigen (mdck cell derived, propiolactone inactivated), influenza b virus b/singapore/wuh4618/2021 antigen (mdck cell derived, propiolactone inactivated) injection, suspension

Product Information			
Product Type	VACCINE	Item Code (Source)	NDC:83703-084
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/VICTORIA/800/2024 CVR-289 (H3N2) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) (UNII: 4HH5SUR63T) (INFLUENZA A VIRUS A/VICTORIA/800/2024 CVR-289 (H3N2) HEMAGGLUTININ ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) - UNII:9V9Y969F8M)	INFLUENZA A VIRUS A/VICTORIA/800/2024 CVR-289 (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

Inactive Ingredients	
Ingredient Name	Strength
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
WATER (UNII: 059QF0KOOR)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83703-084-03	10 in 1 CARTON		
1	NDC:83703-084-04	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	07/01/2025	

Labeler - Bamboo US BidCo LLC (119087615)

