

**FLUZONE TRIVALENT NORTHERN HEMISPHERE- influenza a virus
a/victoria/4897/2022 ivr-238 (h1n1) antigen (formaldehyde inactivated),
influenza a virus a/croatia/10136/rv/2023 (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
2025-2026 Formula
Initial U.S. Approval: 1980**

PRINCIPAL DISPLAY PANEL - 0.5 mL Syringe Label

Influenza Vaccine

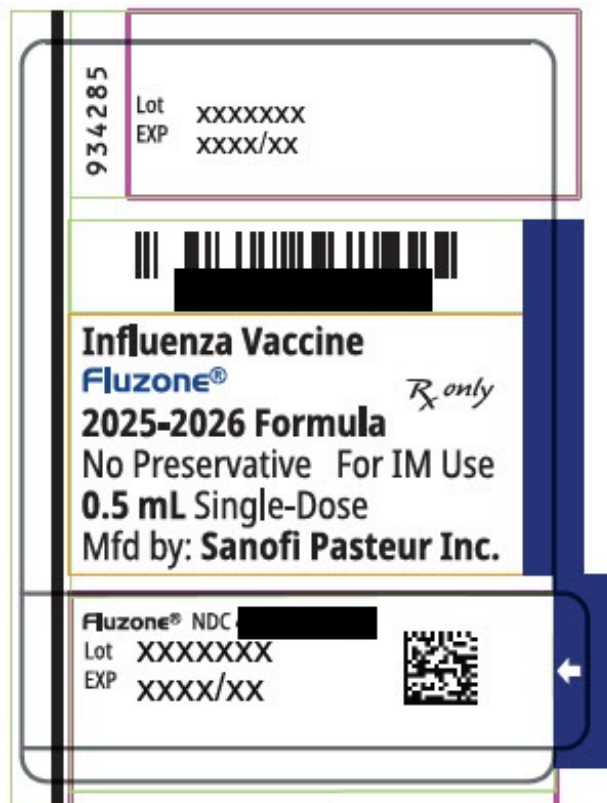
Fluzone[®]
Rx only

2025-2026 Formula

No Preservative
For IM Use

0.5 mL Single-Dose

Mfd by: Sanofi Pasteur Inc.



PRINCIPAL DISPLAY PANEL - 0.5 mL Syringe Package

2025-2026

Formula

Influenza Vaccine

Fluzone[®]

Rx only

For Intramuscular Use

For 6 months of age and older

10 single-dose prefilled syringes 0.5 mL each

sanofi

NDC

2025-2026 Formula

Influenza Vaccine
Fluzone®

For Intramuscular Use

*R_x only***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 2025-2026 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.



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US Govt License #1725
Manufactured by:
Sanofi Pasteur Inc.
Swiftwater, PA 18370 USA

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GTYN: 003482425500

Lot: XXXXXX
EXP: XX/XX/XX
N/S: XXXXXXXX**2025-2026**
Formula**Influenza Vaccine**
Fluzone®*R_x only*

For Intramuscular Use

For 6 months of age and older**10 single-dose prefilled syringes 0.5 mL each****sanofi**

FLUZONE TRIVALENT NORTHERN HEMISPHERE

influenza a virus a/victoria/4897/2022 ivr-238 (h1n1) antigen (formaldehyde inactivated), influenza a virus a/croatia/10136/rv/2023 (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:83703-083
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) HEMAGGLUTININ 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) HEMAGGLUTININ 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 HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED)	15 ug in 0.5 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83703-083-50	10 in 1 PACKAGE		
1	NDC:83703-083-88	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	07/01/2024	

Revised: 2/2026

Bamboo US BidCo LLC