Importation of US-Labelled FLUMIST® QUADRIVALENT [Influenza Vaccine (live, attenuated)] due to Increased Demand for Influenza Vaccine

Date: November 25, 2020

Audience
Healthcare professionals including family physicians, pediatricians, pharmacists, nurses, nurse practitioners and physicians' assistants.

Key messages
There is an increased demand for influenza vaccine in Canada as a result of concerns over the co-circulation of influenza and SARS-CoV-2. As a result, AstraZeneca has been asked to supply doses of US-labelled FLUMIST® QUADRIVALENT 0.2 mL Intranasal Spray in response to the Urgent Public Health Need identified by the Chief Public Health Officer of Canada to help alleviate this demand.

Health Canada has facilitated the temporary importation of two (2) lots of US-labelled FLUMIST® QUADRIVALENT 0.2 mL Intranasal Spray, NDC 66019-307-10:

- Lot MJ3328, Expiry date 2021-Jan-06
- Lot MK2252, Expiry date 2021-Feb-04

US-labelled FLUMIST® QUADRIVALENT is identified on Health Canada's List of Drugs for an Urgent Public Health Need.

AstraZeneca confirms that US-Labelled FLUMIST® QUADRIVALENT is identical in formulation, including strain composition, to the Canadian authorized vaccine, utilizing the same facilities, manufacturing processes and comparable quality controls for production. The manufacturer, MedImmune, is a subsidiary of AstraZeneca PLC.

The US-labelled FLUMIST® QUADRIVALENT can be administered to individuals 2-59 years of age according to the Health Canada approved Product Monograph. Healthcare professionals should consult the Canadian Product Monograph available at www.astrazeneca.ca for full prescribing information.

Additional Information
The US-labelled FLUMIST® 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.

The labelling differences between the US-labelled product and the Canadian labelled product are as follows (and shown in the images and comparison table below):

- The US package label does not feature unique Canadian information such as French language, DIN, manufacturer contact information.
- The US package label does not include the following warning: FLUMIST® QUADRIVALENT should not be administered to anyone with severe allergic reactions to eggs or to egg proteins or a known allergy to any of the other vaccine components.

- The US package leaflet includes the entire US Prescribing Information and features the age of indication of 2-49 years of age and other US specific information.

Consult the Canadian Product Monograph available at www.astrazeneca.ca for full prescribing information. Additional information along with recommendations for influenza vaccination can be found in the Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2020–2021 from the National Advisory Committee on Immunization. (https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2020-2021.html)

Report health or safety concerns

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of serious or unexpected side effects in patients receiving **FLUMIST® QUADRIVALENT** should be reported as below. General questions can be directed to **AstraZeneca Canada, Inc.** and your provincial or territorial local Public Health.

AstraZeneca Canada Inc. Mississauga, Ontario L4Y 1M4

Customer Inquiries — 1 (800) 668-6000

Reporting suspected adverse event(s) following immunization:

For the general public: Should you experience a side effect following immunization, please report it to your doctor, nurse, or pharmacist.

Should you require information related to the management of the side effect, please contact your healthcare provider. The Public Health Agency of Canada, Health Canada, and AstraZeneca Canada Inc. cannot provide medical advice.

For healthcare professionals: If a patient experiences an adverse event following immunization, please complete the Adverse Events Following Immunization (AEFI) Reporting Form appropriate for your province or territory and send it to your local health department in your province or territory.

The AEFI Form, User Guide and federal/provincial/territorial (F/P/T) contact information can be found on the Public Health Agency of Canada website.

AEFI Reporting Form: http://www.phac-aspc.gc.ca/im/aefi-form-eng.php

User Guide: http://www.phac-aspc.gc.ca/im/aefi_guide/index-eng.php

Original signed by

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Vice President, Scientific Affairs

Reference

1. FLUMIST® QUADRIVALENT Influenza Vaccine Product Monograph. AstraZeneca Canada Inc. April 7, 2020.

Images and key comparisons of the US-labelled FLUMIST® QUADRIVALENT to Canadian FLUMIST® QUADRIVALENT are provided below:

	US PRODUCT LABELS	CANADIAN PRODUCT LABELS
Sprayer label	NDC 66019-307-01 Influenza Vaccine Live, Intranasal FluMist® Quadrivalent 2020-2021 For Intranasal Administration Only 0.2 mL dose (0.1 mL per nostril) MedImmune, LLC Gaithersburg, MD 20878 U.S. Govt. License No. 1799 Rx Only EXP LOT 7002954	FluMist® Quadrivalent (2020-2021) Influenza Vaccine (Live, Attenuated) Intranasal Spray Sterile AstraZeneca DIN 02426544 Prod. No 1591 401591 EXP LOT 7002979
Carton label (main panel)	NDC 66019-307-10 2020-2021 FORMULA 3 66019 30710 4 Influenza Vaccine Live, Intranasal FluMist® Quadrivalent STORE REFRIGERATED at 2°- 8°C (35°- 46°F) RX ONLY For 2-49 years of age PROTECT FROM LIGHT FOR INTRANASAL ADMINISTRATION ONLY Contents: 10 pre-filled sprayers One 0.2 mL dose each (0.1 mL per nostril) MedImmune For indications and directions, see enclosed package insert.	Prod. No 1591 DIN 02426544 FluMist® Quadrivalent (2020-2021) Influenza Vaccine (Live, Attenuated) Intranasal Spray Vaccin antigrippal (vivant, atténué) Vaporisateur intranasal 10 x 0.2 mL single-dose pre-filled sprayers 10 vaporisateurs préremplis à dose unique de 0,2 mL For ages 2 to 59 years. See Package Insert for complete dosage and administration. Pour les personnes de 2 à 59 ans. Voir la notice pour les renseignements complets sur la posologie et l'administration. Refrigerate at 2 – 8°C. Do not freeze. Protect from light. Réfrigérer entre 2 et 8 °C. Ne pas congeler. Protéger de la lumière. Sterile, Preservative-Free, Latex-Free Stérile, sans agent de conservation, exempt de latex AstraZeneca
Language	English Only	English and French
Drug description	**FluMist® Quadrivalent** 2020-2021 FORMULA RX ONLY Influenza Vaccine Live, Intranasal	**FluMist® Quadrivalent (2020-2021)** Influenza Vaccine (Live, Attenuated)
Identification Code	NDC 66019-307-10 (Carton) NDC 66019-307-01 (Sprayer Label)	DIN 02426544

	US PRODUCT LABELS	**CANADIAN PRODUCT LABELS**
Contents	10 pre-filled sprayers One 0.2 mL dose each (0.1 mL per nostril)	10 x 0.2 mL single-dose pre-filled sprayers
Method of Administration	FOR INTRANASAL ADMINISTRATION ONLY	Intranasal Spray
Storage Conditions	STORE REFRIGERATED at 2°- 8°C (35°-46°F) PROTECT FROM LIGHT	Refrigerate at 2 – 8°C. Do not freeze. Protect from light. Sterile, Preservative-Free, Latex-Free
Age for Use	**For 2-49 years of age**	**For ages 2 to 59 years.**
Directions for Use	For indications and directions, see enclosed package insert.	See Package Insert for complete dosage and administration. Warning: FluMist® Quadrivalent should not be administered to anyone with a severe allergic reaction to eggs or to egg proteins or a known allergy to any of the other vaccine components. [stated on carton back panel]
Logo	MedImmune	AstraZeneca