Merck Canada Inc.
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December 10, 2025

Importation of United Kingdom (UK) - labelled M-M-RvaxPro® (measles, mumps and rubella vaccine (live)) due to an anticipated increased demand of Canadian-authorized M-M-R® II (measles, mumps and rubella virus vaccine, live, attenuated, Merck Std.)

Dear Healthcare Professionals,

There is an anticipated increased demand of M-M-R® II (measles, mumps and rubella virus vaccine, live, attenuated, Merck Std.) in Canada. To help respond to the increased demand, Health Canada has permitted the exceptional, temporary importation and sale of MSD*'s UK-labelled M-M-RvaxPro® (measles, mumps and rubella vaccine (live)) with English labels by Merck Canada Inc. Health Canada has accepted the addition of MSD's product to the List of drugs for exceptional importation and sale.

In Canada, M-M-R® II is indicated for simultaneous vaccination against measles, mumps, and rubella in persons 12 months of age or older. For additional information on vaccination and to help control measles and mumps outbreaks, please refer to the National Advisory Committee on Immunization (NACI). The prescribing information for the UK-labelled M-M-RvaxPro® states that M-M-RvaxPro® can be administered to infants from 9 months of age under special circumstances. This does not align with the approved indication in Canada. However, the Canadian Product Monograph does include clinical trial data for this age group.

The UK-labelled M-M-RvaxPro® is equivalent to the Canadian-authorized M-M-R®II. The UK-labelled M-M-RvaxPro® can be used in the same manner as the Canadian-authorized M-M-R®II.

The UK-labelled M-M-RvaxPro®, however, differs from the Canadian-authorized M-M-R®II in the following ways:

- The UK-labelled vaccine does not have a drug identification number (DIN) or a barcode that scans in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow the product being dispensed and administered to be properly identified.
- A symbol of POM (Prescription Only Medicine) is on the UK label.

*Merck Sharp & Dohme (MSD) is the affiliate of Merck in United Kingdom.

- "Preservative Free" mention is not on the UK labelling. However, the vaccine is preservative free.
- There are differences in the expression of strength for the medicinal ingredients ($TCID_{50}$ in UK vs. $CCID_{50}$ in Canada). The mumps end-expiry potency for Canadian-labelled M-M-R®II is registered at 3.7 log $TCID_{50}$ (5 000 $TCID_{50}$) and UK-labelled M-M-RvaxPro® is 4.1 log $TCID_{50}$ (12 500 $TCID_{50}$).
- UK labels use the expiry format XX-YYYY, where XX is the two-letter month abbreviation and YYYY is the year. Canadian labels use YYYY-XX-DD, where YYYY is the year, XX is the two-letter month abbreviation and DD is the day.
- UK labels are available in English only whereas the Canadian labels are in both official languages, English and French.

The UK-labelled M-M-RvaxPro® is packaged in cartons containing one (1) vial of vaccine powder with one (1) pre-filled syringe of sterile diluent (solvent) and two (2) needles. By contrast, the Canadian-labelled product and sterile diluent are supplied in separate packages, and the Canadian sterile diluent is provided in 0.7 mL vials rather than syringes. Needles are not provided as part of the package.

Like the Canadian-authorized M-M-R®II, the UK-labelled M-M-RvaxPro® should be stored refrigerated at a temperature of 2°C to 8°C before reconstitution. After reconstitution, the vaccine should be used immediately; however, in-use stability has been demonstrated for 8 hours when refrigerated at 2 °C – 8 °C. Keep the vial of powder in the outer carton in order to protect from light.

Health care professionals should refer to the Canadian Product Monograph for M-M-R®II (measles, mumps and rubella virus vaccine, live, attenuated, Merck Std.) available in English and French at Products List | Merck Canada. The product monograph contains information on the appropriate use of the product, including the:

- indications
- contraindications
- warnings and precautions
- adverse reactions
- dosage and administration
- storage conditions
- handling instructions

Information on the imported product

Brand name	Dosage form, strength and route of administration	Product description and packaging	Country of authorization and identifying code	Authorization holder	DEL holder/ Importer in Canada
M-M-RvaxPro® (Measles, mumps and rubella vaccine (live))	After reconstitution, one dose (0.5 mL) contains: Measles virus Enders' Edmonston strain (live, attenuated): not less than $1x10^3$ $TCID_{50}$ Mumps virus Jeryl Lynn [Level B] strain (live, attenuated): not less than $12.5x10^3$ $TCID_{50}$ Rubella virus Wistar RA 27/3 strain (live, attenuated): not less than $1x10^3$ $TCID_{50}$ Route of administration: intramuscularly (IM) or subcutaneously (SC).	Powder and solvent for suspension for injection in pre-filled syringe. For reconstitution Latex-free Single-dose vial	United Kingdom (UK) PLGB 53095/0041	Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London EC2M 6UR, United Kingdom.	Merck Canada Inc.

Information about UK-labelled M-M-RvaxPro® for health care professionals is available for reference in English in the package leaflet in the individual vial carton and also available at: https://mhraproducts4853.blob.core.windows.net/docs/2724915fafb36a97b581116a2160ee76fa3741e2

Reporting adverse drug reactions

Adverse drug reactions associated with the use of UK-labelled M-M-RvaxPro®, should be reported to Merck Canada Medical Information Centre by phone at: 1-800-567-2594 ext. 2, by email at: medinfocanada@merck.com or to Health Canada or by calling toll-free at 1-866-234-2345.

Questions or concerns

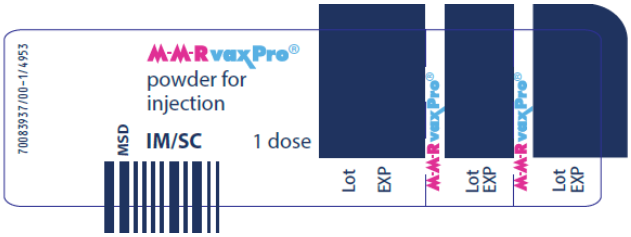
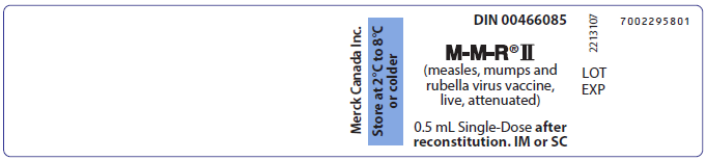
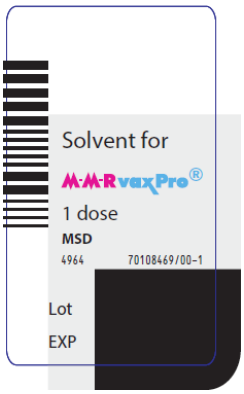
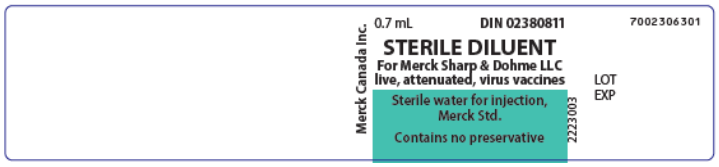
For questions or concerns about UK-labelled M-M-RvaxPro®, including inquiries about stability outside the recommended storage conditions outlined above, please contact Merck Canada Medical Information Centre by phone at: 1-800-567-2594 ext. 2 or by email at medinfocanada@merck.com.

Electronically signed by:
Gretty Deutsch
Reason: Approved
Date: Dec 10, 2025
16:22:50 EST

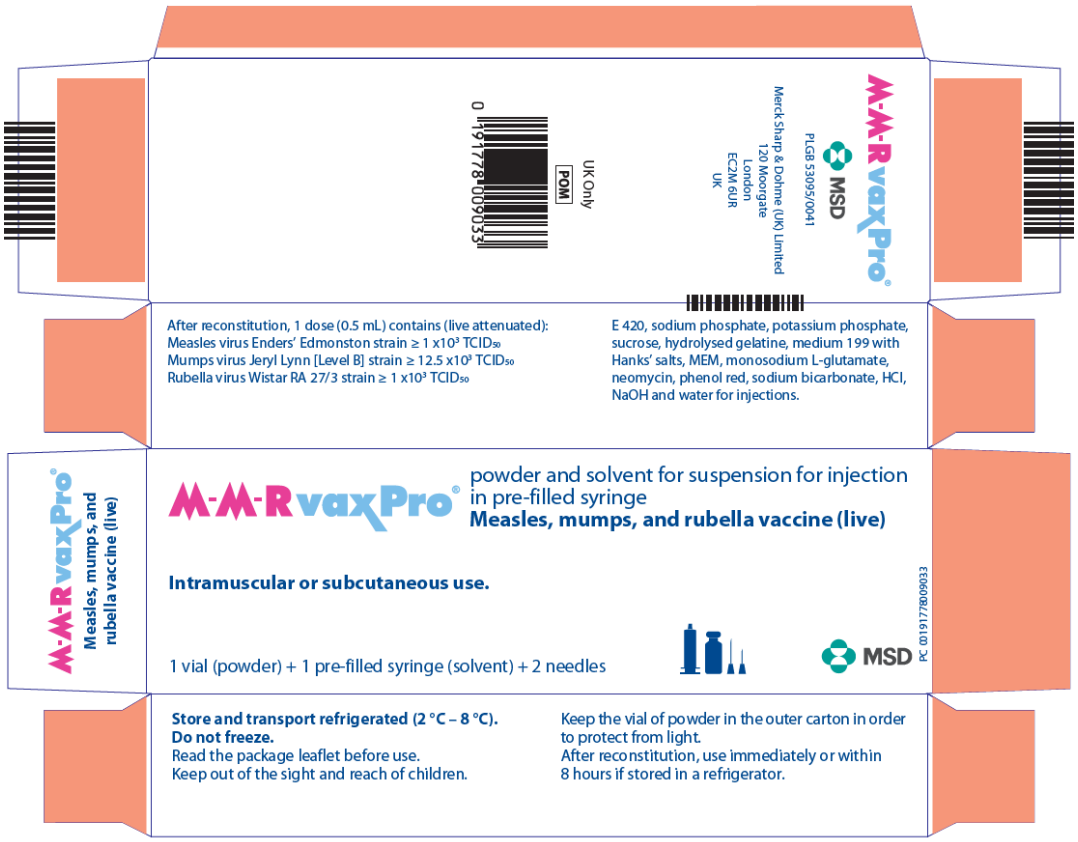
Gretty Deutsch, MD
Country Medical Director
Executive Director Medical & Scientific Affairs
Merck Canada Inc.

Appendix

Healthcare professionals are advised that aspects of the inner and outer labels and packaging of the UK-labelled M-M-RvaxPro® differ from the Canadian-authorized M-M-R®II. **Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.**

UK-LABELLED PRODUCT	CANADIAN-LABELLED PRODUCT
UK Vial Label	**Canadian Vial Label**
	
UK Diluent Label - Syringe	**Canadian Diluent Label - Vial**
	

UK Carton Label



Canadian-Carton Label