



16 January 2023

Medicine Supply Alert Notice

Dalteparin (Fragmin®) 10,000units/1mL solution for injection ampoule

Priority: Level 3*

Valid until: discontinuation - stock to be exhausted by May 2023

Issue

1. Dalteparin (Fragmin®) 10,000units/1mL solution for injection ampoule has been discontinued. Based on forecasted UK demand, stock will be exhausted by May 2023.
2. Alternative strengths and formulations of dalteparin and other low molecular weight heparins remain available and will be able to support increased demand.

Advice and Actions

Primary and Secondary care

3. Clinicians in primary and secondary care, including paediatric tertiary centres should:
 - not prescribe dalteparin (Fragmin®) 10,000units/1ml ampoules for adults where possible and consider alternative dalteparin presentations;
 - continue to prescribe dalteparin (Fragmin®) 10,000units/1ml ampoules for paediatrics and neonates (off-label) where appropriate until local protocols have been amended (see below);
 - identify all patients discharged with dalteparin (Fragmin®) 10,000units/1ml ampoules and ensure they have enough supplies to complete their course;
4. Where patients do not have sufficient supplies for their course, consider prescribing an alternative dalteparin (Fragmin®) preparation taking into account the confidence of the patient/carer to use an alternative presentation:
 - be mindful of the potential risk of dosing errors and patient harm if an alternative presentation is not prescribed, dispensed or administered correctly;
 - ensure doses and volumes are recalculated correctly and patients/carers are counselled on changes in dose and administration technique;
 - annotate prescriptions to highlight changes to dispensing pharmacies to ensure calculations are rechecked and counselling is provided to patients/carers on dose and administration method. For example, a prescription can be annotated with *'please be aware of change in strength and presentation from the previous prescription and consider this when dispensing.'*

- higher concentration multidose vials (dalteparin (Fragmin®) 100,000units/4mL) *should not* be prescribed/dispensed to paediatric and neonate patients;
5. Ensure local guidelines and formularies are reviewed and amended to replace dalteparin (Fragmin®) 10,000units/1mL solution for injection ampoules with an alternative low molecular weight heparin preparation taking into account the age of the patient being treated, presentation, strength and administration guidance. This should be done in advance of May 2023.
 6. Local guidelines and protocols *should not* include the higher concentration multidose vials (dalteparin (Fragmin®) 100,000units/4mL) as an alternative option to the discontinued product, particularly for paediatrics and neonates, to reduce the risk of dosing errors.
 7. Provide appropriate education and training to all those prescribing and administering this product on the new protocol (see Additional Information below).

Additional Information

Off-label use

8. Dalteparin (Fragmin®) is used off-label in neonates and paediatrics for the treatment and prevention of any thrombotic event. Dalteparin (Fragmin®) 10,000unit/1mL solution for injection ampoule is a commonly used presentation in this patient cohort as it allows for doses with high concentrations in low volumes to be achieved. In this patient population, there is a high risk of dosing errors when changing between dalteparin preparations of differing strengths and forms.
9. Pfizer, the sole supplier of dalteparin (Fragmin®), have a 10,000unit/1mL graduated syringe available as well as alternative strength ampoules, vials and pre-filled syringe preparations, but not all presentations will be deemed suitable for use in neonates and paediatrics.
10. Alternative dalteparin (Fragmin®) solution for injection products remain available (see Table 1 below), however, the risk of dosing errors is high without appropriate consideration and training being implemented (see Patient Safety Considerations).

Table 1

Alternative dalteparin (Fragmin®) solution for injection products	Formulation
10,000units/4mL*	Ampoules*
100,000units/4mL	Multidose vial
10,000units/1mL	Graduated pre-filled syringe
2,500units/0.2mL	Pre-filled syringe
5,000units/0.2mL	
7,500units/0.3mL	
10,000units/0.4mL	
12,500units/0.5mL	
15,000units/0.6mL	
18,000units/0.72mL	

*supplies of 10,000units/4mL ampoules will not be able to support an increase in demand until Q2 2023.

Alternative Low Molecular Weight Heparins

11. Alternative low molecular weight heparins, including enoxaparin and tinzaparin, may be a suitable alternative for some patients.

For Health Boards:

12. If protocols are changed to use enoxaparin or tinzaparin instead of dalteparin and Health Boards do not already have access to these products; Health Boards should reach out to suppliers of enoxaparin and/or tinzaparin to ensure stock can be supplied for ongoing use.

Patient Safety Considerations

13. Local guidelines and protocols *should not* include the higher concentration multidose vials (dalteparin (Fragmin®) 100,000units/4mL) as an alternative option to the discontinued product, particularly for paediatrics and neonates, to reduce the risk of dosing errors. There are also increased risks of errors if using 'part-doses' from pre-filled syringes.

14. In addition, where patients/parents/carers are supplied with take-home doses to administer, if an alternative presentation is prescribed, they should be appropriately counselled on the new dose and how to use the device (see links below). Higher concentration multidose vials *should not* be prescribed/dispensed to paediatric and neonate patients.

15. Training should be provided to all healthcare professionals on new protocols which advise on prescribing an alternative product or presentation. This is to ensure changes in drug, concentrations, strengths and formulations are clearly understood. Specific training should also be provided for those administering alternative formulations, particularly in neonates.

16. Particular care should be taken if using alternative dalteparin (Fragmin®) presentations, for example:

- Fragmin® 10,000unit/1mL graduated pre-filled syringe is the same strength as the discontinued product but will have a different administering process; or
- Fragmin® 10,000unit/4mL ampoule (which will be available as a vial presentation in Q2 2023) is currently the same formulation but different strength. Please note, this presentation will not be able to support an increase in demand until Q2 2023

Please refer to the links below for further information

- [SPC's for dalteparin \(Fragmin®\)](#)
- [BNF Dalteparin Sodium](#)

Specialist Pharmacy Service (SPS) website

17. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues.

18. To access the online Medicines Supply Tool you need to register with the [SPS website](#). Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Planning tab and then click on the Medicines Supply option.

19. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool in order to stay up to date concerning medicines supply disruptions.
20. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

Enquiries

21. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to PharmacyTeam@gov.scot (primary care) or NSS.NHSSMedicineShortages@nhs.scot (secondary care).