

FLUZONE QUADRIVALENT NORTHERN HEMISPHERE- influenza a virus a/victoria/2570/2019 ivr-215 (h1n1) antigen (formaldehyde inactivated), influenza a virus a/darwin/9/2021 san-010 (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)
Suspension for Intramuscular Injection
2023-2024 Formula
Initial U.S. Approval (Fluzone Quadrivalent): 2013**

PRINCIPAL DISPLAY PANEL - 0.5 mL Syringe Package

2022 - 2023 Formula

10 Single-Dose
Prefilled Syringes
0.5 mL each

Rx only

4
STRAINS

Influenza Vaccine
Fluzone[®] Quadrivalent

For 6 months of age and older
For intramuscular injection only

SANOFI PASTEUR



2022 – 2023 Formula

10 Single-Dose
Prefilled Syringes
0.5 mL each



R_x only



Influenza Vaccine Fluzone® Quadrivalent

For 6 months of age and older
For intramuscular injection only

Area reserved for: Lot,
Expiry & SN

450

SANOPI PASTEUR

Influenza Vaccine Fluzone® Quadrivalent

For 6 months of age and older
For intramuscular injection only



10 Single-Dose
Prefilled Syringes
0.5 mL each

3-6087-292



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

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

FOR INTRAMUSCULAR INJECTION.

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 2022-2023 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/2570/2019 [VR-215 (H1N1)], A/Darwin/9/2021 SAN-010 (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.

PRINCIPAL DISPLAY PANEL - 10 Syringe Package

2022 - 2023 Formula

10 Single-Dose
Prefilled Syringes
0.5 mL each

Rx only

4
STRAINS

Influenza Vaccine
Fluzone[®] Quadrivalent

For 6 months of age and older
For intramuscular injection only

SANOFI PASTEUR

Influenza Vaccine

Fluzone® Quadrivalent

For 6 months of age and older
For intramuscular injection only



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 INJECTION.

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 2022-2023 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/2570/2019 (H1N1), A/Darwin/9/2021 (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.

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

0167



450 843314

7910



Area reserved for: Lot, Expiry & SN

GTIN: 0034929422508

2022 – 2023 Formula

10 Single-Dose
Prefilled Syringes
0.5 mL each

Rx only



Influenza Vaccine

Fluzone® Quadrivalent

For 6 months of age and older
For intramuscular injection only

SANOFI PASTEUR



FLUZONE QUADRIVALENT NORTHERN HEMISPHERE

influenza a virus a/victoria/2570/2019 ivr-215 (h1n1) antigen (formaldehyde inactivated), influenza a virus a/darwin/9/2021 san-010 (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:83703-044
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
INFLUENZA A VIRUS A/VICTORIA/2570/2019 IVR-215 (H1N1) ANTIGEN (FORMALDEHYDE INACTIVATED) (UNII: WD5E5VYM2E) (INFLUENZA A VIRUS A/VICTORIA/2570/2019 IVR-215 (H1N1) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED) - UNII:ERB9SJ9VMQ)	INFLUENZA A VIRUS A/VICTORIA/2570/2019 IVR-215 (H1N1) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED)	15 ug in 0.5 mL
INFLUENZA A VIRUS A/DARWIN/9/2021 SAN-010 (H3N2) ANTIGEN (FORMALDEHYDE INACTIVATED) (UNII: KJA387FHB2) (INFLUENZA A VIRUS A/DARWIN/9/2021 SAN-010 (H3N2) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED) - UNII:6S4Y8A8UEY)	INFLUENZA A VIRUS A/DARWIN/9/2021 SAN-010 (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:83703-044-50	10 in 1 PACKAGE		
1	NDC:83703-044-88	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	07/01/2022	

Labeler - Bamboo US BidCo LLC (119087615)

Revised: 6/2024

Bamboo US BidCo LLC