Important Safety Information on
Fluzone® High-Dose Quadrivalent Influenza Vaccine –
Importation of U.S. Labelled Influenza Vaccine

SANOFI PASTEUR

2021/11/19

Audience
Health Care Professionals including family physicians, nurses and pharmacists.

Key messages

Supply of U.S. labelled Fluzone® High-Dose Quadrivalent Influenza Vaccine to the Canadian market.

- Fluzone® High-Dose Quadrivalent Influenza Vaccine 0.7 mL prefilled syringe presentation has been authorized for use in Canada under DIN 02500523.
- Fluzone® High-Dose Quadrivalent Influenza Vaccine with approved U.S. labelling will be supplied to the Canadian market for a limited time.
- The production of Fluzone® High-Dose Quadrivalent Influenza Vaccine for the United States market has been confirmed to be in line with the Canadian authorization for the same presentation.
- The Product Monograph approved by Health Canada under DIN 02500523 is available at Vaccines - Sanofi Canada.

What is the issue?
This letter is to inform health care professionals that Sanofi Pasteur Limited, in agreement with Health Canada, is supplying U.S. labelled Fluzone® High-Dose Quadrivalent Influenza Vaccine in a 0.7 mL prefilled syringe presentation to the Canadian market for a limited time, in order to meet public demand for the 2021-2022 Northern Hemisphere season.

U.S.-labelled Fluzone® High-Dose Quadrivalent Influenza Vaccine is identified on Health Canada's List of Drugs for an Urgent Public Health Need.

Products affected
Fluzone® High-Dose Quadrivalent Influenza Vaccine manufactured by Sanofi Pasteur Inc., Finished Good Lot no. UJ763AA, NDC# 49281-121-65, Expiry date 30 June 2022.

Background information
Due to a change in supply for the Canadian market during the 2021-2022 Northern Hemisphere season, U.S.-labelled and packaged Fluzone® High-Dose Quadrivalent is being supplied to meet market demand for a limited time.

Sanofi Pasteur Limited confirms the product composition licensed in the United States for Fluzone® High-Dose Quadrivalent is identical to the product composition currently authorized in Canada utilizing the same facilities, manufacturing processes and comparable quality controls for production.

Health Canada has authorized the Fluzone® High-Dose Quadrivalent 0.7 mL prefilled syringe presentation under DIN 02500523.

Fluzone® High-Dose Quadrivalent is a vaccine indicated for active immunization against influenza caused by the specific strains of influenza virus contained in the vaccine in adults 65 years of age and older.

Information for consumers
Patients should contact their health care professional for more information.

Information for health care professionals

The U.S. FDA approved United States Prescribing Information (USPI) is available only in English. Please refer to the English and French Product Monograph approved by Health Canada under DIN 02500523 available at Vaccines/Vaccins - Sanofi Canada for complete prescribing information.

The U.S.-labelled Fluzone® High-Dose Quadrivalent should be used in the same way as the Canadian authorized product. There are no changes to the storage, dosage strength or dosing requirements.

Labeling differences between U.S. FDA approved and Health Canada approved labeling for the Fluzone® High-Dose Quadrivalent syringe (inner label) and carton (outer label) for the Northern Hemisphere 2021-2022 season are as follows:

Comparison of Inner and Outer Labels		
Section	**U.S. Label**	**Canada Label**
Name	The name on the U.S. packaging is “Influenza Vaccine Fluzone® High-Dose Quadrivalent”.	The name on the Canada packaging is “Fluzone® High-Dose Quadrivalent”.
Common Name	The common name “Influenza Virus Vaccine Quadrivalent Types A and B (Split Virion)” is not present on the U.S. labels.	“Influenza Virus Vaccine Quadrivalent Types A and B (Split Virion)” is present on the Canada labels.
Medicinal Ingredient	No difference.	No difference.
Identification Code	NDC # is present on U.S. packaging as it is specific to the U.S. The Canadian DIN holder name and address are not present on the U.S. packaging.	DIN # is not present on the U.S. packaging because it is specific to Canada.
Indication Text	The U.S. package lacks the red indication text “For 65 years and older.”	Canada package includes the red indication text “For 65 years and older.”
Active Ingredients	The hemagglutinin strains are listed using a different format than the Canadian labels.	The hemagglutinin strains are listed using a different format than the U.S. labels.
Latex Statement	The U.S. labels include the statement “Not made with natural rubber Latex”.	The Canadian Product Monograph states “The container closure system for FLUZONE® High-Dose Quadrivalent does not contain latex (natural rubber). FLUZONE® High-Dose Quadrivalent is considered safe for use in persons with latex allergies.”
Language	All corresponding information in French is not present on the U.S. labels.	Information is presented in English and French.

Key labelling differences between the U.S. FDA approved United States Prescribing Information (USPI) for the 2021-2022 season and the Health Canada approved Product Monograph for the 2021-2022 season are as follows:

Comparison of Prescribing Information and Product Monograph		
Section	**U.S. Prescribing Information (USPI)**	**Canada Product Monograph (PM)**
Indications	Indications - The USPI lists the strain specificity whereas the Canada PM does not • Fluzone® High-Dose Quadrivalent is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. • Fluzone® High-Dose Quadrivalent is indicated for use in persons 65 years of age and older.	FLUZONE® High-Dose Quadrivalent vaccine is indicated for active immunization against influenza caused by the specific strains of influenza virus contained in the vaccine in adults 65 years of age and older.
Adverse Events (AEs)	Under Section 6 Adverse Reactions, all the AEs indicated in the Canada Product Monograph are listed but the USPI also includes “chills”.	Under Section 8 Adverse Reactions, the following AEs are listed: “injection site pruritis, diarrhea, nausea, flushing, arthralgia, pain in extremity and vertigo”.
Adverse Event Contact Information	Phone numbers for adverse event reporting are different: Vaccine Adverse Event Reporting System at 1-800-822-7967	 Vaccine Information Service: 1-888-621-1146.
Address	Manufacturer addresses are the same but the distributor information (Sanofi Pasteur Limited) is not listed on the USPI.	Distributor information (Sanofi Pasteur Limited) is listed.
Clinical Trial Information and Interference on Laboratory and Diagnostic Tests and Repeated Toxicity studies	USPI does not contain this information.	Canadian PM includes the trial “FIM05” and information on “Interference with Laboratory and Diagnostic Tests” and “Repeated Toxicity studies”.
Language	English only.	English and French.

Report health or safety concerns
Managing marketed health product-related adverse reactions depends on health care professionals reporting them. Any case of anaphylaxis or serious allergic reaction or other serious or unexpected side effects in patients receiving Fluzone® High-Dose Quadrivalent should be reported to Sanofi Pasteur, Health Canada, and/or your provincial or territorial local public health unit.

Sanofi Pasteur Limited
1755 Steeles Avenue West, Toronto, Ontario, Canada M2R 3T4
Tel: 1-888-621-1146

If a patient experiences a side effect following immunization, you may report any suspected adverse reactions associated with the use of Fluzone® High-Dose Quadrivalent by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Complete the Adverse Events Following Immunization (AEFI) Reporting Form (http://www.phac-aspc.gc.ca/im/aefi-form-eng.php) appropriate for your province or territory and send it to your local health department. The AEFI User Guide is available at http://www.phac-aspc.gc.ca/im/aefi_guide/index-eng.php

Sincerely,

Miggi TOMOVICI
Miggi TOMOVICI (Nov 19, 2021 16:47 EST)

Antigona Tomovici, MD
Director, Medical Affairs
Sanofi Pasteur Limited

Appendix

- U.S Labeling – Syringe and Carton (English and French)

References

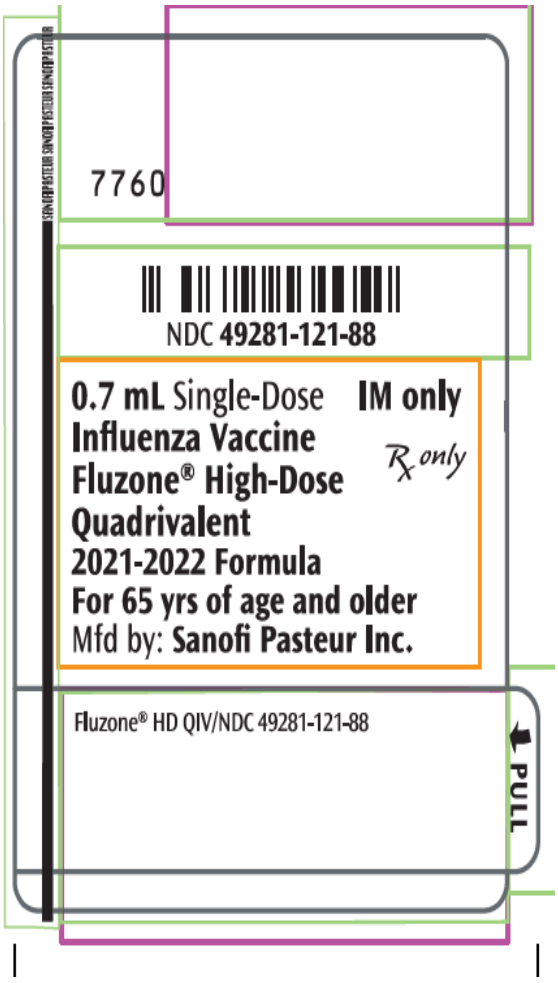
1. FLUZONE® High-Dose Quadrivalent, High-Dose Quadrivalent Influenza Virus Vaccine Types A and B (Split Virion), Suspension for Intramuscular Injection, Submission Control 251432, Product Monograph, Sanofi Pasteur. 14 APR 2021

2. Fluzone High-Dose Quadrivalent (Influenza Vaccine), Suspension, for Intramuscular Injection 2021-2022 Formula, Initial U.S. Approval: 2019, version 3

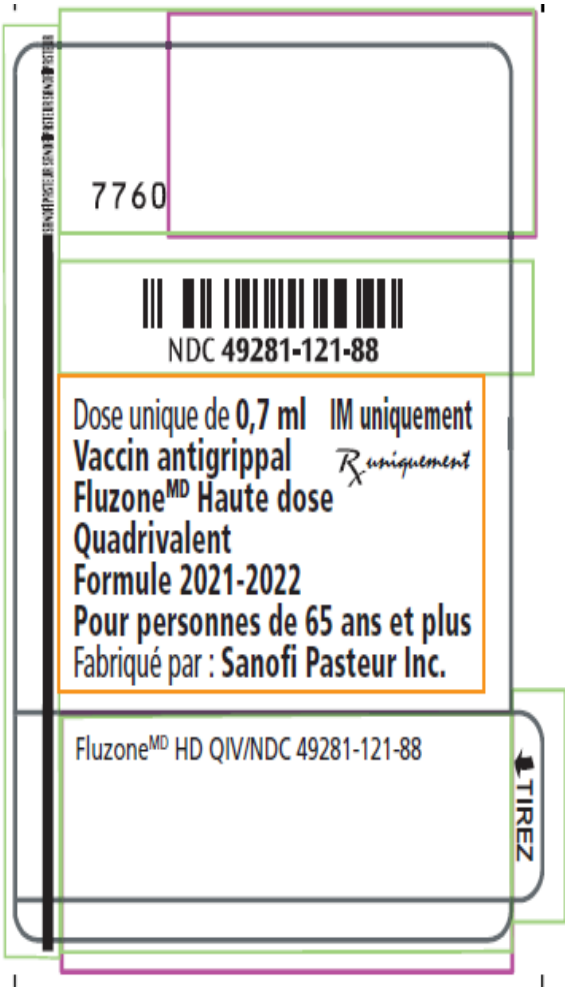
Appendix

FLUZONE® High-Dose Quadrivalent Syringe Label (NDC# 49281-121-88)

English Text

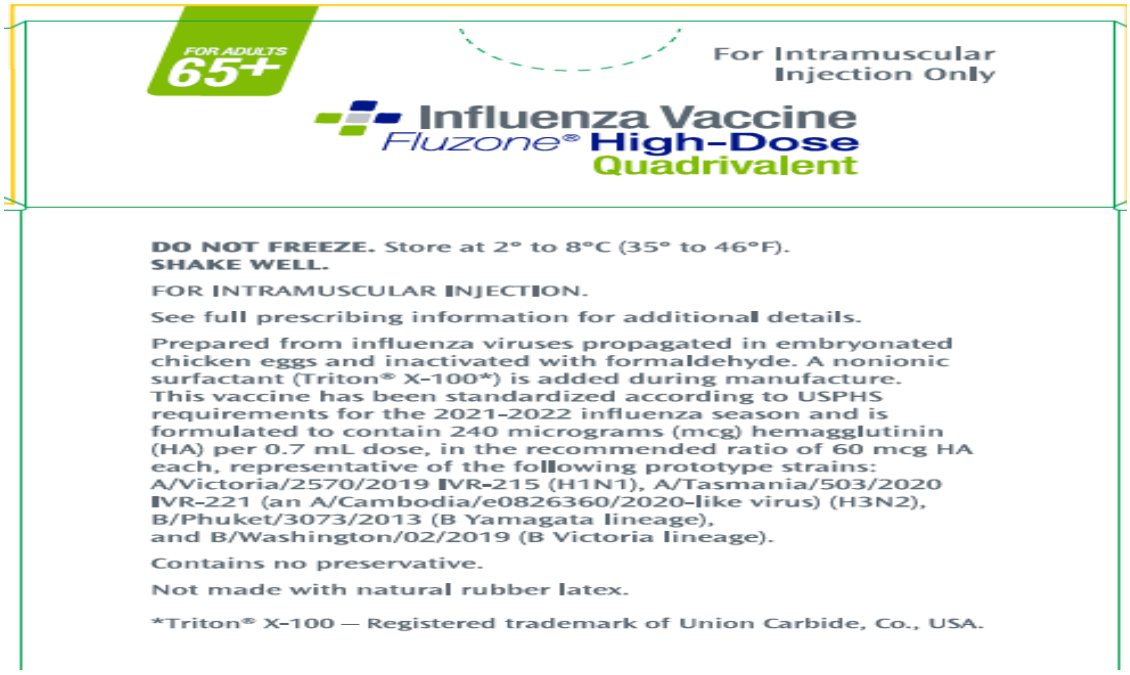


French Text

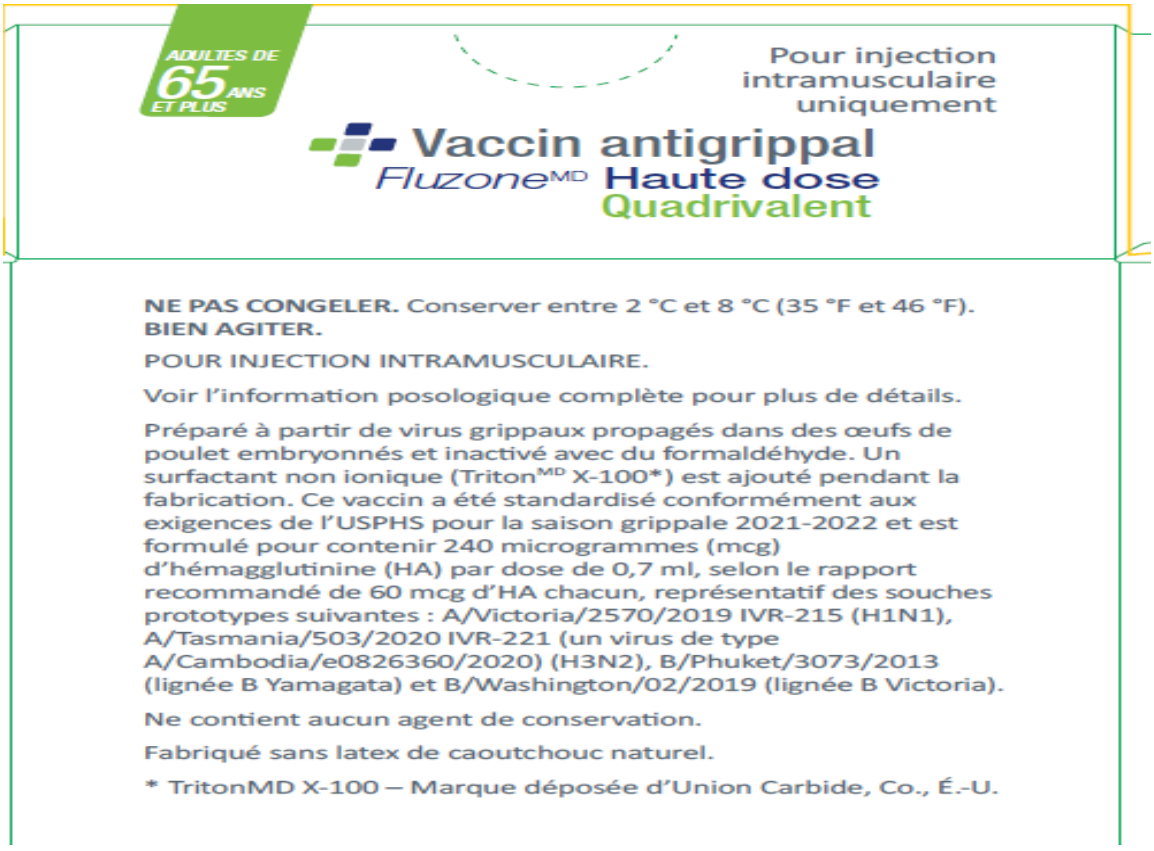


FLUZONE® High-Dose Quadrivalent Carton Label (NDC# 49281-121-88)

English Text



French Text:



Final Fluzone DHCPL ENG

Final Audit Report 2021-11-19

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