

To:  
All GP Practices  
Trust Heads of Pharmacy  
Community Pharmacies

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16<sup>th</sup> January 2019

Dear Colleague

## **URGENT CLEXANE<sup>®</sup> 40MG INJECTION SUPPLY ISSUE**

HSCB has been informed that there has been a quality issue with Sanofi's most recent batch of Clexane<sup>®</sup> 40mg injection that was due to arrive in the UK week commencing 7<sup>th</sup> January 2019. It is anticipated that all wholesalers will now be out of stock of Clexane<sup>®</sup> 40mg injection with an anticipated resupply date of week commencing **18<sup>th</sup> February 2019**. This date may be brought forward to end of January/early February if the current batch passes further quality assurance testing.

Clexane<sup>®</sup> is a biological medicine and the latest HSCB generic exception list states that biological medicines (including biosimilar medicines) must be prescribed by brand name  
<http://niformulary.hscni.net/PrescribingNewsletters/generic/unsuitable/Pages/default.aspx>

### ***Alternative options:***

#### **Clexane<sup>®</sup> (Sanofi) Imported stock – available from 23<sup>rd</sup> January 2019**

- Over the past 2 weeks Sanofi have imported Clexane<sup>®</sup> 40mg stock from Italy to help cover an anticipated shortfall in stock. This product is imported under a batch specific variation to the UK and is therefore classed as licensed in the UK.
- Sanofi are working with the MHRA and this product should be available to order from the 23<sup>rd</sup> January 2019. Once available it can be ordered via the usual routes.
- Key differences are as follows:

Comparative table of PREVENTIS and ERIS devices features	CLEXANE ITALY PREVENTIS	CLEXANE UK ERIS
Single use 40mg/0.4ml dose	✓	✓
Blistered pre-filled syringes	✓	✓
Auto-Activated ERIS needle protective sleeve	✗	✓
User activated PREVENTIS needle protective sleeve	✓	✗
Audible click when activating the safety device	✓	✓
Plunger colour	Yellow	White
Number of Syringes per pack	6	10
Pack dimensions (mm)	63 x 86 x 169	138 x 84 x 162

- The most important difference between the Italian and UK preparations is the difference in the needle guard device. To deploy the Preventis<sup>®</sup> needle shield on the Italian syringes, users will need to firmly push the plunger after completing the injection. The user will hear an audible “click” to confirm the activation of the protective sleeve and the protective sleeve will automatically cover the needle. Patients and healthcare professionals will need to be trained on this new device; instructions for use can also be found within the Patient Information Leaflet (PIL). This product will NOT be over-labelled in English but an English PIL will be included in the pack. Artwork, which gives further detail of what the packaging and device looks like, is available at the link detailed below in this letter.

### ***Enoxaparin biosimilar agents:***

#### **Inhixa<sup>®</sup> 4,000 IU (40mg) in 0.4ml solution for injection pre-filled syringe (supplied by Techdow)**

- Techdow supply Inhixa<sup>®</sup> (enoxaparin) and have confirmed that they have sufficient stock of Inhixa<sup>®</sup> 40mg injection to cover the additional demand: <https://www.medicines.org.uk/emc/product/784/smpc>
- If you wish to switch Clexane<sup>®</sup> 40mg to Inhixa<sup>®</sup> please see attached support / training materials and link to online video: <https://www.youtube.com/watch?v=E8AytPojtVI>
- For further support and to arrange a visit with a field director who can provide training on how to use Inhixa<sup>®</sup> please contact: [selina.temperton@uk.techdow.com](mailto:selina.temperton@uk.techdow.com) 07376280709 or [jo.phillips@uk.techdow.com](mailto:jo.phillips@uk.techdow.com) 07540979066.
- Orders for product can be placed via wholesalers.

## **Arovi<sup>®</sup> 4,000 IU (40mg) in 0.4ml pre-filled syringe (supplied by Rovi Biotech)**

- Rovi Biotech supply Arovi<sup>®</sup> (enoxaparin) and have confirmed that they have sufficient Arovi<sup>®</sup> 40mg injection to cover additional demand in primary care.
- If you wish to switch Clexane<sup>®</sup> 40mg to Arovi<sup>®</sup> please see attached supporting / educational material and link to further online material: <https://www.rovi.es/en/biosimilar-de-enoxaparina>
- For any queries or to order training material please contact: Blanca Esteban, [besteban@rovi.com](mailto:besteban@rovi.com) 0203 642 06 77.
- Orders for Arovi<sup>®</sup> can be placed via Alliance Healthcare.

## **Resources**

A number of resources are available to support healthcare professionals manage this shortage of Clexane<sup>®</sup> 40mg at the link below:

<http://www.hscboard.hscni.net/our-work/integrated-care/pharmacy-and-medicines-management/correspondence-pharmacy-medicines-management/prescqipp-newsletters/>

These include:

- How to Inject Inhixa<sup>®</sup>
- Preventis<sup>®</sup> Safety Device: Instructions for Use
- Inhixa<sup>®</sup> :Dosing Chart
- Inhixa<sup>®</sup> :Ordering Information
- Information on imported (Italian) Clexane<sup>®</sup> 40mg artwork
- Arovi<sup>®</sup> :Educational Materials

## **Action Required for GPs**

- Review your current Clexane<sup>®</sup> (enoxaparin) 40mg injection patients and determine if they have sufficient supplies until the next Clexane<sup>®</sup> 40mg stock becomes available – 23<sup>rd</sup> January 2019 for the Italian imported (UK licensed) stock and currently 18<sup>th</sup> February 2019 for further UK Clexane<sup>®</sup> 40mg stock.
- GPs and pharmacies should work closely together to discuss local management options.
- If product is required before 23<sup>rd</sup> January 2019 – use one of the suggested alternatives above and **prescribe by brand**.

### Action Required for Community Pharmacists

- GPs and pharmacies should work closely together to discuss local management options and agree which **brand** should be prescribed.
- If product is required before 23<sup>rd</sup> January 2019 – use one of the suggested alternatives above and ensure patient is adequately counselled and trained on any new device.

Alternative Clexane<sup>®</sup> presentations remain available, however, Sanofi cannot support increased ordering of any other presentations to support the shortfall in 40mg syringes. Pharmacies are asked to continue to order all other strengths in line with historical demands.

If you have any queries about the supply of Clexane<sup>®</sup> 40mg injection please contact your local HSCB Pharmacy Adviser.

Yours sincerely,



**Joe Brogan**  
**Assistant Director of Integrated Care**  
**Head of Pharmacy and Medicines Management**

CC. Cathy Harrison, Acting Chief Pharmaceutical Officer, DoH  
Chris Garland, Principal Pharmaceutical Officer, DoH  
Veranne Lynch, Drug Tariff Co-ordinator, HSCB  
Noel Dunn, Deputy Regional Pharmaceutical Officer, NHSC

#### Contact details for Local Integrated Care Offices:

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