5 May 2022

LINK
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RE: Shortage of DBL HEPARIN SODIUM 5000 IU/0.2 mL ampoule 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 a shortage of the Australian registered **DBL HEPARIN SODIUM (porcine mucous) 5000IU/0.2mL injection BP ampoule (AUST R 16349)**, LINK has arranged the supply of an alternative product. LINK can **supply Heparin-Natrium-5000-ratiopharm**, **heparin sodium 5000 IU/0.2 mL ampoules** registered and marketed in Germany. This product is also from porcine intestinal mucosa origin.

Heparin-Natrium-5000-ratiopharm, **heparin sodium 5000 IU/0.2 mL ampoules** are NOT registered in Australia and supply is granted under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the Therapeutic Goods Act, 1989 until **30 June 2022.**

Heparin-Natrium-5000-ratiopharm, heparin sodium 5000 IU/0.2 mL ampoules are approved for use under Section 19A for the following indications:
'Heparin 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.'

Heparin-Natrium-5000-ratiopharm, heparin sodium 5000 IU/0.2 mL ampoules are registered in Germany and are therefore packaged in German language. The active ingredient 'heparin' and strength '5000 IU/0.2 mL' are clearly identified in English language. Please disregard the German language product insert and refer to the Australian Product Information for DBL HEPARIN SODIUM (porcine mucous) 5000IU/0.2mL injection BP ampoule available at https://www.ebs.tga.gov.au/

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-Natrium-5000-ratiopharm**, **heparin sodium 5000 IU/0.2 mL ampoules** 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.

For further information please contact Link Healthcare Customer Service on **1800 181 060** or via email at customerservice@linkhealthcare.com.au.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the shortage of **DBL Heparin Sodium 5000iu/0.2mL Injection ampoules**.

Yours sincerely,

C Griffin

Charlotte Griffin
Medicine Access Associate