

## **Factsheet: Enoxaparin biosimilar (Inhixa)**

### **Key messages:**

- **Inhixa will be replacing Clexane as the first choice Enoxaparin across East Kent ICP for new initiations only from 2<sup>nd</sup> November 2020. There will be no active switching of existing patients. Clexane will also remain on formulary for existing patients.**
- **We recommend prescribing Enoxaparin by brand with the generic name in brackets e.g. “ Inhixa (Enoxaparin)” in line with MHRA advice and to ensure consistency for patients.**
- **Familiarity with the name Inhixa is vital for all Primary Care staff involved in prescribing, dispensing and administration, to avoid inadvertent co-prescribing with other anticoagulants.**
- **Staff should familiarize themselves with the unique administration technique, and with the product and colour coded strengths to avoid potential selection error.**
- **Patients must be trained to use the brand of Enoxaparin which they have been prescribed / dispensed.**
- **GP practices should review if they should be prescribing Enoxaparin in each case according to East Kent agreed prescribing pathways (page 5).**

## Introduction

- Until recently, Clexane® was the only enoxaparin product on the market. Inhixa®, an enoxaparin biosimilar, was launched in the UK in September 2017.
- East Kent Hospitals have made a decision to change their preferred Enoxaparin from the Clexane brand to Inhixa. This change will be implemented from **2<sup>nd</sup> November 2020** for new initiations. East Kent Prescribing Group have taken a decision to adopt Inhixa as the preferred brand of Enoxaparin for primary care prescribing in East Kent for continuity and safety. Clexane will remain on formulary for existing patients and those who are not able to administer the Inhixa.
- East Kent Hospitals will be introducing the switch gradually from this date. There may be some patients discharged on Clexane, after this date, while stocks are used up.
- This factsheet is aimed at GPs, practice nurses/pharmacists and community pharmacists, which summarises the key information and practical considerations associated with the introduction of this biosimilar product.
- NHS England has published “What is a Biosimilar Medicine” for clinical and non-clinical stakeholders ([here](#)), and for patients, the European Commission has published information for patients on biosimilar medicines ([here](#)) .
- Full prescribing information (SPC) and a Patient Information Leaflet (PIL) for Inhixa is available ([here](#)) .

## Indications and Dose

- The indications and recommended doses for Inhixa are the same as Clexane at the time when this factsheet was written. These are detailed in the SPC and PIL.
- Inhixa is available as 20mg, 40mg, 60mg, 80mg, 100mg, 120mg and 150mg pre-filled syringes.

## Cost

- Patients may be concerned that Inhixa is a ‘cheap copy’ of Clexane but they can be reassured that it has been manufactured to the same high standards as Clexane and the lower price does not mean it is of a lower quality.

## Efficacy and Safety

- Inhixa can be expected to be as effective and safe as Clexane when used appropriately.
- The European Medicines Agency (EMA), who has strict regulatory requirements for approving biosimilars and ensures that there are no clinically meaningful differences between the biosimilar and the reference (original) medicine in terms of quality, efficacy, safety and immunogenicity profile, has granted approval for Inhixa.

- Inhixa has black triangle status so is subject to additional monitoring. Any side effects should be reported via the Yellow Card Scheme [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)
- A UKMi safety assessment report for Inhixa provides further details on safety and comparison to Clexane which can be found ([here](#))

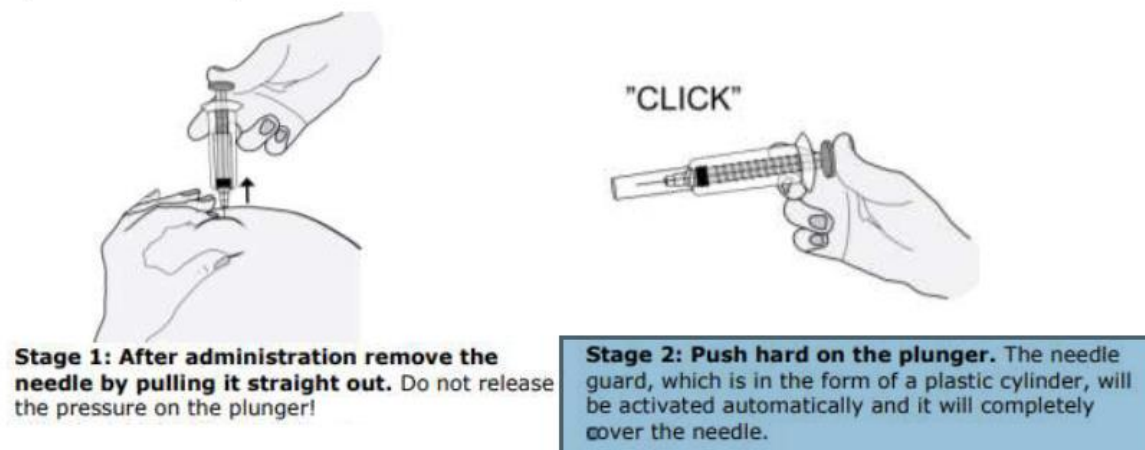
## Prescribing and Dispensing

- The MHRA recommends that it is good practice to prescribe all biological medicines by brand name to ensure that automatic substitution doesn't occur when the medicine is dispensed or administered ([here](#)).
- Patients should ideally remain on the same brand, and any decision on switching should involve the prescriber in consultation with the patient.
- With more than one brand of enoxaparin now available, prescribers may need to adjust their current practice as the majority of prescribing of enoxaparin is currently generic.
- Prescribers and pharmacists will need to take care to select the correct product for prescribing or dispensing.
- Prescribing of Enoxaparin should be by brand with the generic name in brackets e.g. "Inhixa (Enoxaparin)". In primary care this can be done by adding "(Enoxaparin)" to the directions field.
- Hospital discharge letters should provide details of the required brand of enoxaparin for patients needing ongoing supplies. Primary care prescribers may need to check if this information is not provided.
- Community pharmacists receiving a generic prescription should take necessary steps to try and confirm the brand required before dispensing. If this is not possible, or if the required brand is not available, a professional judgement will need to be made, taking into account the clinical urgency for supply. In most cases, supplying something will be better than supplying nothing.
- If generic prescribing becomes necessary due to national shortages of one or more brands, the preferred brand should be included in brackets in the directions field.
- Ensure that patients switching brands receive counselling on differences in administration technique (see below). Please refer to the PIL if required.
- **Techdow supply Inhixa through the following wholesalers: Phoenix and AAH.**

## Administration

- Practice staff will need to ensure they select the correct product for administration.
- Administration instructions for Inhixa are detailed in the PIL. ([here](#))
- These are essentially the same as for Clexane, but a key difference lies with the needle guard. This is discussed in further detail in the UKMi Safety assessment report detailed above. The needle guard on the Clexane syringes is

automatically released and provides a protective cover as the needle is withdrawn from the administration site. However, the needle guard on the Inhixa syringe has to be activated by holding the plunger down when withdrawing the needle, and pressing it down further after withdrawal of the needle (illustrated below).



## Patient considerations

- Healthcare professionals and patients accustomed to using Clexane may need specific training on this, and it may be that some patients do not have the strength or dexterity to release the needle guard with Inhixa and may be better suited to Clexane.
- The labels and calibrations on Inhixa syringes may be more difficult to see than with Clexane syringes, so this should also be assessed when training patients.
- All patients should receive training before self-injecting enoxaparin and staff will need to ensure patients are taught administration where necessary with the appropriate brand.
- Patients who are self-administering should be assessed to ensure they can operate the syringe safely.
- On dispensing either brand, pharmacists should check patients' understanding and capability of safe administration and highlight any concerns to the prescriber.

## Staff Training

- A company video, demonstrating the administration technique for Inhixa including the deployment of the needle guard, should be watched by all healthcare

professionals who will be administering, prescribing, dispensing or teaching patients to administer Inhixa. This can be found by following the link:

<http://www.techdow-pharma.co.uk/productsInfo/>

- As there may be difficulty in reading the labels on some of the Inhixa syringes, staff should familiarise themselves with the product and colour coded strengths to avoid potential selection error.



The Techdow representative may be contacted by practices to arrange a supply of dummy syringes or to provide training for staff.

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- Techdow patient instructions for administering Inhixa are provided with this Factsheet.

## Enoxaparin Prescribing Pathways in East Kent

- Primary care should review if they should be prescribing Enoxaparin in each case, or whether the acute is responsible under the agreed Enoxaparin supply process. Support is available from the CCG Medicines Optimisation team.
- GPs may be involved in prescribing in the following pathways:
  - DVT – where the GP may initiate prior to ultra sound scan on the advice of DVT clinic.
  - Obstetrics – initiation by GP following written instructions from an obstetrician and ongoing prescribing in circumstance detailed in supply process.
  - Where contraindications exist to oral anticoagulants – ongoing prescribing
  - Oncology – For patients undergoing chemotherapy, as an interim arrangement until the pathway has been agreed, East Kent Prescribing Group advise that while it is preferable that supplies are made by EKHFT, GPs could prescribe if they have received written information confirming the drug, dose and monitoring needed.  
For ongoing treatment following completion of chemotherapy.
  - GPs taking part in the planned new East Kent Deep Vein Thrombosis (DVT) Triage and Assessment Service – Wells Score and D-dimer.
  - Estuary View DVT Service

- It has been agreed that if EKHFT patients require enoxaparin treatment prior to surgery or hospital procedures, then as part of the tariff arrangement the enoxaparin should be provided by EKHFT.

### **Company Contact Details**

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Clexane: Sanofi 0800 035 2525

Acknowledgement: This factsheet is based on ones produced by University Hospital Southampton and Medicines Management IESCCG.