LINK
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Dear Healthcare Professional

Shortage of FLUDARABINE JUNO fludarabine phosphate 50 mg powder for injection vial AUST R: 147831 and alternative supply arrangement under section 19A of the *Therapeutic Goods Act 1989*

The Australian registered medicine, FLUDARABINE JUNO fludarabine phosphate 50 mg powder for injection vial AUST R: 147831 sponsored by Juno Pharmaceuticals Pty Ltd is currently unavailable or in short supply. It is in the interest of public health to continue supply of an overseas substitute product.

LINK has been able to arrange supply of an alternative product, **BENDARABINE fludarabine 50mg powder for injection or infusion (Germany)** on a temporary basis. This product is NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until **30 April 2024** for the following indication(s):

- Treatment of B-cell chronic lymphocytic leukaemia.

BENDARABINE fludarabine 50mg powder for injection or infusion (Germany) is registered and marketed in Germany.

Please refer to the Australian Product Information for FLUDARABINE JUNO fludarabine phosphate 50mg powder for injection vial available at https://www.ebs.tga.gov.au when prescribing and administering **BENDARABINE fludarabine 50mg powder for injection or infusion (Germany)**.

Please refer to the table below which lists the important differences between the Australian registered product and the S19A approved product

	Australian Product **Fludarabine JUNO 50mg Injection** **ARTG 147831**	**S19A Product** **BENDARABINE fludarabine 50mg powder for injection or infusion (Germany)**
Storage	Store below 25°C Infusion solutions: stable for 6 hours below 25 °C or 24 hours at 2 to 8 °C	Do not store above 30°C Infusion solutions: stable for 8 hours below 25 °C or 24 hours at 2 to 8 °C

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 **BENDARABINE fludarabine 50mg powder for injection or infusion (Germany)** should be reported by healthcare professionals and

patients to the LINK healthcare Pharmacovigilance at pv@linkhealthcare.co or 1800 181 060. Alternatively, this information can be reported to the TGA at https://www.tga.gov.au/reporting-problems

Any product complaints regarding **BENDARABINE fludarabine 50mg powder for injection or infusion (Germany)** should be reported to LINK on 1800 161 181.

Please forward this information to relevant staff members in your organisation.
For further information, please contact LINK on 1800 161 060 or email customerservice@linkhealthcare.com.au.

Yours faithfully

Ameena Rabe

Ameena Rabe B.Pharm
Head of Unlicenced Medicines and Access Services
Link Healthcare