



6 August 2021

## **Medicine Supply Alert Notice**

### **Tinzaparin sodium (10,000 IU/ml) 3,500 units in 0.35 ml and 4,500 units in 0.45 ml pre-filled syringes**

**Priority: Level 3\***

**Valid until: January 2022**

#### **Issue**

1. Tinzaparin sodium 3,500units in 0.35 ml and 4,500units in 0.45 ml pre-filled syringes will be unavailable between middle of October 2021 and January 2022 (date TBC).
2. All other presentations of tinzaparin remain unaffected by this supply disruption.
3. Organisations who use tinzaparin for both prophylaxis and treatment of venous thromboembolism will need to consider if they wish to switch to an alternative low molecular weight heparin (LMWH) for all indications or just for prophylaxis.
4. Impacted organisations will need to work with the relevant supplier to ensure their likely demand can be supported and take early steps to make certain their organisation can switch over safely before mid-October.
5. Organisations should continue to order the impacted presentations of tinzaparin in line with demand while they work to switch over to an alternative LMWH. Leo Pharma will continue to monitor ordering patterns.

#### **Advice and Actions**

6. Health Board pharmacy procurement teams affected by this shortage should work with clinical leads, nursing leads and other key stakeholders, to decide if the organisation will switch all tinzaparin prescribing to an alternative agent or just thrombo-prophylactic indications. Once agreed they should:
  - Notify National Procurement (NP) of their planned approach by 10<sup>th</sup> August. NP will then contact the LMWH suppliers to ensure that they have sufficient capacity to support a switch within the required timeframe.
  - work with National Procurement and the supplier to agree an implementation plan for their health board;
  - review the materials the supplier can provide and agree an education and communication plan to support all affected staff with this change;
  - ensure prescribing systems, dosing charts and aide memoirs in use across organisation are reviewed and amended; and
  - work with primary care to ensure they are fully aware of local changes in prescribing practise.
7. For patients prescribed tinzaparin sodium 3,500units in 0.35 ml and 4,500units in 0.45 ml pre-filled syringes in **Primary Care**. GPs and Health Care Professionals who prescribe tinzaparin should identify all patients that may be impacted and ensure that:

- their treatment is reviewed, with support from secondary care colleagues if appropriate, and the patient is switched to another LMWH before mid-October 2021;
- the impacted patients receive appropriate counselling to support a safe switch; and
- no new patients are initiated on treatment with the impacted products.

### Additional Information

8. Specialist Pharmacy Service (SPS) Medicines Information team has put together a table of LMWHs and fondaparinux that can be used by organisations to support their review of alternatives. This can be accessed via this [link](#). Please note an [SPS portal](#) account will be required. Those without an account can register via this [link](#).
9. Following comprehensive engagement by NHS England and NHS Improvement's Commercial Medicines Unit with suppliers of LMWHs, the information below has been compiled to support organisations affected by this supply disruption to agree a local mitigation plan. This is a brief summary of products available to support this supply disruption, but more detail should be sought from the manufacturers directly before a local management plan is agreed and finalised, including the training support and training materials they can make available.

Product	Manufacturer	Training support on offer
Fragmin (dalteparin)	Pfizer	One clinically trained field colleague Self-administration one-page graphic Venous Thromboembolism booklet Self-administration booklet Healthcare professional website (efficacy, safety and patient resources) <a href="#">Fragmin®   Home   PfizerPro UK</a> Patient website (Self administration video, animations and other resources) <a href="#">Welcome to the Fragmin (dalteparin sodium) website</a>
Arovi (enoxaparin)	Rovi Biotech LTD	Educational materials (booklet, poster and video) A link to AROVI's web page where Health Boards can access visuals of the product, a PDF copy of the User Information Guide and a video explaining the injection technique: <a href="https://www.rovi.es/uk/productos">https://www.rovi.es/uk/productos</a>  Train the trainer sessions can be arranged upon request. Supplier has requested confirmation of which Health Boards wish to switch ASAP so they can secure supply.
Inhixa (enoxaparin)	Techdow Pharma	Educational materials (both for patients and healthcare professionals) including online videos, alongside patient material demonstrating how to inject, dosing charts and showing how the titrations work. Remote online support via teams/Zoom can be provided on request. Face to face training is by exception only and must be pre-agreed with Techdow and individual Health Boards.
Arixtra (fondaparinux)	Viatrix	Materials are currently being drafted and are anticipated to be ready mid-September.

## **Product details**

10. Tinzaparin sodium Syringe 10,000 IU/ml [PL 00043/0204]

- 3,500 anti-Factor Xa IU in 0.35 ml
- 4,500 anti-Factor Xa IU in 0.45 ml

Tinzaparin [SPC](#)

## **Background**

11. Leo Pharma are the sole supplier of tinzaparin. Leo is experiencing capacity issues at the production plant in France where tinzaparin is manufactured due to an increase in global demand and resulting technical difficulties. It is expected these will be resolved later in the year and supply will return to normal from early 2022.

## **Enquiries**

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