SERVIER CANADA INC.

Importation of US-labelled Oncaspar due to the anticipated shortage of Canadian-authorized Pegaspargase Injection

Servier Canada Inc.
3224 Jean-Beraud Avenue, suite 270
Laval, Quebec, Canada
H7T 2S4

February 14, 2023

Dear: Healthcare professionals (HCPs) including pharmacists, nurses, nurse practitioners and oncologists or any other HCP at the point of use of the treatment:

There is a critical shortage of Oncaspar (pegaspargase injection) in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Servier Pharmaceuticals LLC's US-labelled Oncaspar, with English-only labels, by Servier Canada Inc.

Health Canada has accepted the addition of Servier Pharmaceuticals LLC's product to the List of drugs for exceptional importation and sale.

In Canada, pegaspargase injection is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukaemia (ALL).

The US-labelled product has the **same** active ingredient, strength, dosage form, route of administration, product formulation and volume as the Canadian-authorized product.

When using the US-labelled Oncaspar, please refer to the Canadian product monograph, available in English and French on the Drug Product Database, for all instructions of use including:

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

Patients may be directed to the Patient Medication Information section of the product monograph for Canadian-specific product information.

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
Oncaspar	Solution for Injection/Infusion; 3750 U per 5 mL (750 U per mL) Intramuscular; Intravenous	ONCASPAR is a clear, preservative-free, colourless, sterile solution for injection/infusion. ONCASPAR is supplied in Type I glass vials containing 3,750 Units of L-asparaginase per 5 mL solution. Each carton contains one single-use vial and one package insert.	United States (NDC): 72694-954-01	Servier Pharmaceuticals LLC.	Servier Canada Inc.

Health care professionals are advised that aspects of the inner, outer labels and packaging of the US-labelled product differ from pegaspargase injection products marketed in Canada. Some important **Canadian-specific information** is absent from the package insert provided with the US version of Oncaspar. Please refer to appendix 1 for a summary of these differences. **Proper selection of the intended product must be verified to avoid confusion with other products 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. Please refer to appendix 2 for images and text of the US English-only vial and carton labels.

Reporting adverse drug reactions

Adverse drug reactions associated with the use of Oncaspar should be reported to Servier Canada Inc. For more information, please contact medical information at medical.information-ca@servier.com. or to Health Canada or by calling toll-free at 1-866-234-2345.

Questions or concerns

For questions or concerns about US-labelled Oncaspar, please contact Servier Canada Inc. or contact medical information at medical.information-ca@servier.com

Sincerely,

DocuSigned by:
Dounia Maizi
Signer Name: Dounia Maizi
Signing Reason: I approve this document
Signing Time: 14 February 2023 | 4:16:19 PM CET
B0B724A6801F48A398647B8C7147A2F5

Dounia Maizi
Director Regulatory Affairs and Compliance, Servier Canada Inc.

Appendix

Appendix 1: Summary table of important Canadian information missing from the English-only US labels for Oncaspar

Canadian information absent from the US English-only vial and carton labels	Canadian information absent from the US English-only package insert

• The Canadian DIN number assigned by Health Canada: DIN 02461900
• The fact that Oncaspar is a sterile product in the label
• The name and address of the Canadian importer (Servier Canada Inc.)
• All corresponding information in French
	• All corresponding information in French
	• For Dosage and administration: Recommended pre-medication is mentioned in the US label which is under review in Canada.
	• Information on the non-medicinal ingredients is missing in the section dosage forms and strengths and not presented in a table format.
	• The following warnings for Oncaspar:
	  ○ Central Nervous System Toxicity
	  ○ Infections (Myelosuppression)
	  ○ Information on Monitoring and measurement of L-asparaginase activity level in serum and plasma.
	  ○ Renal: May develop uric acid nephropathy
	  ○ Fertility: Men and women should use contraception during treatment and 6 months after Oncaspar discontinuation.
	  ○ Information that there is a risk of hepatotoxicity when combining imatinib for Philadelphia Chromosome-Positive patients.
	• Under Section storage and handing the US leaflet does not mention
	  ○ Discard any unused portion.
	  ○ Do not use beyond the expiration date printed on the carton or vial.
	• The US label does not have a section Patient Medication Information.

Appendix 2: English-only carton and vials for US-labelled Oncaspar

PC
EXP:DD/MMM/YYYY
LOT:
SN

NDC : 72694-954-01
Oncaspar pegaspargase injection 3750 International Units per 5mL (750 International Units per mL)

For intravenous or intermuscular use.
Single-use vial.
Discard unused portion.
RX ONLY

Dosage: See package insert for complete prescribing information.
Store at 2°C to 8°C (36-46°F). Do not freeze or shake.
Store in carton to protect from light.

ONCASPAR ® is a registered trademark of Servier IP UK Ltd, a wholly owned indirect subsidiary of Les Laboratoires Servier. Servier and the Servier logo are trademarks of Les Laboratoires Servier.
Mfd by:
Servier Pharmaceuticals LLC

Boston, MA 02210 USA
U.S. License No. 2125

ACTIVE INGREDIENTS:
Contains 6.5 mg of L-asparaginase protein
(conjugated to multiple 5k0a mPEG)sper ml.
E. coli is used in the manufacture of the product.
INACTIVE INGREDIENTS:

Oibasic SodiumPhosphate	5.58 mg
Monobasic Sooium Phosphate	1.2 mg
Sodium Chloride	8.5 mg
Water for lnjection	Q.s to 1.0 ml

No U.S. Standard of Potency
Contains no preservative

NDC : 72694-954-01

Oncaspar pegaspargase injection 3750 International Units per 5mL (750 International Units per mL)

For intravenous or intermuscular use.
Single-use vial.
Discard unused portion.

Dosage: See package insert for complete prescribing information.
Store at 2°C to 8°C (36-46°F). Do not freeze or shake.
Store in carton to protect from light.
RX only

Mfd by: Servier Pharmaceuticals LLC
Boston, MA 02210 USA
U.S. License No. 2125

LOT:

EXP: