Department of Health & Social Care

NHS

Supply Disruption Alert

SDA/2021/008 Issued: 29/07/2021

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

Summary

- 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).
- All other presentations of tinzaparin remain unaffected by this supply disruption.
- 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.
- 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.
- 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.

Action

Trust/Health Board pharmacy procurement teams affected by this shortage should work with clinical leads, the local Medication Safety Officer (MSO), 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:

- contact the supplier of their agent of choice to ensure that they have sufficient capacity to support a switch within the required timeframe. This action should be completed by **16th August 2021**;
- work with the supplier and agree an implementation plan for their trust /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.

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.

Product details

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

SPC

Supporting Information

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.

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) Fragmin® | Home | PfizerPro UK** **Patient website (Self administration video, animations and other resources) Welcome to the Fragmin (dalteparin sodium) website**
Arovi (enoxaparin)	**Rovi Biotech LTD**	**Educational materials (booklet, poster and video)** **A link to AROVI's web page where Trusts/Health Boards can access visuals of the product, a PDF copy of the User Information Guide and a video explaining the injection technique: https://www.rovi.es/uk/productos** **Train the trainer sessions can be arranged upon request.** **Supplier has requested confirmation of which Trusts/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 Trusts/Health Boards.**
Arixtra (fondaparinux)	**Viatris**	**Materials are currently being drafted and are anticipated to be ready mid-September.**

Background

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.

Distribution (delete as appropriate)

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- All departments
- All staff
- All wards
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Anti-coagulation clinics
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Chief pharmacists
- Clinical governance leads
- Clinical Procurement Specialists [NEW]
- Community diabetes specialist nurses
- Community hospitals
- Community midwives
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- District nurses
- Emergency Preparedness and Response officer [NEW]
- Fracture clinics
- Gastroenterology departments
- Gastroenterology, directors of
- Gastro-intestinal surgeons

- General surgeons
- General surgery
- General surgical units, directors of
- Gynaecologists
- Gynaecology departments
- Gynaecology nurses
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Maternity units
- Medical directors
- Medical oncologists
- Medical oncology, directors of
- Medical physics departments
- Mental Health Trusts
- Mental Health Specialists
- Midwifery departments
- Midwifery staff
- Neonatology departments
- Neonatology directors
- Nursing executive directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Oncology nurse specialists
- Oral surgeons
- Orthopaedic surgeons
- Outpatient clinics
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Peritoneal dialysis units
- Pharmaceutical advisors
- Pharmacists

- Purchasing managers
- Renal medicine departments
- Renal medicine, directors of
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments

NHS England and NHS Improvement Regional Offices

For onward distribution to:

- Community pharmacists

General Practice

For onward distribution to:

- General practitioners
- General practice managers
- General practice nurses

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Care homes providing nursing care (adults)
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Enquiries

England

Enquiries from NHS Trusts in England should in the first instance be directed to your trust pharmacy team who will escalate issues to the Regional Pharmacy Procurement Specialist and national teams if required.

REGION	Full Name	Email
East Midlands	Andi Swain	andi.swain@nhs.net
East of England	James Kent	james.kent@southend.nhs.uk
London	Jackie Eastwood	jacqueline.eastwood@lpp.nhs.uk
North East	David Cook Umair Hamid	david.cook20@nhs.net umair.hamid2@nhs.net
North West	Glenn Harley	Glenn.Harley@liverpoolft.nhs.uk
South Central	Alison Ashman	Alison.Ashman@berkshire.nhs.uk

South East Coast	Richard Bateman	richard.bateman2@nhs.net
South West	Danny Palmer	Danny.Palmer@uhbw.nhs.uk
West Midlands	Diptyka Hart	Diptyka.Hart@uhb.nhs.uk
Yorkshire & Humber	David Allwood	davidallwood@nhs.net

Scotland

nss.nhssmedicineshortages@nhs.scot

Wales

MedicinesShortages@gov.wales

Northern Ireland

RPHPS.Admin@northerntrust.hscni.net

All other organisations should send enquiries about this notice to the DHSC Medicines Supply Team, quoting reference number SDA/2021/008

Email: DHSCmedicinesupplyteam@dhsc.gov.uk