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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 VePesid® (Etoposide Capsules, USP) due to the anticipated shortage of Canadian-authorized VEPESID (Etoposide) Capsules

Date: 22 October 2026

Dear Healthcare professionals (physicians, nurses, pharmacists), wholesalers, HealthPro and Medbuy GPO members,

There is an anticipated shortage of VEPESID (etoposide) capsules in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Amneal Pharmaceuticals LLC's US-labelled VePesid® (Etoposide Capsules, USP), and Onesource Specialty Pharma Limited's US-labelled VePesid® (Etoposide Capsules, USP) with English-only labels, by SteriMax Inc.

Health Canada has accepted the addition of VePesid® (Etoposide Capsules, USP) 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).

The US-labelled product from Amneal Pharmaceuticals LLC and Onesource Specialty Pharma Limited have the same tradename as VePesid® (Etoposide Capsules, USP), however both products have different National Drug Code (NDC) for blister packs and carton pack. Refer to the Table-1 for NDC information.

In Canada, VEPESID (etoposide) capsules, 50 mg. (DIN 00616192) is a prescription drug indicated for the treatment of small cell carcinoma of the lung, malignant lymphoma, and non-small cell carcinoma of the lung. The drug is also indicated for testicular malignancies in combination with other effective chemotherapeutic agents.

The US-labelled product has the **same active ingredient (etoposide), strength (50 mg), dosage form (capsule), and route of administration (oral) as the Canadian-authorized product**. The US-labelled product, however, **differs in the following ways**:

- **Indications:** The US-labelled product is indicated for the management of small cell lung cancer in combination with other approved chemotherapeutic agents as first line treatment.
- **Packaging:** The US-labelled product is supplied as a **blister pack of 10 capsules**. Each sale pack contains 2 blister strips of 10 capsules each.
- **Capsule Appearance:** The US-labelled product is supplied as pink capsules with the **text "V3545" printed in black on the capsule shell**.
- **Non-medicinal Ingredients:** Citric acid anhydrous, polyethylene glycol 400, glycerol anhydrous, purified water, gelatin, sorbitol liquid partially dehydrated, titanium dioxide, red iron oxide, and Glycerol 85%. The capsules are printed with black edible ink, containing isopropyl alcohol, purified water, hypromellose, propylene glycol, FD&C red #40, FD&C blue #1.
- **Storage: The US-labelled product must be stored under refrigeration, between 2°C to 8°C (36°F to 46°F), and must not be frozen.**

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Healthcare professionals are advised of the following:

- **The US-labelled product must be stored under refrigeration, between 2°C to 8°C (36°F to 46°F), and must not be frozen, in accordance with the storage instructions in the US product labelling.**
- **For all other information, including indications, contraindications, warnings and precautions, adverse reactions, and dosage and administration, healthcare professionals should refer to the Canadian Product Monograph for VEPESID (etoposide) capsules, 50 mg from CHEPLAPHARM Arzneimittel GmbH (DIN 00616192) available in English and French on the Health Canada Drug Product Database (https://health-products.canada.ca/dpd-bdpp/info?lang=eng&code=5963).**
- As there are differences in the non-medicinal ingredients between the US-labelled product and the Canadian-authorized product, and in the absence of bioavailability and bioequivalence comparisons, **patients should be closely monitored for side effects. Appropriate blood tests such as blood counts as well as renal and hepatic function tests should be conducted regularly when switching to and during the use of the US-labelled product.**
- Consistent with the dosing instructions in the Canadian Product Monograph for VEPESID (etoposide) capsules, **the recommended dose is 100 – 200 mg/m^2 daily for 5 days.** Daily doses greater than 200 mg should be divided and given twice daily.
- Healthcare professionals responsible for dispensing of the US-labelled product are advised to **counsel patients of the differences in packaging, capsule appearance, and storage conditions between the US-labelled product and the Canadian-authorized product, and that the US-labelled product must be stored under refrigeration, between 2°C to 8°C (36°F to 46°F), and must not be frozen.**

Table-1: Information on the imported product

Brand name	Dosage form, strength and route of administration	Product description and packaging	Country of authorization and identifying code	Foreign authorization holder	Importer in Canada
VePesid® (Etoposide Capsules, USP)	Capsule, 50 mg, Oral	Pink soft gelatin capsules with “V3545” printed in black edible ink. Available in a blister pack of 10 capsules. Each sale pack contains 2 blister strips of 10 capsules each.	United States NDC (Blister pack) 69238-2811-1 NDC (Carton pack) 69238-2811-2	Amneal Pharmaceuticals LLC.	SteriMax Inc., 2770 Portland Drive, Oakville, ON, L6H 6R4
			United States NDC (Blister pack) 83270-451-02 NDC (Carton pack) 83270-451-05	Onesource Specialty Pharma Limited	

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Additional information about US-labelled VePesid® (Etoposide Capsules, USP) for healthcare professionals is available for reference in the English US Prescribing Information at:

Amneal Pharma Product (NDC 69238-2811-2):
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2a40f3ed-4a36-4616-af6c-b616140fd5ee

Onesource Specialty Pharma Limited Product (NDC 83270-451-05)
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7bc994df-ee84-4ed7-80fa-737f70918953

Images of the US-labelled product can be found in the Appendix.

Healthcare professionals are advised that the carton and blister labels and packaging of the US-labelled product differ from the Canadian-authorized VEPESID (etoposide) capsules. **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 barcode sticker may be required to enable barcode scanning and allow the product being dispensed and administered to be properly identified.

Reporting adverse drug reactions

Adverse drug reactions associated with the use of US-labelled VePesid® (Etoposide Capsules, USP, 50 mg) should be reported to SteriMax Inc. or to Health Canada:

SteriMax Inc., 2770, Portland Drive, Oakville, ON, L6H 6R4
Phone: +1-800-881-3550
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 VePesid® (Etoposide Capsules, USP, 50 mg), please contact SteriMax Inc. at medinfo@sterimaxinc.com OR visit the SteriMax website (https://www.sterimaxinc.com/contact)

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Appendices:

- Appendix 01 – Product and blister images of US-labelled VePesid® (Etoposide Capsules, USP, 50 mg)
- Appendix 02 – Images of the US blister back foil and carton labels: NDC 69238-2811-2: US-labelled VePesid® (Etoposide Capsules, USP, 50 mg) (Amneal Pharmaceuticals LLC.)
- Appendix 03 – Images of the US blister back foil and carton labels: NDC 83270-451-05: US-labelled VePesid® (Etoposide Capsules, USP, 50 mg) (Onesource Specialty Pharma Limited)

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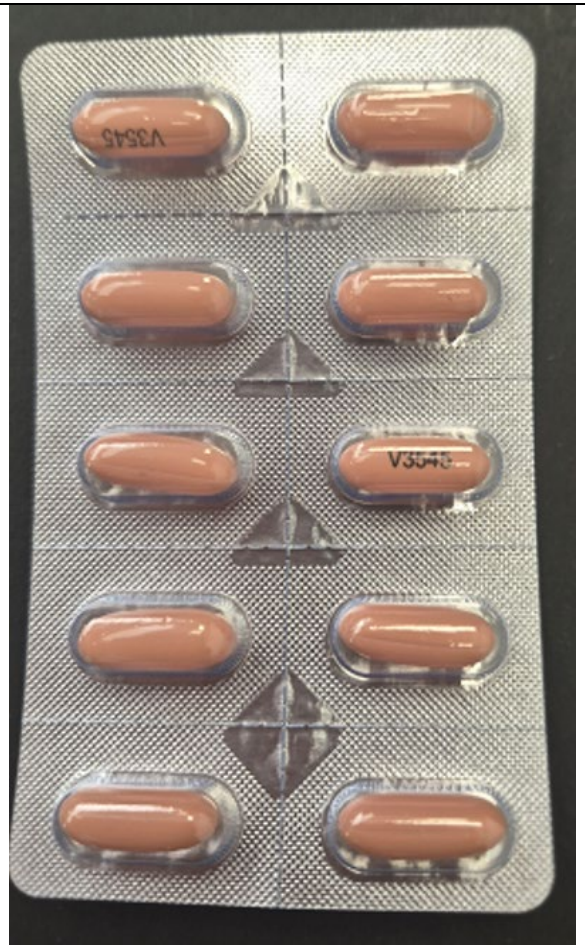
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Ritesh Acharya, M. Pharm.
Chief Scientific Officer, SteriMax Inc., Oakville, ON

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Appendix 01 – Product and blister images of US-labelled VePesid® (Etoposide Capsules, USP, 50 mg):

Product description	Foreign authorization holder and NDC	Product image	Blister image
VePesid® (Etoposide Capsules, USP, 50 mg) Pink soft gelatin capsules imprinted with “V3545” in black ink.	**Amneal Pharmaceuticals LLC.** **Blister pack:** NDC 69238-2811-1 **Carton pack:** NDC 69238-2811-2		
	Onesource Specialty Pharma Limited **Blister pack:** NDC 83270-451-02 **Carton pack:** NDC 83270-451-05		

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Appendix 02 – Images of the US blister back foil and carton labels: Amneal Pharmaceuticals LLC.

NDC 69238-2811-1: Blister back foil:
VePesid® (Etoposide Capsules, USP, 50 mg)



NDC 69238-2811-2: Product carton pack : VePesid® (Etoposide Capsules, USP, 50 mg)



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Appendix 03 – Images of the US blister back foil and carton labels: Onesource Specialty Pharma Limited

NDC 83270-451-02: Blister back foil
VePesid® (Etoposide Capsules, USP, 50 mg)



NDC 83270-451-05: Product carton pack : VePesid® (Etoposide Capsules, USP, 50 mg)

