4 February 2022

LINK
A CLINIGEN COMPANY

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RE: Shortage of DBL HEPARIN SODIUM 5000IU/1mL (porcine mucous) injection BP ampoule (AUST R: 12881) and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

Dear Healthcare Professional,

This notification is sent by LINK to inform your organisation that due to the shortage of Australian registered **DBL HEPARIN SODIUM 5000IU/1mL (porcine mucous) injection BP ampoule (AUST R: 12881) ,** LINK has arranged the supply of an alternative product, **Heparin Sodium Injection, USP 5000 Units/mL solution (McKesson/Sky)** registered and marketed in the **USA.**

Heparin Sodium Injection, USP 5000 Units/mL solution (McKesson/Sky**) *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 31 March 2022

Heparin Sodium Injection, USP 5000 Units/mL solution (McKesson/Sky) *is* indicated for:

The prophylaxis and treatment of thromboembolic disorders such as thrombophlebitis, pulmonary embolism, and occlusive vascular disease. It is also used to prevent thromboembolic complications arising from cardiac and vascular surgery, frostbite, dialysis, and other perfusion procedures. Heparin is also used as an anticoagulant in blood transfusions.

The S19A approved USA product is identical in active ingredient and strength to the Australian registered product. Please note that the s19A product contains parabens*.

Please note the following information regarding the differences between the Australian registered product and the s19A product.

	Australian registered product **DBL HEPARIN SODIUM 5000IU/1mL (porcine mucous) Injection BP (AUST R: 12881)**	**s19A product** **Heparin Sodium Injection, USP 5000 Units/mL solution (McKesson/Sky)**
Excipients	hydrochloric acid sodium hydroxide water for injections	sodium chloride water hydrochloric acid sodium hydroxide methylparaben* propylparaben*
Storage	Store below 25°C	Store at 20° to 25°C
Presentation	ampoule	Vial
Usage	single use	multiple dose**
Pack size	5 x 1mL ampoules	25 x 1mL vials

**** The s19A product is labelled "Multiple Dose". However, it is recommended that it is used as a single-use product (in line with the Australian registered product).The s19A product is supplied in boxes of 25 vials.** .

Please disregard the enclosed package insert and refer to the Australian Product Information in particular, *Section 4 Clinical Particulars* for DBL HEPARIN SODIUM 5000IU/1mL (porcine mucous) injection BP ampoule (AUST R: 12881) **(**available at https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2018-PI-01871-1) when prescribing and administering ***Heparin Sodium Injection, USP 5000 Units/mL solution (McKesson/Sky).***

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 **Heparin Sodium Injection, USP 5000 Units/mL solution (McKesson/Sky)** ***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.

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.

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 DBL HEPARIN SODIUM 5000IU/1mL (porcine mucous) injection BP ampoule (AUST R: 12881)

Yours sincerely,

A.Sharma

Anita Sharma B.Pharm
Medicine Access Associate