FLUZONE QUADRIVALENT NORTHERN HEMISPHERE- influenza a virus a/victoria/4897/2022 ivr-238 (h1n1) antigen (formaldehyde inactivated), influenza a virus a/california/122/2022 san-022 (h3n2) antigen (formaldehyde inactivated), influenza b virus b/phuket/3073/2013 antigen (formaldehyde inactivated), and influenza b virus b/michigan/01/2021 antigen (formaldehyde inactivated) injection, suspension
Bamboo US BidCo LLC

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

Fluzone Quadrivalent (Influenza Vaccine)
Injectable Suspension, for Intramuscular Use
2024-2025 Formula
Initial U.S. Approval: 2013

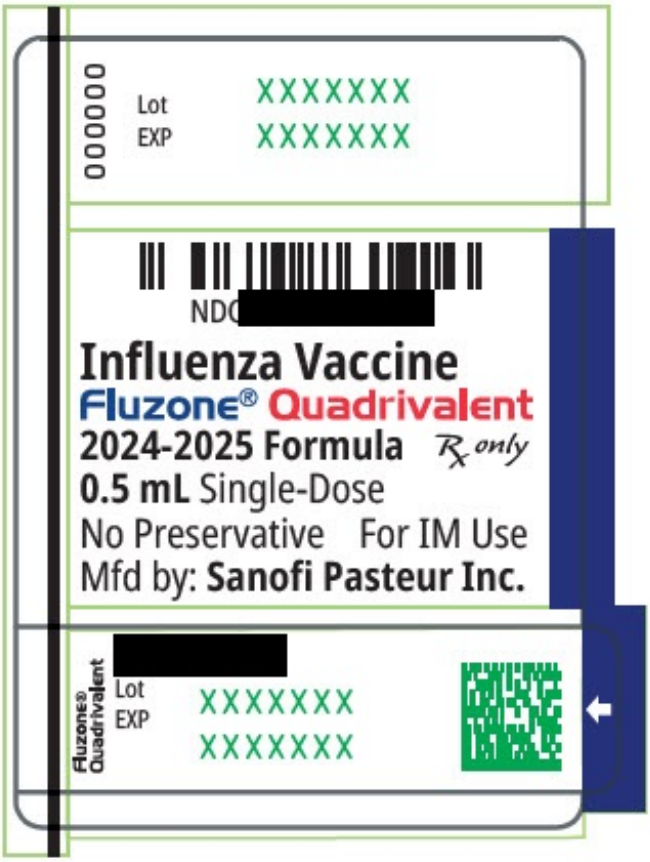
PRINCIPAL DISPLAY PANEL - 0.5 mL Syringe Label

Influenza Vaccine

Fluzone ®Quadrivalent

2024-2025 Formula
Rx only

0.5 mL Single-Dose
No Preservative
For IM Use
Mfd by: Sanofi Pasteur Inc.



PRINCIPAL DISPLAY PANEL - 0.5 mL Syringe Carton

2024-2025

Formula

Influenza Vaccine
Fluzone ®Quadrivalent

Rx only

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

sanofi

[redacted]

2024-2025 Formula

Influenza Vaccine

Fluzone® Quadrivalent

℞ only

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 2024-2025 influenza season and is formulated to contain 60 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/California/122/2022 SAN-022 (an A/Thailand/8/2022-like virus) (H3N2), B/Phuket/3073/2013 (B Yamagata lineage), 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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GTIN: 00349281924507

S/N xxxxxxxxxxxxxx

LOT xxxxxxx

EXP xxxxxxx

[redacted]

2024-2025 Formula

Influenza Vaccine

Fluzone® Quadrivalent

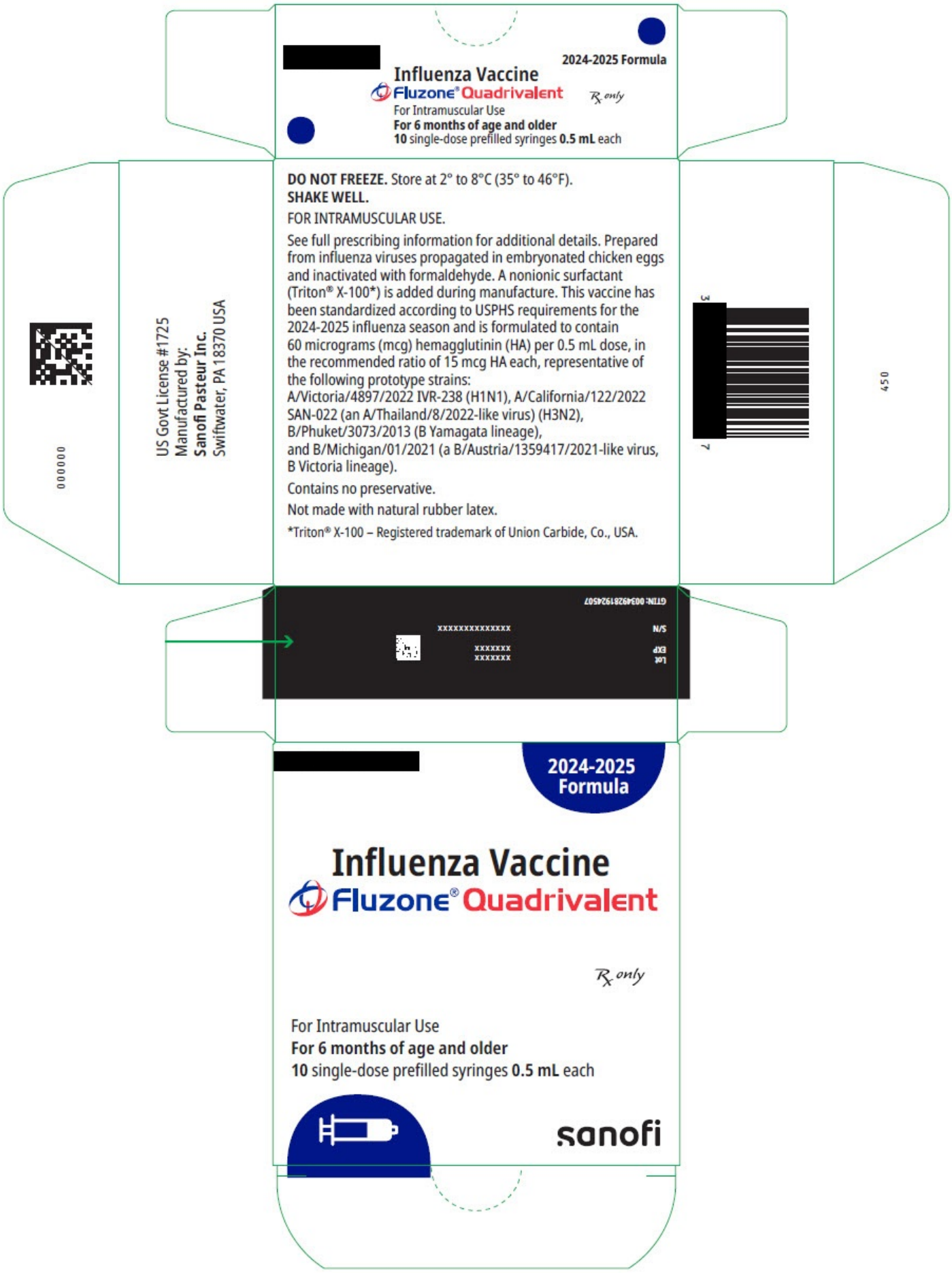
℞ only

For Intramuscular Use

For 6 months of age and older

10 single-dose prefilled syringes **0.5 mL** each

sanofi


2024-2025 Formula
Influenza Vaccine
Fluzone® Quadrivalent
℞ only
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 2024-2025 influenza season and is formulated to contain 60 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/California/122/2022 SAN-022 (an A/Thailand/8/2022-like virus) (H3N2), B/Phuket/3073/2013 (B Yamagata lineage), and B/Michigan/01/2021 (a B/Austria/1359417/2021-like virus, B Victoria lineage).
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US Govt License #1725
Manufactured by:
Sanofi Pasteur Inc.
Swiftwater, PA 18370 USA
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GTIN: 00349281924507
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2024-2025 Formula
Influenza Vaccine
Fluzone® Quadrivalent
℞ only
For Intramuscular Use
For 6 months of age and older
10 single-dose prefilled syringes 0.5 mL each
sanofi

FLUZONE QUADRIVALENT NORTHERN HEMISPHERE

influenza a virus a/victoria/4897/2022 ivr-238 (h1n1) antigen (formaldehyde inactivated), influenza a virus a/california/122/2022 san-022 (h3n2) antigen (formaldehyde inactivated), influenza b virus b/phuket/3073/2013 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:83703-079
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/CALIFORNIA/122/2022 SAN-022 (H3N2) ANTIGEN (FORMALDEHYDE INACTIVATED) (UNII: N7CB2U8HAC) (INFLUENZA A VIRUS A/CALIFORNIA/122/2022 SAN-022 (H3N2) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED) - UNII:8L9R8S52VV)	INFLUENZA A VIRUS A/CALIFORNIA/122/2022 SAN-022 (H3N2) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED)	15 ug in 0.5 mL
INFLUENZA B VIRUS B/PHUKET/3073/2013 ANTIGEN (FORMALDEHYDE INACTIVATED) (UNII: B93BQX9789) (INFLUENZA B VIRUS B/PHUKET/3073/2013 HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED) - UNII:9HB0XUS9TM)	INFLUENZA B VIRUS B/PHUKET/3073/2013 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:83703-079-50	10 in 1 PACKAGE		
1	NDC:83703-079-88	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	

Labeler - Bamboo US BidCo LLC (119087615)

Revised: 6/2025 Bamboo US BidCo LLC