



Safety Notice 010/19

Heparin sodium injection 5000 units/0.2 mL – disruption to supply

05 August 2019

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation & Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Heads of departments
- Directors of Medical Services
- Directors of Pharmacy
- Directors of Nursing and Midwifery
- Drug and Therapeutics Committee

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer, MoH
- Chief Pharmacist Unit, MoH
- HealthShare NSW
- Members of CEC Anticoagulant Working Party

Clinical Excellence Commission

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Internet Website:
<http://www.health.nsw.gov.au/sabs>

Intranet Website
<http://internal.health.nsw.gov.au/quality/sabs/>

Review date

5 August 2020

Background

DBL heparin sodium injection 5000 units/0.2 mL ampoules have been unavailable since November 2018. Return to normal supply has been delayed until mid-September 2019.

The German registered product Heparin Natrium 5000 Ratiopharm (heparin sodium 5000 units/0.2 mL) ampoules, accessible via Link Medical Products P/L, has been approved for limited supply under an exemption granted by the Therapeutic Good Administration under section 19A (S19A) of the Therapeutic Goods Act 1989 since the disruption to supply of DBL product. However, the supply of the German registered product has become sporadic which may lead to a shortfall in meeting demand.

Heparin sodium injection 5000 units/0.2 mL is used subcutaneously for the prevention of venous thromboembolism (VTE).

To manage the shortfall, where appropriate, use an alternative e.g. low molecular weight heparin such as enoxaparin. Reserve use of heparin sodium injection 5000 units/0.2 mL for where it is the only suitable option e.g. for patients with severe renal impairment (creatinine clearance less than 30 mL/min) or when rapid reversal of anticoagulant effect is required.

Heparin is a high-risk medicine; refer to the NSW [High-Risk Medicines Management Policy](#) (PD2015_029) for relevant Standards relating to its use.

Suggested actions by Local Health Districts/Networks

1. Distribute this notice to all relevant staff and clinical departments.
2. Develop a local plan to manage the shortage, including:
 - a. Assess the current status of heparin sodium injection 5000 units/0.2 mL injection stock available, ensuring location of all stock is identified.
 - b. Where appropriate, use an alternative e.g. low molecular weight heparin such as enoxaparin (seek haematology advice for dosing in renal impairment).
 - c. Reserve existing stock of heparin sodium injection 5000 units/0.2 mL for situations where it is the only suitable option e.g. for patients with severe renal impairment (creatinine clearance less than 30 mL/min) or when rapid reversal of anticoagulant effect is required.
 - d. Communicate any therapy changes to relevant staff.
3. Inform relevant staff when supply of heparin sodium injection 5000 units/0.2 mL returns to normal.
4. Ensure a system is in place to document actions taken.
5. Confirm receipt of this notice to CEC-MedicationSafety@health.nsw.gov.au