

4 March 2022



**RE: Shortage of CeeNU lomustine 40mg capsules and alternative supply arrangement under Section 19A of the Therapeutic Goods Act.**

PO Box 718  
Mona Vale  
NSW 1660  
Australia

Dear Healthcare Professional,

+61 2 8401 9777  
+61 2 8401 9788  
info@linkhealthcare.com.au

This notification is sent by LINK to inform your organisation that due to the shortage of Australian registered **CeeNU lomustine 40mg capsules (Aust R 19249)**, LINK has arranged the supply of an alternative product, **Cecenu lomustine 40mg capsules (Medac)** registered and marketed in *Germany*.

**Cecenu lomustine 40mg capsules (Medac)** 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 **31 May 2022**.

**Cecenu lomustine 40mg capsules (Medac)** are indicated 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 should be used as alternative therapy in the treatment of disseminated Hodgkin's disease in patients refractory to other established treatment regimens.*

**The s19A approved German product is identical in active ingredient and strength to the Australian registered product.** The two products differ in their excipient ingredients. These differences are noted below:

	<b>CeeNU lomustine 40mg capsules (Aust R 19249)</b>	<b>Cecenu lomustine 40mg capsules (Medac)</b>
<b>Excipients</b>	mannitol magnesium stearate	lactose wheat starch talc magnesium stearate gelatine titanium dioxide indigo carmine

Healthcare professionals should advise patients upon dispensing that *Cecenu lomustine 40mg capsules (Medac)* contains gluten and lactose. **This information is not displayed on the bottle label.**

Please refer to the Australian Product Information for **CeeNU lomustine 40mg capsules (Aust R 19249)** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **Cecenu lomustine 40mg capsules (Medac)**.

**Cecenu lomustine 40mg capsules (Medac)** are registered in **Germany** with the outer package and package insert in both **German**. **An English translated copy of the product information is available.** The active ingredient, strength and dosage form included on the bottle label are in **German**.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Cecenu lomustine 40mg capsules (Medac)** should be reported by healthcare professionals and patients to Link Healthcare Medical Information. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Link Healthcare Medical Information can be contacted by phone on 1800 181 060 or via email at [medinfo@linkhealthcare.com.au](mailto:medinfo@linkhealthcare.com.au).

Link Healthcare Customer Service contact details

Link Healthcare Customer Service can be contacted via phone on 1800 181 060 or via email at [customerservice@linkhealthcare.com.au](mailto:customerservice@linkhealthcare.com.au).

Please contact Link Healthcare Customer Service for further information.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the shortage of the Australian registered **CeeNU lomustine 40mg capsules (Aust R 19249)**.

Yours sincerely,



Charlotte Griffin

Medicine Access Associate