

**FLUCELVAX- influenza a virus a/georgia/12/2022 cvr-167 (h1n1) antigen (mdck cell derived, propiolactone inactivated), influenza a virus a/sydney/1304/2022 (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**

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**FLUCELVAX (Influenza Vaccine)**

**These highlights do not include all the information needed to use FLUCELVAX<sup>®</sup> safely and effectively. See full prescribing information for FLUCELVAX.**

**Injectable Suspension, for Intramuscular Use  
2024-2025 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

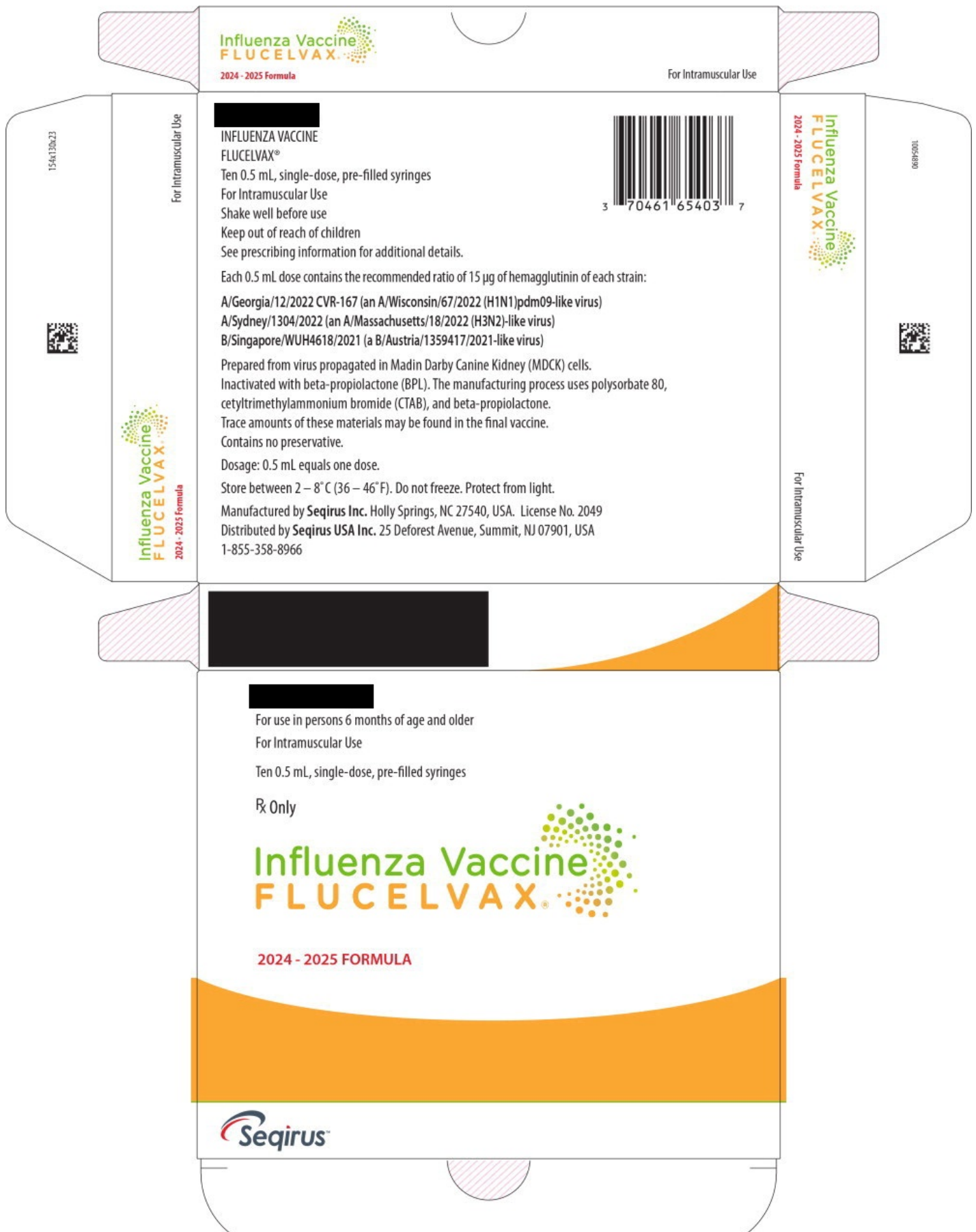
Ten 0.5 mL, single-dose, pre-filled syringes

Rx Only

**Influenza Vaccine  
FLUCELVAX<sup>®</sup>**

**2024 - 2025 FORMULA**

***Seqirus*<sup>™</sup>**



**Principal Display Panel - 0.5 mL Syringe Label**

**Influenza Vaccine  
FLUCELVAX®**

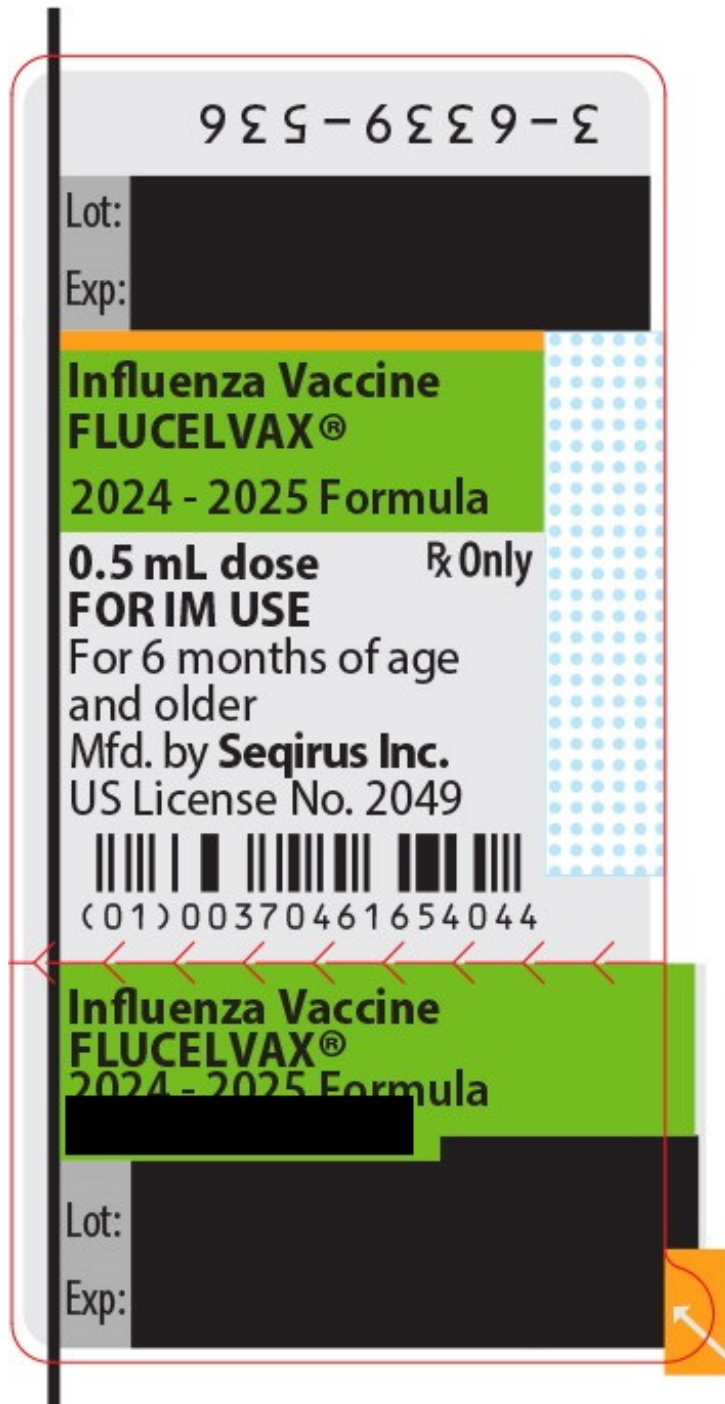
**2024 - 2025 FORMULA**

**0.5 mL dose**

**Rx Only**

**FOR IM USE**

For 6 months of age  
and older



influenza a virus a/georgia/12/2022 cvr-167 (h1n1) antigen (mdck cell derived, propiolactone inactivated), influenza a virus a/sydney/1304/2022 (h3n2) antigen (mdck cell derived, propiolactone inactivated), influenza b virus b/singapore/wuh4618/2021 antigen (mdck cell derived, propiolactone inactivated) injection, suspension

## Product Information

<b>Product Type</b>	VACCINE	<b>Item Code (Source)</b>	NDC:83703-062
<b>Route of Administration</b>	INTRAMUSCULAR		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>INFLUENZA A VIRUS A/GEORGIA/12/2022 CVR-167 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)</b> (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
<b>INFLUENZA A VIRUS A/SYDNEY/1304/2022 (H3N2) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)</b> (UNII: 2DVY566JY6) (INFLUENZA A VIRUS A/SYDNEY/1304/2022 HEMAGGLUTININ ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) - UNII:5CH2Y25VXX)	INFLUENZA A VIRUS A/SYDNEY/1304/2022 HEMAGGLUTININ ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)	15 ug in 0.5 mL
<b>INFLUENZA B VIRUS B/SINGAPORE/WUH4618/2021 ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)</b> (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
<b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)	
<b>SODIUM PHOSPHATE, DIBASIC, DIHYDRATE</b> (UNII: 94255I6E2T)	
<b>POTASSIUM PHOSPHATE, MONOBASIC</b> (UNII: 4J9FJ0HL51)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83703-062-03	10 in 1 CARTON		
1	NDC:83703-062-04	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

07/01/2024

**Labeler** - Bamboo US BidCo LLC (119087615)

Revised: 12/2024

Bamboo US BidCo LLC