



Importation of UK-authorized Lomustine capsules, 40 mg due to the anticipated critical shortage of Canadian-authorized CeeNU (lomustine) capsules, 40 mg

Septa Pharmaceuticals Inc.
7035 Maxwell Road, Unit 2
Mississauga, ON
L5S 1R5

Oct 30, 2025

Dear: Group purchasing organizations, wholesalers, healthcare professional associations, and hospital pharmacists or pharmacies.

There is an anticipated critical shortage of CeeNU (lomustine) capsules, 40 mg in Canada due to its discontinuation at the end of November 2025. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of UK-authorized Lomustine capsules, 40 mg, with English only labels, by Septa Pharmaceuticals Inc.

Health Canada has accepted the addition of UK-authorized Lomustine 40 mg (Lomustine) capsules, 40 mg product to the [List of Drugs for Exceptional Importation and Sale \(https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html).

In Canada, CeeNU (lomustine; capsules 10 mg and 40 mg) is indicated for the treatment of:

- Brain tumours – both primary and metastatic, in patients who have already received appropriate surgical and/or radiotherapeutic procedures.
- Hodgkin's disease – as a secondary therapy, alone or in combination with other active drugs.
- Other tumours – in combination with other therapeutic agents in lung cancer (squamous cell, anaplastic large cell, and adenocarcinoma), malignant melanoma and breast cancer (advanced disease) only after other conventional methods have failed.

The UK-authorized product has the **same active ingredient (lomustine), strength (40 mg), dosage form (capsule), and route of administration (oral)** as the Canadian-authorized product. The products, however, **differ in brand name, capsule appearance, and non-medicinal ingredients (see table below), as well as a contraindication linked to the differences in non-medicinal ingredients.** In addition, clinicians should be aware that **bioequivalence between the Canadian-authorized drug product and the UK-authorized drug product has not been demonstrated**, which could potentially impact efficacy and the occurrence of adverse effects.

Differences Between the UK-authorized and Canadian-authorized Drug Products

Features	UK-Authorized Product	Canadian-Authorized Product
Brand Name	Registered brand name: Lomustine 40 mg Labelled as: Lomustine 40 mg	CeeNU (lomustine) capsules
40 mg Capsule Appearance	Hard gelatin capsules with blue cap and body	White cap and moss green body, and are imprinted in black ink, parallel to the longitudinal axis of the capsule with "CPL" over

		"3031" on the cap and "40MG" on the body of the capsule.
Non-Medicinal Ingredients	<p><i>Capsule contents: lactose (anhydrous), wheat starch, talc, magnesium stearate.</i></p> <p><i>Capsule shell: gelatine, indigo carmine E132 and titanium dioxide E171</i></p>	<i>All capsules contain mannitol and magnesium stearate as inert ingredients.</i>

Healthcare professionals are advised of the following:

- Lomustine has low aqueous solubility, which makes any variation between different drug product formulations more likely to affect bioavailability, absorption rate, and resulting effectiveness of the drug. Furthermore, lomustine is highly toxic, and interchangeability between lomustine based products would normally require careful bioequivalence assessment. The UK-authorized Lomustine capsules, 40 mg formulation and its bioequivalence to the Canadian-authorized CeeNU (lomustine) capsules, 40 mg has not been assessed. Interchangeability between the CeeNU (lomustine) capsules, 40 mg and the UK-authorized Lomustine capsules, 40 mg may represent a risk due to the above stated reasons. **Healthcare providers are advised to enhance their monitoring of the safety and effectiveness for the imported formulation for the intended disease condition. Careful follow-up and potential blood test monitoring must be undertaken during the product switch.**
- Pharmacists are advised to inform patients of the differences in brand name and capsule appearance between the UK-authorized product and Canadian-authorized drug product and that the UK-authorized product should be used in the same manner as the Canadian-authorized product.**
- The UK-authorized Lomustine capsules, 40 mg contains clinically relevant non-medicinal ingredients (i.e., **lactose, wheat starch**, talc, colorant) - the **UK-authorized Lomustine is contraindicated in patients with a wheat allergy**. Moreover, patients with sensitivity to wheat or lactose should be aware that the UK-authorized Lomustine contains these non-medicinal ingredients.
- Healthcare professionals should refer to the Canadian Product Monograph for CeeNU (lomustine) capsules, 40 mg from Bristol-Myers Squibb Canada available in [English](#) and [French](#) on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/>) for information on the appropriate use of the product, including the:**

 - indications
 - contraindications (with an additional contraindication for patients with a wheat allergy)
 - warnings and precautions
 - adverse reactions
 - dosage and administration
 - storage conditions

- handling instructions

Information on the imported product

Brand name	Dosage form and route of administration	Product description and packaging	Country of authorization and identifying code	Foreign authorization holder	Importer in Canada
Lomustine, 40 mg	Capsules Oral	Lomustine capsules, 40 mg is gelatin coated and are available in individual bottles of 20 capsules each	UK PL 11587/0003	medac Gesellschaft für klinische Spezialpräparate mbH	Septa Pharmaceuticals Inc.

Healthcare professionals are advised that aspects of the bottle and carton labels and packaging of the UK-authorized product may differ from marketed Bristol-Myers Squibb products in Canada. **Proper selection of the intended product must be confirmed to avoid confusion with other products and prevent medication errors.**

The UK-authorized product does not have a Drug Identification Number or a barcode that scans 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.

Additional information about UK-authorized Lomustine capsules, 40 mg for reference by healthcare professionals is available in English only at <https://www.medicines.org.uk/emc/product/1401/smpc>

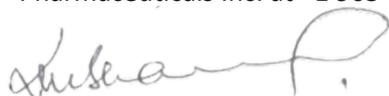
Images of the UK-authorized product can be found in the Appendix.

Reporting adverse drug reactions

Adverse drug reactions associated with the use of UK-authorized Lomustine capsules, 40 mg should be reported to Septa Pharmaceuticals Inc. by calling +1 905-564-5665, or to [Health Canada](#) 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.

Questions or concerns

For questions or concerns about UK-authorized Lomustine capsules, 40 mg, please contact Septa Pharmaceuticals Inc. at +1 905-564-5665.



Original signed by

Devinder Kumar

President & CEO

Septa Pharmaceuticals Inc.

Appendix

UK-authorized Lomustine) capsules, 40 mg Labels:

UK-authorized Lomustine) capsules, 40 mg Outer carton label:

Lomustine 40 mg
Lomustine
POM
UK only

Lomustine 40 mg
Lomustine

Each capsule contains 40 mg of lomustine.

Excipients: lactose and wheat starch.
See package leaflet for further information.

To be used as directed by the physician.

Store below 25°C

Store in the original container in
Order to protect from light and
moisture.

PL 00287/0003

Lomustine 40 mg

Lomustine

20 capsules

Cytotoxic

medac GmbH
Theaterstr. 6
22880 Wedel
Germany

Lomustine 40 mg

Lomustine

Caution!

Contact with, or inhalation of the
contents of a damaged capsule
should be avoided

Lomustine is inactivated by
20% ammonium hydroxide/
Ethanol (96%) 1 : 10.

If lomustine comes into contact
with the skin or mucous
membranes rinse thoroughly
with large quantities of water.

Read the package leaflet
before use.

Keep out of the sight and reach
of children.

UK-authorized Lomustine) capsules, 40 mg Inner bottle label:



Lot
EXP

Lomustine

40 mg

Lomustine

POM

20 capsules

PL 11587/0003

medac GmbH – Theaterstr. 6

22880 Wedel – Germany

Each capsule contains 40 mg lomustine. Excipients: lactose and wheat starch. Read the package leaflet before use. To be used as directed by the physician. Store below 25 °C. Store in the original container in order to protect from light and moisture. Keep out of the sight and reach of children.

Caution! Contact with, or inhalation of the contents of a damaged capsule should be avoided. Lomustine is inactivated by 25 % ammonium hydroxide/ethanol (96 %) 1 : 10. If lomustine comes into contact with the skin or mucous membranes rinse thoroughly with large quantities of water.

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UK-authorized Lomustine Capsules, 40 mg:

Lomustine Capsules, 40 mg:

