

**FLUZONE HIGH DOSE 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
Patheon Manufacturing Services LLC**

NDC 49281-125-65

FOR ADULTS
65+

 **Influenza Vaccine**
Fluzone® High-Dose
2025-2026 Formula
For Intramuscular Use
10 single-dose prefilled syringes 0.5 mL each

Rx only

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 180 micrograms (mcg) hemagglutinin (HA) per 0.5 mL dose, in the recommended ratio of 60 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.



934379

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



372



Lot XXXXXXXX
EXP XXXX/XX
S/N XXXXXXXX
GTIN: 00949281125652

NDC 49281-125-65

**2025-2026
Formula**

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sanofi

FLUZONE HIGH DOSE 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:63552-722
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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)	60 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)	60 ug in 0.5 mL
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)	60 ug in 0.5 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
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:63552-722-10	5 in 1 PACKAGE		
1	NDC:63552-722-05	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	09/01/2025	

Labeler - Patheon Manufacturing Services LLC (079415560)

Registrant - Patheon Manufacturing Services LLC (062331516)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Manufacturing Services LLC		062331516	analysis(63552-722) , label(63552-722) , manufacture(63552-722) , pack(63552-722)

Revised: 11/2025

Patheon Manufacturing Services LLC