



2023/11/16

Importation of US-labelled Prostin VR Pediatric (Alprostadil Injection) due to Shortage of Canadian-labelled Alprostadil Injection

Audience

Healthcare professionals including cardiologists, critical care physicians, internists, obstetricians, gynecologists, neonatologists, pediatricians, and surgeons.

Dear Healthcare Professionals,

Key Messages

- Pfizer is experiencing a shortage of Prostin VR Sterile Solution (Alprostadil Injection) on the Canadian market due to disruption in the manufacture of the drug.
- Given the medical necessity of this product in Canada and to help mitigate the current shortage, Health Canada has permitted the exceptional, temporary importation and sale of Pfizer's US-labelled Prostin VR Pediatric and has added this product to the [List of Drugs for Exceptional Importation and Sale](#).
- The Canadian-authorized product is indicated to temporarily maintain the patency of the ductus arteriosus until corrective or palliative surgery can be performed in neonates who have congenital heart defects and who depend upon a patent ductus arteriosus for survival.
- The US-labelled product has the **same strength, volume, and formulation** as the Canadian-authorized product, but the two products **differ with respect to the administration**. The US-labelled product is labelled for intravenous route of administration, while the **Canadian product is authorized for intravenous or intra-arterial administration. However, the US-labelled product can be used and administered in the same manner as the Canadian-authorized product.**
- **Healthcare professionals should refer to the available English and French Canadian Product Monograph for Prostin VR Sterile Solution on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>) for information on appropriate use including the indications, contraindications, warnings and precautions, adverse reactions, dosage and administration, and storage conditions.**

Imported product

Product Name	Strength & Format	US NDC	Lot Number	Expiry
Prostin VR Pediatric (Alprostadil Injection, USP)	500 mcg/mL 1 mL ampoules	0009-3169-06	HD4035	11/2025

Information for healthcare professionals

Healthcare professionals should refer to the available English and French Canadian Product Monograph for Prostin VR Sterile Solution on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>) for information on appropriate use including the indications, contraindications, warnings and precautions, adverse reactions, dosage and administration, and storage conditions.

The ampoule and carton labels of the US-labelled product are in English. Images of the US-labelled product can be found in the table below along with the French-translated text of the ampoule and carton labels.

Information about US-labelled Prostin VR Pediatric for healthcare professionals is available for reference in English at https://www.pfizer.com/products/product-detail/prostin_vr_pediatric.

The US-labelled product does not have a Drug Identification Number (DIN) and the barcode may not scan in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow proper identification of the product being dispensed and administered. Proper selection of the intended product must be confirmed to avoid confusion with other products.

Report health or safety concerns

Adverse drug reactions associated with the use of Prostin VR Pediatric should be reported to Pfizer Canada ULC by calling 1-866-723-7111, through our web based portal at www.pfizersafetyreporting.com or to Health Canada directly at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> or by calling toll-free at 1-866-234-2345.

For Medical Inquiries, please contact Medical Information at 1-800-463-6001 or you can also access Medical Information via <https://www.pfizermedicalinformation.ca/en>.

For Allocation Inquiries, please contact our Allocation Specialist via email: allocation@pfizer.com, or by phone at 1-888-999-8750.

For General Inquiries, please contact our Customer Service Group at 1-800-387-4974.

Sincerely,



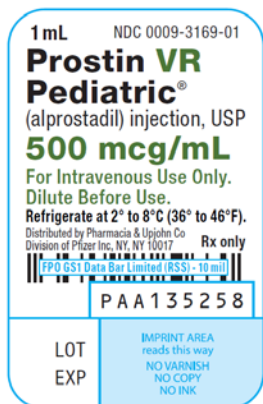
Vratislav Hadrava M.D., Ph.D.
Vice President & Medical Director
Pfizer Canada ULC

Image of the US Ampoule



US Ampoule Label

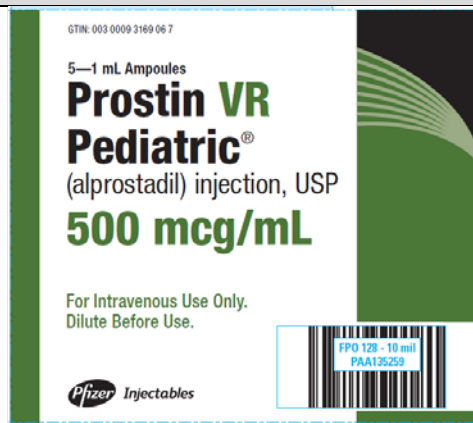
French-translation



1 mL NDC 0009-3169-01
Prostin VR Pediatric
 (alprostadil injectable, USP)
500 mcg/mL
 Réservé à l'administration intraveineuse.
 Diluer avant l'administration.
 Conserver au réfrigérateur entre 2 et 8 °C (36 et 46 °F).
 Distribué par Pharmacia & Upjohn Co
 Une division de Pfizer Inc., New York (New York) 10017
 Produit d'ordonnance

US Outer Carton Labels

French-translation



GTIN : 003 0009 3169 06 7
 5 ampoules de 1 mL
Prostin VR Pediatric®
 (alprostadil injectable, USP)
500 mcg/mL
 Réservé à l'administration intraveineuse.
 Diluer avant l'administration.
 Pfizer Injectables

Store in a refrigerator between 2° to 8°C (36° to 46°F).
 Discard any solution more than 24 hours old.
DOSAGE AND USE: See accompanying prescribing information.
 Each mL contains: 500 micrograms alprostadil in dehydrated alcohol.



Distributed by Pharmacia & Upjohn Co
 Division of Pfizer Inc
 NY, NY 10017

Conserver au réfrigérateur entre 2 et 8 °C (36 et 46 °F).
Jeter toute solution diluée depuis plus de 24 heures.
POSOLOGIE ET ADMINISTRATION : Voir les renseignements thérapeutiques ci-inclus.
 Chaque mL de cette solution contient 500 microgrammes d'alprostadil dans de l'alcool déshydraté.
 Distribué par Pharmacia & Upjohn Co
 Une division de Pfizer Inc.
 New York (New York) 10017