Safety Notice 008/23

Issue date
3 April 2023

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:
- Intensive Care Units
- Emergency Departments
- Cardiology
- Haematology
- Dialysis Units
- Medical
- Nursing/Midwifery
- Pharmacy Services

Drug & Therapeutics Committees
All other relevant clinicians and clinical departments where these products are prescribed, stored and administered

Expert Reference Group
Content reviewed by:
Medicine Shortage Assessment and Management Team
Medication Safety Expert Advisory Committee

Clinical Excellence Commission
Tel: 02 9269 5500
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Internet
Intranet

Review date
September 2023

Disruption to supply: Heparin sodium (Pfizer®) 5000 units/5 mL injection ampoule

Situation

The Australian registered medicine heparin sodium (Pfizer) 5000 units/5 mL injection (AUST R: 49232) is currently in short supply due to manufacturing issues.

An alternative product is currently being considered for supply under Section 19A (S19A) of the Therapeutic Goods Act. If approved, details of the alternative will appear on the TGA S19A approvals database.

Background

- Heparin is a parenteral anticoagulant used for several indications including treatment and prevention of venous and arterial thromboembolic disease, treatment of acute coronary syndromes, atrial fibrillation, and prosthetic heart valves.
- Heparin 5000 units/5 mL is the recommended product for administration of intravenous bolus doses under the CEC Intravenous Unfractionated Heparin Recommended Standard.
- Heparin has a narrow therapeutic index, and over- or under-anticoagulation can result in significant adverse patient outcomes.
- Due to the high risk nature of heparin, it is included in the Anticoagulant Standard which exists as part of the NSW Health Policy Directive *High-Risk Medicines Management* PD2020_045.

Assessment

In the absence of a S19A alternative, NSW Health facilities may not be able to maintain sufficient stock of heparin 5000 units/5 mL to satisfy normal demand. Pfizer have confirmed that supply of heparin 5000 units/0.2 mL and 5000 units/1 mL continue to be available.

Clinical Recommendations

- Assess the current status and availability of heparin 5000 units/5 mL in each facility, ensuring all locations of stock are identified.
- Develop a local plan to manage the supply shortage that includes (but is not limited to); assessing local stock holdings, historical stock usage, ability to obtain alternative supply, and ongoing clinical needs.
- Reserve remaining Australian registered supply of heparin 5000 units/5 mL for patients receiving at-home care (e.g. dialysis patients).
- In the absence of the registered product, clinicians wishing to prepare a heparin 5000 units/5 mL (1000 units/1 mL) preparation can do so using alternative products (see **Table 1**).
- Extra caution should be taken to avoid confusion as the recommended alternative product may differ from local clinical protocols.

PTO

- Patients receiving heparin should be closely monitored for signs and symptoms of sub- or supra-therapeutic dosing. Laboratory testing (e.g. aPTT levels) should be continued as per local protocols and evidence-based references.

Table 1. Preparation instructions to achieve required concentration of 5000 units/5 mL (1000 units/1 mL)

Alternate product	Preparation to achieve required concentration of 5000 units/5 mL (1000 units/1 mL)
Heparin 5000 units/0.2 mL	Dilute with 4.8 mL of sodium chloride 0.9%. Use solution immediately after dilution.
Heparin 5000 units/1 mL	Dilute with 4 mL of sodium chloride 0.9%. Use solution immediately after dilution.

- In accordance with NSW Health Policy Directive High Risk Medicines Management PD2020_045, clinicians are reminded that a second person check should be undertaken prior to the preparation and administration of heparin.

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians and clinical departments where heparin 5000 unit/5 mL is held, prescribed, and administered, and include this Safety Notice in relevant handovers and safety huddles.
2. Undertake a local risk assessment and incorporate the above recommendation to manage the disruption to supply.
3. Ensure a system is in place to document actions taken in response to this Safety Notice.
4. Report any incidents associated with this disruption to supply into the local incident management system e.g., ims+.
5. Confirm receipt and distribution of this Safety Notice within **72 hours** to CEC-MedicationSafety@health.nsw.gov.au.