NSW Health

UPDATED: Disruption to supply: Heparin sodium (Pfizer®) injection ampoules (multiple strengths)

SAFETY NOTICE 036/24

Issue date:	16 December 2024
Replaces:	SN:026/24
Content reviewed by:	Medication Safety Expert Advisory Committee, Medication Shortage Assessment and Management Team, Infection Prevention and Control
Distributed to:	Chief Executives; Directors of Clinical Governance; Director, Regulation and Compliance Unit
KEY MESSAGE:	NSW Health facilities are informed of the disruption to the supply of heparin sodium (Pfizer) injection ampoule (multiple strengths), availability of international alternatives and associated safety considerations.
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance
REQUIRED ACTION:	1. Distribute this **updated** Safety Notice to all relevant clinicians and clinical departments where heparin sodium (Pfizer) injection 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 below recommendations 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.
DEADLINE:	19 December 2024
We recommend you also inform:	Directors, Managers and Staff of: • Intensive Care Units • Emergency Departments • Cardiology • Haematology • Dialysis Units • Pharmacy Services • Nursing/Midwifery • Medical Services • Digital Health/ICT Drug and Therapeutics Committees All other relevant clinicians, departments and committees.
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html

Contact: Clinical Excellence Commission
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What is updated in this Safety notice from SN:026/24?

This Safety Notice replaces SN:026/24 *Disruption to supply: Heparin sodium (Pfizer) 5,000 units/5 mL injection ampoule* which has now been rescinded. The Safety Notice provides information about additional supply disruptions affecting multiple strengths of Australian registered heparin sodium (Pfizer) products.

The Safety Notice should be read in conjunction with the factsheet: *Heparin sodium (Pfizer®) injection ampoules (multiple strengths) disruption to supply – International alternatives and associated safety considerations* which includes details about the availability and safety considerations associated with internationally registered alternative heparin products available under Section 19A (S19A) of the *Therapeutic Goods Act 1989* or via the Therapeutic Goods Administration's (TGA) Special Access Scheme (SAS).

Situation

The following strengths of the Australian registered medicine heparin sodium (Pfizer) are currently in short supply due to manufacturing issues and unexpected increase in customer demand:

- 5,000 units/1 mL injection (AUST R: 12881) until April 2025
- 5,000 units/5 mL injection (AUST R: 49232) until June 2025
- 25,000 units/5 mL injection (AUST R: 49236) until January 2025.

At the time of publication, supply of heparin 5,000 units/0.2 mL continues to be available.

Alternative internationally registered products are available for each strength of heparin under S19A of the *Therapeutic Goods Act 1989 or* via SAS. The S19A and SAS alternatives differ from the Australian registered product in overall volume, presentation, route of administration and storage requirements. Of note, some alternatives contain **preservatives**.

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 has a narrow therapeutic index, and over- or under- anticoagulation can result in significant adverse patient outcomes.
- Heparin (Pfizer) 5,000 units/5 mL is the recommended product for administration of intravenous bolus doses as per the CEC Intravenous Unfractionated Heparin Recommended Standard.
- As heparin is classed a high-risk medicine, an Anticoagulant Standard exists as part of the NSW Health *High-Risk Medicines Management* Policy Directive (PD2024_006).

Assessment

Tables 1, 2 and **3** in the factsheet: *Heparin sodium (Pfizer®) injection ampoules (multiple strengths) disruption to supply – International alternatives and associated safety considerations* outline the differences between the Australian registered heparin sodium products and the international alternative(s) available via S19A or SAS supply, including important safety considerations to note. Refer to the electronic version of this factsheet, as additional products may be added.

Please note, the S19A and SAS alternatives may also be impacted by global supply chain constraints, leading to intermittent availability during the shortage period. All staff are advised to check the TGA Medicine Shortage Reports Database for updates regarding further changes to supply dates and the TGA S19A approvals database for updates on S19A alternatives.

Clinicians should determine the suitability of the S19A and SAS alternatives prior to prescribing, dispensing or administration to a patient.

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Recommendations

- Assess the current status and availability of all affected heparin sodium products in each facility, ensuring all locations of stock are identified.
- Develop a local plan to manage the disruptions to supply that includes (but is not limited to);
    - evaluation of local stock holdings, historical usage, local protocols to determine clinical indication(s) for each affected concentration
    - identification of the most suitable alternative option(s) based on local usage, clinical needs and accounts for the lead time/availability of the S19A and SAS alternatives.
- Reserve remaining supply of Australian registered heparin sodium 5,000 units/5 mL, heparin sodium 5,000 units/1 mL and preservative free S19A/SAS alternatives for:
    - Patients for whom preservative-containing alternatives are not clinically appropriate, such as maternity and neonatal patients.
    - Patients receiving at home care (e.g., dialysis patients). Please note, clinicians are to ensure formulations provided to at home care patients are not presented in glass ampoules/vials.
- Ensure vials of the S19A and SAS alternatives containing preservatives are restricted to single use in accordance with the NSW Health *Medication Handling* Policy Directive (PD2022_032) and NSW Health *Infection Prevention and Control in Health Care Settings* Policy Directive (PD2023_025).
- If using the Hospira S19A 10,000 units/10 mL alternative:
    - Ensure clinicians are aware of the difference in total overall volume (10 mL) compared to the Australian product (5 mL).
    - Only withdraw the required volume for the dose. For example, withdraw 5 mL if 5,000 units is intended to be administered and **discard** the remaining product.
- In the absence of the Australian registered product or where the S19A or SAS alternatives are unavailable/contraindicated, clinicians wishing to prepare a heparin 5,000 units/5 mL (1,000 units/1 mL) or heparin 5,000 units/1 mL preparation can do so using the alternative Australian registered products (see **Table 1**).

Table 1. Preparation instructions to achieve required concentration of 5,000 units/5 mL (1,000 units /1 mL) or 5,000 units/1 mL

Alternate Australian registered product (still available)	Preparation to achieve required concentration of 5,000 units/5 mL (1,000 units/1mL)	Preparation to achieve required concentration of 5,000 units/1 mL (5,000 units/1mL)
Heparin 5,000 units/0.2 mL	Dilute with 4.8 mL of sodium chloride 0.9% Use solution immediately after dilution	Dilute with 0.8 mL of sodium chloride 0.9% Use solution immediately after dilution

- Extra caution should be taken to avoid confusion between the different heparin preparations available as alternative products may differ from local clinical protocols.
- Patients receiving heparin should be closely monitored for signs and symptoms of sub- or supra-therapeutic dosing. Laboratory testing (for example, aPTT levels) should be continued as per local protocols and evidence-based references.
- In accordance with NSW Health *High-Risk Medicines Management* Policy Directive (PD2024_006) and the NSW Health *Medication Handling* Policy Directive (PD2022_032), clinicians are reminded that an independent second person check should be undertaken prior to the preparation and administration of heparin.
- Consider the need to update configurations (for example, order sentences and product catalogues) within Electronic Medication Management (eMM) systems where required to reflect change in products based on local availability.

References

1. Hull RD, Garcia, DA., Burnett, AE., Heparin and LMW heparin: Dosing and adverse effects. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2023.

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