Factsheet: Enoxaparin biosimilar (Inhixa▼)

Introduction

- Until recently, Clexane® was the only enoxaparin product on the market. Inhixa®▼, an enoxaparin biosimilar, was launched in the UK in September 2017, and Arovi®▼, another enoxaparin biosimilar, was launched in March 2018.
- From September 2020, Inhixa will become the preferred brand of enoxaparin in the Basingstoke, Southampton and Winchester area due to anticipated supply shortages and possible price increases of other brands.
- This factsheet, aimed at GPs, practice nurses/pharmacists and community pharmacists, summarises the key information and practical considerations associated with Inhixa.
- Information on biosimilars is available for healthcare professionals: "Biosimilars in the EU. Information Guide for Healthcare Professionals", and for patients: "What I need to know about Biosimilar Medicines. Information for patients" and "Biosimilar medicines in the EU" (animated video).
- Full prescribing information (SmPC) and Patient Information Leaflets (PIL) for Inhixa are available at www.medicines.org.uk

Indications and Dose

- The indications and recommended doses for Inhixa are identical to Clexane. These are detailed in the SmPC and PIL.
- Inhixa is available as standard strength (100mg/ml) pre-filled syringes containing 20mg, 40mg, 60mg, 80mg or 100mg enoxaparin, or as higher strength (150mg/ml) pre-filled syringes containing 120mg or 150mg enoxaparin.

Cost

- Inhixa has the same list price as Clexane. Some clinical commissioning groups (CCGs) receive a lower price for Inhixa making it more cost effective than Clexane.
- 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 doesn't mean it is lower quality.

Efficacy and Safety

- Inhixa can be expected to be **as effective and safe** as Clexane when used appropriately.
- Approval for Inhixa has been granted by the European Medicines Agency (EMA), who have strict regulatory requirements for approving biosimilars to ensure there are no clinically meaningful differences between the biosimilar and the reference (original) medicine in terms of quality, efficacy, safety and immunogenicity profile.
- As a new biological medicine, 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 .
- A UKMi safety assessment report for enoxaparin biosimilars provides further details on safety and comparison to Clexane; available via www.sps.nhs.uk.

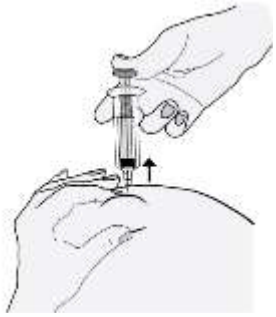
Prescribing and Dispensing

- 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.
- 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 to avoid generic prescribing of enoxaparin.
- Prescribers and pharmacists will need to take care to select the correct product for prescribing or dispensing.
- 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.
- 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. Ensure that patients switching brands receive counselling on differences in administration technique (see below).

Administration

- Practice staff will need to ensure they select the correct product for administration.
- Administration instructions for Inhixa are detailed in the PIL. A video is also available on the company (Techdow Pharma) website (link here).
- Administration is essentially the same as for Clexane, but a key difference lies with the **needle guard**. This is discussed in more detail in the UKMi Safety assessment report detailed above. With Clexane syringes, the needle guard is automatically released and provides a protective cover as the needle is withdrawn from the administration site, but with Inhixa the needle guard 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).

Stage 1: After administration remove the needle by pulling it straight out. Do not release the pressure on the plunger!



Stage 2: Push hard on the plunger. The needle guard, which is in the form of a plastic cylinder, will be activated automatically and it will completely cover the needle.

- 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.
- Another concern is that 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.

Prepared by: Samantha Owen, Principal Pharmacist Critical Evaluation, University Hospital Southampton on 9th November 2017 (updated 14th September 2020)

- All patients should receive training before self-injecting enoxaparin and staff will need to ensure patients are taught administration with the appropriate brand.
- On dispensing either brand, pharmacists should check patients' understanding and capability of safe administration and highlight any concerns to the prescriber.

References/Further information

- NHS England (updated May 2019): "What is a biosimilar Medicine?"
- European Commission (2016): What I need to know about Biosimilar Medicines – Information for patients
- British Biosimilars Association: Facts about biosimilars
- MHRA Drug Safety Update (2008): Biosimilar products
- European Medicines Agency: Biosimilar medicines; Biosimilars in the EU Information Guide for Healthcare Professionals
- UKMi (updated Dec 2018): In Use Product Safety Assessment Report for enoxaparin biosimilars (Inhixa and Arovi)

Company Contact Details

- Inhixa: Techdow Pharma Ltd 01271 334 609
- Clexane: Sanofi 01483 505 515
- Arovi: ROVI Biotech Limited 0203 642 0677

For further advice or information speak to your CCG Medicines Management pharmacy team or the Southampton Medicines Advice Service (023 8120 6908/9; medicinesadvice@uhs.nhs.uk)

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