Safety Notice 012/21

Enoxaparin (Clexane®) 20 mg and 40 mg syringes – Disruption to supply

1 June 2021

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 of Medical Services
- Directors of Pharmacy
- Directors of Nursing
- Drug and Therapeutics Committees and subcommittees

Expert Reference Group

Content reviewed by:

- State Preparedness and Response Branch
- Chief Pharmacist Unit
- Medication Safety Expert Advisory Committee

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

January 2022

Background

There is a disruption to the supply of enoxaparin (Clexane®) 20 mg and 40 mg syringes as a result of manufacturing issues. Enoxaparin 20 mg and 40 mg syringes contain a low-molecular weight heparin (LMWH) used primarily in the prevention of venous thromboembolism (VTE) in patients assessed to be at moderate to high risk. Clexane® is the only registered brand of enoxaparin marketed in Australia.

The sponsor of enoxaparin (Clexane®) has indicated that there may be ongoing disruptions to the supply of 20 mg and 40 mg syringes throughout 2021. **Note**: supply of the 60 mg, 80 mg, 100 mg, 120 mg and 150 mg strengths of enoxaparin syringes used in the treatment of VTE are currently unaffected.

To supplement the limited stock at wholesalers, NSW health facilities can access both affected strengths through NSW HealthShare. Follow order process as distributed by HealthShare. For urgent requirement or problems submitting requests, contact Noman.Masood@health.nsw.gov.au

A UK registered product (Inhixa) of enoxaparin 20 mg and 40 mg syringes (accessible via Orspec Pharma P/L) has been approved for limited supply under an exemption granted by the Therapeutic Goods Administration under section 19A of the Therapeutic Goods Act 1989. Allow 7 – 10 business days lead time.

A factsheet for clinicians regarding alternatives to enoxaparin for VTE prophylaxis during the disruption to supply has been prepared. The choice of alternative agent should be guided by the patient's current condition, formal clinical assessment, availability of agents, locally endorsed guidelines and Drug and Therapeutics Committee approval. Potential alternatives include:

- Use of enoxaparin 60 mg syringes (which have graduated markings) to obtain a 20 mg or 40 mg dose – *clinicians must exercise caution to ensure accurate dosing and prevent inadvertent over- or under- dosing.*
- Dalteparin (Fragmin®) – *alternate LMWH that is registered in Australia.*
- Unfractionated heparin – *may be the preferred alternative in patients with severe renal impairment or when rapid reversal of anticoagulation may be necessary. Note unfractionated heparin has a higher-incidence of heparin-induced thrombocytopenia compared to LMWH.*
- Direct-acting oral anticoagulants – *apixaban, dabigatran and rivaroxaban may be appropriate for specific indications.*
- Fondaparinux – *may be appropriate for specific indications. Consider reserving for patients with diagnosis of suspected or confirmed vaccine-induced thrombotic thrombocytopenia (VITT).*

Clinicians can also refer to the Therapeutic Guidelines and Australian Medicines Handbook for further guidance – both are accessible via CIAP.

References

1. *Australian Medicines Handbook* 2021 (online). Adelaide: Australian Medicines Handbook Pty Ltd; 2021 January. Available from: https://amhonline.amh.net.au/
2. *eTG complete* [digital]. Melbourne. Therapeutic Guidelines Limited; 2021 Mar. Available from: https://www.tg.org.au

Suggested actions by Local Health Districts/Networks

1. Distribute this Safety Notice to all stakeholders and clinical departments affected by the disruption to the supply of enoxaparin 20 mg and 40 mg syringes.
2. Develop a local plan to manage the disruption which should include –
    a. An assessment of the current status of enoxaparin 20 mg and 40 mg syringes available in each facility, ensuring all locations of stock are identified and monitored.
    b. An assessment of the current status of the alternative agents available in each facility and procurement of additional stock if required.
    c. Where appropriate, alternatives should be used and residual enoxaparin 20 mg and 40 mg syringes quarantined for use in patients where there is no other viable option or for patients requiring these doses on discharge.
    d. Communicate any therapy changes to the patient and relevant staff.
    e. In facilities utilising eMM systems, liaison with local eMeds/ICT teams to review and modify available order sentences, care sets and PowerPlans (or similar).
3. Ensure a system is in place to document actions taken in response to this Safety Notice.
4. Confirm receipt of this notice to CEC-MedicationSafety@health.nsw.gov.au