STERIMAX
2770 Portland Drive, Oakville, Ontario, Canada L6H 6R4
Tel.: 905-890-0661, 1-800-881-3550 ● Fax: 905-890-0508, 1-877-546-7667 ● Web: www.sterimaxinc.com

Importation of US-labelled Proleukin (Aldesleukin) for injection due to the current shortage of Canadian-authorized Proleukin

Date: 10 January 2025

Dear Healthcare professionals (oncologists, haematologists, oncology nurses and pharmacists), chief of medicines in hospitals, hospital pharmacist and cancer clinics.

There is a critical shortage of Proleukin injection, 22 million IU, DIN 02130181 in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Iovance's US-labelled Proleukin injection, 22 million IU with English only labels, by SteriMax Inc., Oakville, ON.

Health Canada has accepted the addition of Proleukin injection, 22 million IU to the List of drugs for exceptional importation and sale (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html).

In Canada, Proleukin is a prescription drug product indicated for the treatment of adults (≥18 years of age) with metastatic renal cell carcinoma (metastatic RCC) and with metastatic malignant melanoma (metastatic MM).

The US-labelled product has the **same active ingredient, strength (22 million internation units per vial (1.3mg)) and route of administration (intravenous infusion) as the Canadian marketed products**. The Package Insert / Prescribing Information for the US-labelled product, however, differs in the following ways compared to the Canadian product monograph:

- Dosing consideration for the **US-labelled Proleukin** is not based on Eastern Cooperative Oncology Group performance status (ECOG PS). Refer to the Canadian Product Monograph, section 4.1 Dosing Consideration for detailed dosing information based on ECOG PS.
- Additional course of treatment for the US-labelled Product is based on a treatment response following the last course, and the patient did not experience any adverse reactions in previous course while the Canadian product monograph indicates additional course of treatment to be given only if tumor shrinkage following the last course and retreatment is not contraindicated. Refer to the Canadian Product Monograph Section 4.2 and table-2 for more information on retreatment.
- The Package Insert / Prescribing Information for the US-labelled Proleukin does not include contraindication for retreatment in patients with an abnormal thallium stress test or abnormal pulmonary function tests. The Canadian Product Monograph includes additional information in the

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section 2 Contraindications for retreatment. Similar information can be located in the Section 2.4, Table-2 of the package insert provided with the US-labelled Proleukin.

- The Package Insert / Prescribing Information for the US-labelled Proleukin does not include below listed "Warnings and Precautions" which have been included in the Canadian Product Monograph. Refer to Section 7 of the Canadian Product Monograph for detailed "Warnings and Precautions".
  - Warning regarding risk of tumor lysis syndrome when used in combination with cis-platinum, vinblastine and dacarbazine
  - Warning regarding potential impact on CNS function, affecting patients ability to drive and operating machinery
  - Information related to risk of infections
  - Information related to hypersensitivity reactions

Healthcare professionals are advised of the following:

- **The US-labelled Proleukin can be used in the same manner as the Canadian marketed product.**

- **Healthcare professionals should refer to the Canadian Product Monograph for** Proleukin injection, DIN 02130181 **available in English and French on the Health Canada** Drug Product Database (https://health-products.canada.ca/dpd-bdpp/)**.** The Canadian Product Monographs in the database contain information on the appropriate use of the product, including the indications, contraindications, warnings and precautions, adverse reactions, dosage and administration, and storage conditions.

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Information on the imported US-labelled 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
Proleukin (Aldesleukin), 22 million IU (1.3mg) per vial	Powder for solution (Sterile) Each ml of reconstituted solution contains 18 million IU (1.1mg) Proleukin, 50mg Mannitol, 0.19mg Sodium dodecyl sulfate buffered with 0.19mg monobasic sodium phosphate and 1.12mg dibasic sodium phosphate Administration by Intravenous infusion solution.	White cake Each clear glass vial contains 1.3mg (22 million IU) of Aldesleukin. Available in cartons of 1 vial. Lot: W006127 Exp: 2027-11-30	United States NDC 73776-022-01	Iovance Biotherapeutics Manufacturing LLC., Philadelphia, PA 19112	SteriMax Inc., 2770 Portland Drive, Oakville, ON, L6H 6R4

Information about US-labelled Proleukin for healthcare professionals is available for reference in the English US Prescribing Information at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f3c516ad-d405-4fbe-af6a-962080dbfa7d.

Refer to Appendix – 01 for product image of US-labelled Proleukin.
Refer to Appendix – 02 for Inner and Outer label text for US-labelled Proleukin.

Healthcare professionals are advised that aspects of the product labels and packaging of the US-labelled product may differ from the Canadian marketed Proleukin. **Proper selection of the intended product must be verified to avoid confusion with other product and prevent medication errors.**

The US-labelled product 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.

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Reporting adverse drug reactions:

Adverse drug reactions associated with the use of US-labelled Proleukin should be reported to SteriMax or to Health Canada.

SteriMax Inc.,
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Fax: +1-877-546-7667
E-mail: pv@sterimaxinc.com

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect™ Canada's Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax.

Questions or concerns

For questions or concerns about US-labelled Proleukin, please contact SteriMax medical information team at medinfo@sterimaxinc.com OR visit SteriMax website (https://sterimaxinc.com/contact-us).

Appendices:

Appendix 01 – Product vial images of US-labelled Proleukin (Aldesleukin) for injection, Lot W006127
Appendix 02 – Inner and Outer label information for US-labelled Proleukin.
- NDC 73776-022-01: Proleukin (Aldesleukin) for injection.

Original signed by

Ritesh Acharya, M. Pharm.
Executive Vice President, Scientific Affairs
SteriMax Inc., Oakville, ON

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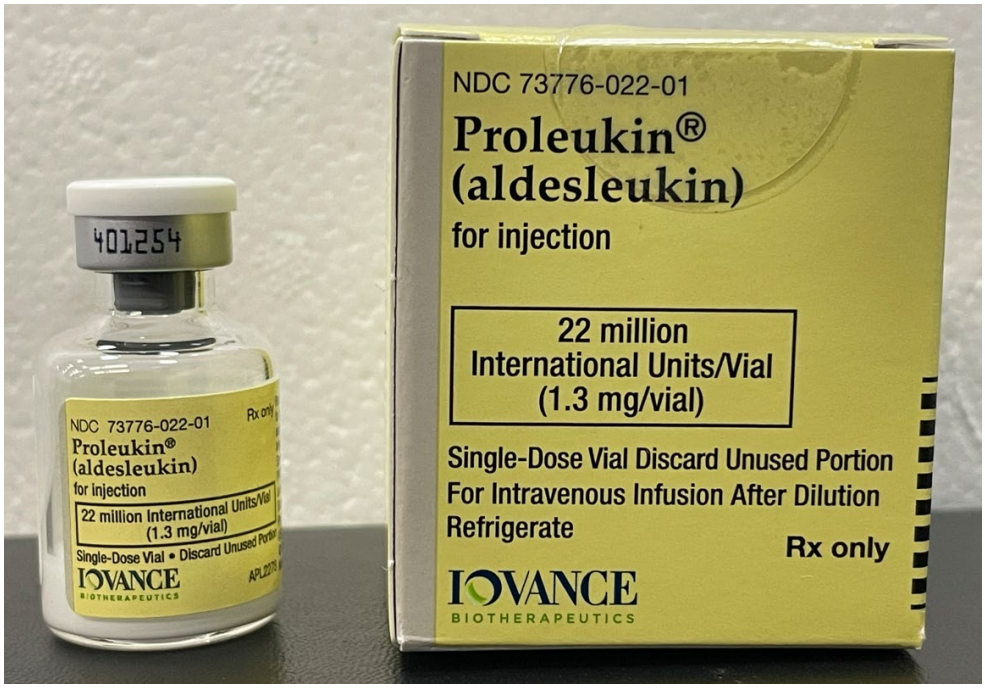
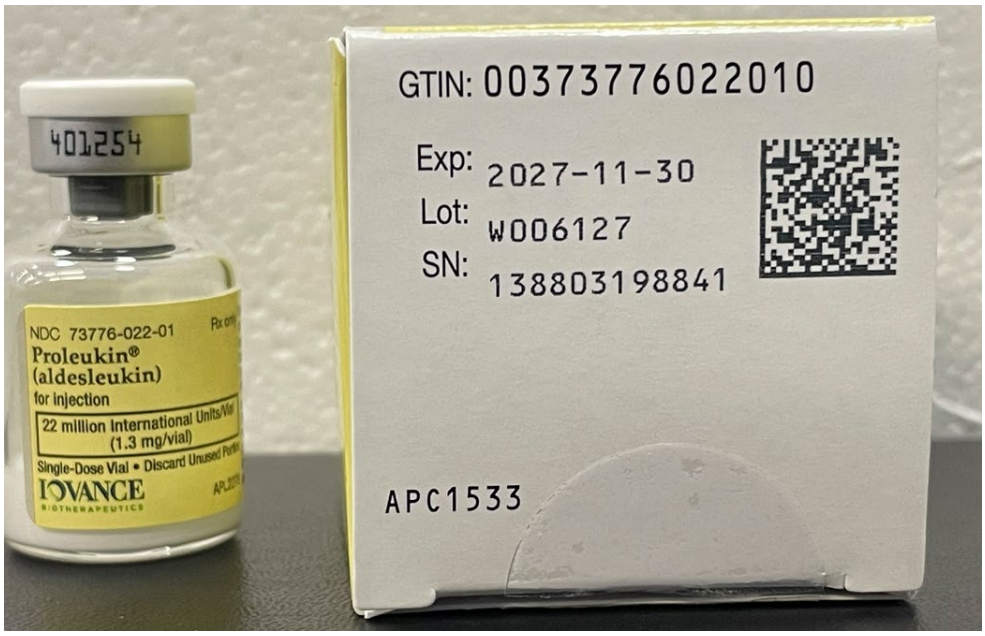
Appendix 01 – Product and vial images of US-labelled Proleukin:

Product description	Vial Image	Product image
NDC 73776-022-01: Proleukin (Aldesleukin) for injection, 22million international units / vial (1.3mg/ vial) Clear glass vial with gray rubber stopper and aluminum seal with white color flip off cap.		

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Appendix 02 – Inner and outer label information for US-labelled Proleukin:

NDC 73776-022-01: Proleukin (Aldesleukin) for injection

Inner label text (Vial label):

NDC 73776-022-01 Rx only Proleukin® (aldesleukin) for Injection 22 million International Units/Vial (1.3mg/vial) Single-Dose Vial Discard Unused Portion IOVANCE	Reconstitute with 1.2 mL Sterile Water for Injection, USP. When reconstituted, each mL contains 18 million International Units (1.1mg) Proleukin. Store in refrigerator 2° - 8°C (36° - 46°F). PROTECT FROM LIGHT. Store in carton until time of use. Mfd. By: Iovance Biotherapeutics Manufacturing LLC, Philadelphia, PA 19112 US Lic. No. 2353 © Iovance Biotherapeutics	Linear Barcode with Lot # and Expiry Details

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Outer label text (Carton):

		Proleukin® (aldesleukin) for Injection 22 million International Units/Vial (1.3mg/vial)	
NDC 73776-022-01 Rx only Proleukin® (aldesleukin) for Injection 22 million International Units/Vial (1.3mg/vial) Single-Dose Vial Discard Unused Portion For Intravenous Infusion After Dilution Refrigerate IOVANCE	Before and after reconstitution, store in a refrigerator 2° - 8°C (36° - 46°F). PROTECT FROM LIGHT. Store in carton until time of use. Use within 48 hours after reconstitution. **RECONSTITUTE WITH 1.2 mL STERILE WATER FOR INJECTION, USP. WHEN RECONSTITUTED, EACH mL CONTAINS 18 MILLION INTERNATIONAL UNITS (1.1 mg) PROLEUKIN**, mannitol (50mg), sodium dodecyl sulfate (0.19 mg), buffered with disodium hydrogen phosphate dihydrate (1.12 mg) and sodium dihydrogen phosphate dihydrate (0.19 mg) to a pH of 7.5 (range 7.2 to 7.8). Swirl gently. **DO NOT SHAKE.** Contains no preservative. Dosage: See Prescribing Information.	Proleukin should be administered only to well-informed patients in a hospital setting under the supervision of a qualified physician experienced in the use of cancer therapeutic agents. Professional assistance is available by calling toll-free: 1-844-845-IOVA (1-844-845-4682) Mfd. By: Iovance Biotherapeutics Manufacturing LLC, Philadelphia, PA 19112 US Lic. No. 2353 At: Boehringer Ingelheim Pharma, Biberach/Riss, Germany Product of Austria © Iovance Biotherapeutics	Linear Barcode
GTIN, Lot, Expiry and Serial No. information			