

**FLUZONE TRIVALENT SOUTHERN HEMISPHERE- influenza a virus
a/victoria/4897/2022 ivr-238 (h1n1) antigen (formaldehyde inactivated),
influenza a virus a/croatia/10136rv/2023 x-425a (h3n2) antigen (formaldehyde
inactivated), and influenza b virus b/michigan/01/2021 antigen (formaldehyde
inactivated) injection, suspension
Bamboo US BidCo LLC**

**Fluzone (Influenza Vaccine) injectable suspension, for intramuscular use 2025
Formula
Initial U.S. Approval: 1980**

**These highlights do not include all the information needed to use Fluzone
® Southern Hemisphere safely and effectively. See full prescribing information
for Fluzone Southern Hemisphere.**

PRINCIPAL DISPLAY PANEL - 0.5 mL Syringe Label

Influenza Vaccine

Fluzone ®

Southern Hemisphere

2025 Formula

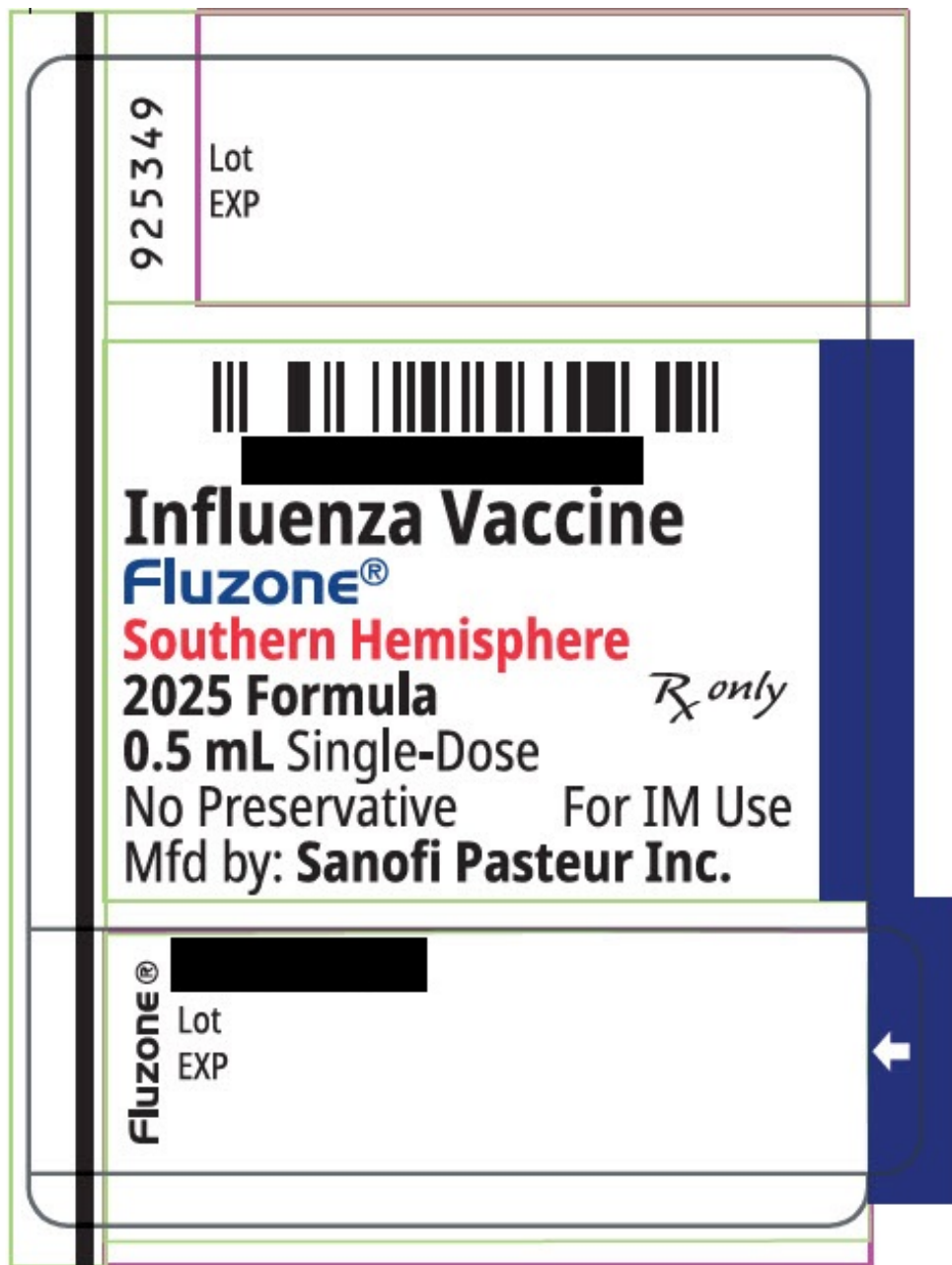
0.5 mL Single-Dose

No Preservative

Mfd by: Sanofi Pasteur Inc.

Rx only

For IM Use



PRINCIPAL DISPLAY PANEL - 0.5 mL Syringe Carton

2025

Formula

Influenza Vaccine

Fluzone®

Southern Hemisphere

Rx only

For Intramuscular Use

For 6 months of age and older

10 single-dose prefilled syringes 0.5 mL each

sanofi

Influenza Vaccine
Fluzone®

Southern Hemisphere

Rx only

2025 Formula

For Intramuscular Use

For 6 months of age and older

10 single-dose prefilled syringes 0.5 mL each

DO NOT FREEZE. Store at 2° to 8°C (35° to 46°F).
SHAKE WELL.

FOR INTRAMUSCULAR USE.

See full prescribing information for additional details.
Prepared from influenza viruses propagated in embryonated chicken eggs and inactivated with formaldehyde. A nonionic surfactant (Triton® X-100*) is added during manufacture. This vaccine has been standardized according to USPHS requirements for the 2025 influenza season and is formulated to contain 45 micrograms (mcg) hemagglutinin (HA) per 0.5 mL dose, in the recommended ratio of 15 mcg HA each, representative of the following prototype strains:
A/Victoria/4897/2022 IVR-238 (H1N1),
A/Croatia/10136RV/2023 X-425A (H3N2),
and B/Michigan/01/2021 (a B/Austria/1359417/2021-like virus, B Victoria lineage).

Contains no preservative.

Not made with natural rubber latex.

*Triton® X-100 – Registered trademark of Union Carbide, Co., USA.



925353

US Govt License #1725

Manufactured by:

Sanofi Pasteur Inc.

Swiftwater, PA 18370 USA



371

GTIN: 00949281325502

S/N
EXP
Lot

**2025
Formula**

Influenza Vaccine
Fluzone®

Southern Hemisphere

Rx only

For Intramuscular Use

For 6 months of age and older

10 single-dose prefilled syringes 0.5 mL each



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FLUZONE TRIVALENT SOUTHERN HEMISPHERE

influenza a virus a/victoria/4897/2022 ivr-238 (h1n1) antigen (formaldehyde inactivated), influenza a virus a/croatia/10136rv/2023 x-425a (h3n2) antigen (formaldehyde inactivated), and influenza b virus b/michigan/01/2021 antigen (formaldehyde inactivated) injection, suspension

Product Information

Product Type	VACCINE	Item Code (Source)	NDC:83703-080
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
INFLUENZA A VIRUS A/VICTORIA/4897/2022 IVR-238 (H1N1) ANTIGEN (FORMALDEHYDE INACTIVATED) (UNII: AU5C98U4BB) (INFLUENZA A VIRUS A/VICTORIA/4897/2022 IVR-238 (H1N1) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED) - UNII:C46XJT9FQ9)	INFLUENZA A VIRUS A/VICTORIA/4897/2022 IVR-238 (H1N1) ANTIGEN (FORMALDEHYDE INACTIVATED)	15 ug in 0.5 mL
INFLUENZA A VIRUS A/CROATIA/10136RV/2023 X-425A (H3N2) ANTIGEN (FORMALDEHYDE INACTIVATED) (UNII: HQW9FZS4YK) (INFLUENZA A VIRUS A/CROATIA/10136RV/2023 X-425A (H3N2) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED) - UNII:SD82XNG5M6)	INFLUENZA A VIRUS A/CROATIA/10136RV/2023 X-425A (H3N2) ANTIGEN (FORMALDEHYDE INACTIVATED)	15 ug in 0.5 mL
INFLUENZA B VIRUS B/MICHIGAN/01/2021 ANTIGEN (FORMALDEHYDE INACTIVATED) (UNII: FF9YP4D23C) (INFLUENZA B VIRUS B/MICHIGAN/01/2021 HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED) - UNII:CQV855H5FG)	INFLUENZA B VIRUS B/MICHIGAN/01/2021 ANTIGEN (FORMALDEHYDE INACTIVATED)	15 ug in 0.5 mL

Inactive Ingredients

Ingredient Name	Strength
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
FORMALDEHYDE (UNII: 1HG84L3525)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83703-080-50	10 in 1 PACKAGE		
1	NDC:83703-080-88	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	BLA103914	03/06/2025	

Revised: 6/2025

Bamboo US BidCo LLC