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 due to manufacturing reasons. 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 **FLUDARABIN ACTAVIS fludarabine 50mg/2mL (25 mg/mL), concentrate for solution for injection or infusion (Teva Sweden)** 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.

FLUDARABIN ACTAVIS fludarabine 50mg/2mL (25 mg/mL), concentrate for solution for injection or infusion (Teva Sweden) is registered and marketed in Sweden. Labelling is therefore in Swedish, with product information in both Swedish and English.

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 **FLUDARABIN ACTAVIS fludarabine 50mg/2mL (25 mg/mL), concentrate for solution for injection or infusion (Teva Sweden).**

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** **FLUDARABIN ACTAVIS fludarabine 50mg/2mL (25 mg/mL), concentrate for solution for injection or infusion (Teva Sweden)**
Presentation	Powder for injection, 50mg vial	Concentrated solution for injection, 25mg/mL (50mg vial)
Storage	Store below 25°C	Store at 2-8°C
Excipients	Mannitol Sodium Hydroxide	Disodium phosphate dihydrate Sodium Hydroxide Water for Injections

Preparation and administration	Each vial is to be reconstituted with water for injections 2 mL. For intravenous bolus injection, this dose is further diluted in physiological saline 10 mL. Alternatively, the required dose drawn up in a syringe may be diluted in physiological saline 100 mL and infused over approximately 30 minutes.	Is already in solution. For intravenous bolus injection, this dose is further diluted in 10 ml of 0.9 % sodium chloride. Alternatively, for infusion, the required dose may be diluted in 100 ml of 0.9 % sodium chloride and infused over approximately 30 minutes

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 **FLUDARABIN ACTAVIS fludarabine 50mg/2mL (25 mg/mL), concentrate for solution for injection or infusion (Teva Sweden)** 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 FLUDARABIN ACTAVIS fludarabine 50mg/2mL (25 mg/mL), concentrate for solution for injection or infusion (Teva Sweden) 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
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Link Healthcare