



ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD

ABN: 20 605 457 430

www.propg.com.au

Dear Healthcare Professional,

Discontinuation of CEENU lomustine 10mg capsule bottle (AUST R: 19252)

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of CEENU lomustine 10mg capsule bottle (AUST R: 19252) in Australia.

The Australian registered medicine, CEENU lomustine 10mg capsule bottle (AUST R: 19252) sponsored by Bristol-Myers Squibb Australia Pty Ltd is expected to be discontinued on 30 June 2024.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **GLEOSTINE (lomustine) 10mg capsules (USA)**. This product is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until **30th June 2026** for the following indication(s):

Lomustine may be used for the treatment of:

- 1. Brain tumours (primary and secondary)*
- 2. Hodgkin's disease (as secondary therapy).*

Lomustine is used in addition to appropriate surgical and/or radiotherapeutic procedures or as a component of various chemotherapeutic regimens in the palliative treatment of primary and metastatic brain tumours. Lomustine containing combinations should be used as alternative therapy in the treatment of disseminated Hodgkin's disease in patients refractory to other established treatment regimens.

GLEOSTINE (lomustine) 10mg capsules (USA) is registered and marketed in USA by NextSource Biotechnology, LLC. The medicine is identical in formulation to CEENU lomustine 10mg capsule bottle (AUST R: 19252).

It is important to note that the Australian registered CEENU lomustine 10mg capsule bottle (AUST R: 19252) came in bottles of 20 capsules, whereas the S19A product **GLEOSTINE (lomustine) 10mg capsules (USA)** comes in **bottles of 5 capsules**.

Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing for various indications, available at: <https://www.ebs.tga.gov.au/>

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **GLEOSTINE (lomustine) 10mg capsules (USA)** must be reported by healthcare professionals, pharmacists, and patients to the TGA at <https://www.tga.gov.au/reporting-problems> or to Pro Pharmaceuticals Group on 1300077674 or email regulatory@propg.com.au

Any product complaints with **GLEOSTINE (lomustine) 10mg capsules (USA)** should be reported to Pro Pharmaceuticals Group on 1300 077674 or email regulatory@propg.com.au

For any orders please contact Pro Pharmaceuticals Group on 1300077674 or email orders@propg.com.au

Please forward this information to relevant staff members in your organisation.

For further information, please contact Pro Pharmaceuticals Group on 1300077674 or email info@propg.com.au

Sincerely,

Sandip Manku – Director Pro Pharmaceuticals Group