



**Importation of USA-authorized Gleostine (lomustine) capsules, 10 mg and 40 mg due to the anticipated critical shortage of Canadian-authorized CeeNU (lomustine) capsules, 10 mg and 40 mg**

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

April 08, 2025

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

There is an anticipated critical shortage of CeeNU (lomustine) capsules, 10 mg and 40 mg in Canada due to its upcoming discontinuation at the end of March 2025. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of USA-authorized Gleostine (lomustine) capsules, 10 mg and 40 mg, with English only labels, by Septa Pharmaceuticals Inc.

Health Canada has accepted the addition of USA-authorized Gleostine (lomustine) capsules, 10 mg and 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 are 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 USA-authorized product has the **same active ingredient (lomustine), strength (10 mg and 40 mg), dosage form (capsule), and route of administration (oral)** as the Canadian-authorized product. The product, however, **differs in brand name, pack size, and capsule appearance**.

**Differences Between USA-Authorized and Canadian-Authorized Products**

Features	USA-Authorized Product	Canadian-Authorized Product
<b>Brand Name</b>	Gleostine (lomustine) capsules	CeeNU (lomustine) capsules
<b>Pack Size</b>	5 capsules per bottle	20 capsules per bottle
<b>10 mg Capsule Appearance</b>	White cap and body, and are imprinted in black ink, parallel to the longitudinal axis of the capsule with "CPL" over "3030" on the cap and "10mg" on the body of the capsule. Size is 16mm.	White cap and body, and are imprinted in black ink, parallel to the longitudinal axis of the capsule with "CPL" over "3030" on the cap and "10MG" on the body of the capsule.
<b>40 Mg Capsule Appearance</b>	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. Size	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

	is 18mm.	the capsule.
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Pharmacists are advised to inform patients of the differences in brand name, and capsule appearance between the USA-authorized product and Canadian-authorized drug product and that the USA-authorized product should be used in the same manner as the Canadian-authorized product. Healthcare professionals should refer to the Canadian Product Monograph for CeeNU (lomustine) capsules, 10 mg and 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
- 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	Authorization holder	DEL holder/Importer in Canada
Gleostine (lomustine) capsules, 10 mg	Capsules Oral	Gleostine 10 mg capsules are gelatin coated and are available in individual bottles of 5 capsules each	USA NDC: 58181-3040-05	NextSource Biotechnology, LLC, USA*	Septa Pharmaceuticals Inc.
Gleostine (lomustine) capsules, 40 mg	Capsules Oral	Gleostine 40 mg capsules are gelatin coated and are available in individual bottles of 5 capsules each	USA NDC: 58181-3041-05	NextSource Biotechnology, LLC, USA*	Septa Pharmaceuticals Inc.

\* NextSource Pharma is DBA as NextSource Biotechnology, LLC.

Healthcare professionals are advised that aspects of the inner and outer labels and packaging of the USA-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 USA-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 USA-authorized Gleostine (lomustine) capsules, 10 mg and 40 mg for reference by healthcare professionals is available in English only at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7f77526b-4c40-409c-82ea-d0f934d89cc2>

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

#### **Reporting adverse drug reactions**

Adverse drug reactions associated with the use of USA-authorized Gleostine (lomustine) capsules, 10 mg and 40 mg should be reported to Septa Pharmaceuticals Inc. by calling +1 905-564-5665, or to [Health Canada](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) 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 USA-authorized Gleostine (lomustine) capsules, 10 mg and 40 mg, please contact Septa Pharmaceuticals Inc. at +1 905-564-5665.

A handwritten signature in black ink, appearing to read "Devinder Kumar", with a large, stylized flourish at the end.

**Original signed by**

Devinder Kumar

President & CEO

Septa Pharmaceuticals Inc.

## Appendix

USA-authorized Gleostine (lomustine) capsules, 10 mg and 40 mg Labels:

### Gleostine (lomustine) Capsules, 10 mg Labels:

#### Outer Carton Label:



#### Inner Pack Label:



**Caution: Cytotoxic Agent**  
**Wear gloves at all times when**  
**Handling containers and**  
**Capsules.**

**Usual Dosage:**  
**Adults: 130 mg/m<sup>2</sup> every 6 weeks**

**See Package Insert**  
Store at 25°C (77°F); excursions  
Permitted to 15°C to 30°C (59°F to 86°F)  
Avoid excessive heat (over 40°C, 104°F).  
Dispense in tight Containers. Protect  
from Light.

NDC 58181-3040-5

## 5 Capsules

Gleostine®  
(Iomustine) Capsules  
10 mg per Capsule

**Caution: DO NOT DISPENSE ENTIRE**  
**CONTAINER.**  
**Dispense only enough capsules for one dose.**

NEXTSOURCE  
PHARMA

Rx Only

Manufactured by Latina Pharma S.p.A.,  
Sermoneta (LT), Italy for:  
NextSource Pharma  
Pompano Beach, FL 33069 USA

3001077A2

N3 58181 3040 5 0

Lot:

Exp:

## Gleostine (Iomustine) Capsules, 40 mg Labels

### Outer Carton Label:



### Inner Pack Label:



**Caution: Cytotoxic Agent**

**Wear gloves at all times when handling  
containers and capsules.**

**Usual Dosage:**

**Adults: 130 mg/m<sup>2</sup> every 6 weeks**

**See Package Insert**

Store at 25°C (77°F); excursions

Permitted to 15°C to 30°C (59°F to 86°F)

Avoid excessive heat (over 40°C, 104°F).

Dispense in tight Containers. Protect  
from Light.

NDC 58181-3041-5

## 5 Capsules

Gleostine®

(Iomustine) Capsules

40 mg per Capsule

**Caution: DO NOT DISPENSE ENTIRE  
CONTAINER.**

**Dispense only enough capsules for one dose.**

NEXTSOURCE

PHARMA

Rx Only

Manufactured by Latina Pharma S.p.A.,

Sermoneta (LT), Italy for:

NextSource Pharma

Pompano Beach, FL 33069 USA

3001079A2

N3 58181 3041 5 9

Lot:

Exp:

USA-authorized Gleostine (lomustine) Capsules, 10 mg and 40 mg:

**Gleostine (lomustine) Capsules, 10 mg:**



**Gleostine (lomustine) Capsules, 40 mg:**

