



3 August 2021

Medicine Supply Alert Notice

Clexane[®] (enoxaparin) pre-filled syringes

Priority: Level 2*

Valid until: November 2021

Issue

1. A shortage of the ERIS[™] automatic safety system will impact the availability of several Clexane[®] prefilled syringes (listed below) from September until November 2021:
 - 4000IU (40mg/0.4ml)
 - 6000IU (60mg/0.6ml)
 - 8000IU (80mg/0.8ml)
 - 10,000IU (100mg/1ml)
2. All other Clexane[®] preparations are unaffected and remain available.
3. To mitigate the supply issue during this period, Sanofi will supply Clexane[®] with the PREVENTIS[™] automatic safety system for the affected presentations only. This will be a UK licensed product.
4. Other brands of enoxaparin biosimilars remain available but cannot support an uplift in demand.
5. Organisations who use Clexane[®] should prepare to have syringes with two different safety devices in use across the portfolio and ensure appropriate communication and training of health care professionals and patients is undertaken before September.

Advice and Actions

6. Health Board pharmacy procurement teams affected by this shortage should work with clinical leads and nursing leads, to ensure that by September:
 - a local mitigation plan is agreed, and implementation timed to ensure a sufficient training period and a clear local communication pathway that encompasses all clinical areas and dispensing points impacted;
 - health care professionals who administer Clexane[®] are made aware of the difference in how the two safety devices are activated and receive additional training on the PREVENTIS[™] safety system if required;
 - healthcare professionals who administer or counsel patients in the use of Clexane[®] can determine whether they are dispensing Clexane[®] with the ERIS[™] safety system or the PREVENTIS[™] safety system; and
 - healthcare professionals who counsel patients in the use of Clexane[®] are aware of the difference in how the two safety devices are activated and can confidently counsel patients on the use of each device and issue the relevant patient information pack at initiation of treatment.

7. General Practice and Community Pharmacies who prescribe or dispense Clexane® should ensure that:
- healthcare professionals who prescribe Clexane® are aware of this supply disruption and can advise patients that the safety device they may be familiar with will temporarily be replaced with an alternative; and
 - healthcare professionals who counsel patients in the use of Clexane® are aware of the difference in how the two safety devices are activated and can confidently counsel patients on the use of each device.

Additional Information

8. Sanofi can fully support historic demand, with Clexane® containing the PREVENTIS™ safety device. Further supporting information can be found in the Dear Healthcare Professional (DHCP) letter which accompanies this MSAN (see Annex A) and will also be sent out by Sanofi to their customer base.

Enquiries

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



Direct Healthcare Professional Communication

August 2nd, 2021

Clexane® (enoxaparin sodium) device – Important Information regarding differences between PREVENTIS and ERIS needle guard safety systems

Dear Healthcare Professional,

Sanofi, in agreement with the Medicines and Healthcare products Regulatory Agency, would like to inform you of the following:

Summary

- To ensure continuity of supply of Clexane pre-filled syringes, which are currently provided with the ERIS needle guard safety system, from August 2021, Clexane pre-filled syringes provided with the PREVENTIS safety system will also be available.
- Clexane pre-filled syringes with both ERIS and PREVENTIS safety systems will be in the supply chain simultaneously, so please be vigilant and talk to the patient to ensure that they are familiar with the system being dispensed to them.
- Patients should be informed that the operation of the needle guard safety system in the PREVENTIS device is different to that of the ERIS device.
- After injecting and removing the needle from the injection site, users of the PREVENTIS device will need to firmly push down the plunger and wait for an audible 'click' sound to activate the safety system (unlike the ERIS device where the safety system activates automatically).
- Prescribing and dispensing healthcare professionals should be aware and check whether the patient is familiar with how to administer Clexane with that particular safety system device.
- Training materials for healthcare professionals and patients on how to administer Clexane are available and users should refer to these to ensure correct administration

Background on the safety concern

This Direct Healthcare Professional Communication (DHPC) relates to the following Clexane pre-filled Syringes, which are currently provided with the ERIS needle guard safety system:

- Clexane® Syringes 2,000 IU (20 mg) / 0.2 mL solution for injection in pre-filled syringes
- Clexane® Syringes 4,000 IU (40 mg) / 0.4 mL solution for injection in pre-filled syringes
- Clexane® Syringes 6,000 IU (60 mg) / 0.6 mL solution for injection in pre-filled syringes
- Clexane® Syringes 8,000 IU (80 mg) / 0.8 mL solution for injection in pre-filled syringes
- Clexane® Syringes 10,000 IU (100 mg) / 1.0 mL solution for injection in pre-filled syringes

These products are indicated in adults for:

- Prophylaxis of venous thromboembolic disease in moderate and high-risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery.
- Prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure, respiratory insufficiency, severe infections, or rheumatic diseases) and reduced mobility at increased risk of venous thromboembolism.



- Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery.
- Prevention of thrombus formation in extracorporeal circulation during haemodialysis.
- Acute coronary syndrome:
 - Treatment of unstable angina and Non-ST-segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid.
 - Treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent percutaneous coronary intervention (PCI).

The purpose of this DHPC is to communicate the availability of the PREVENTIS device in addition to the existing ERIS device in the UK and to highlight the differences in the needle guard safety systems (protective sleeve to cover the needle) between the two devices.

The ERIS device is automatically activated upon depression of the plunger on removal of the needle from the injection site. In contrast, after removal of the needle from the injection site the PREVENTIS device requires the plunger to be firmly pushed down and an audible 'click' to be heard to confirm activation of the protective sleeve. Users should be aware of how to inject Clexane using the PREVENTIS device to prevent improper use.

Updated HCP and patient guides are available to support this activity. The Patient Information Leaflet for this product, which includes directions for using the relevant needle guard safety system, will be provided within each box of syringes. It will also be available to download from the eMC website, in the product information associated with Clexane (enoxaparin sodium) pre-filled syringes.

Cartons of Clexane containing a PREVENTIS needle guard safety system will be clearly marked to differentiate from the current stock of Clexane containing the ERIS device. To allow clear differentiation, all future productions of Clexane will be clearly labelled on the carton and Patient Information Leaflet to indicate whether they contain the ERIS or PREVENTIS needle guard safety system. To assist with recognition of the correct drug dose, the colour coding of the cartons and syringe labels used to indicate the different strengths of the ERIS device, will be maintained with Clexane supplied with the PREVENTIS device.

A copy of this letter will also be available on the eMC website www.medicines.org.uk.

Call for Reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

It is easiest and quickest to report ADRs online via the Yellow Card website – <https://yellowcard.mhra.gov.uk/> or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, you can report to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.



When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies, and advanced therapies) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card Scheme.

Suspected adverse reactions should also be reported to Sanofi.

Tel: 0800 090 2314

Email: UK-drugsafety@sanofi.com

Company contact point

Should you have any questions or require additional information, please contact **Medical Information** at Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT

Tel: 0800 035 2525

Email: uk-medicalinformation@sanofi.com

Yours faithfully,

A handwritten signature in black ink, appearing to read "D Woods", written over a white background.

Debbie Woods

Head of Medical
General Medicines UK and Ireland

CERTIFICATE FOR NON-PROMOTIONAL ITEMS (PMCPA)

Version: 2 . 0

Document Number: MAT-GB-2102564

Document Name: DHPC Letter - Clexane Safety Device

Country: United Kingdom

Product: Clexane

Material Type: Mail / e-mail

Material Intent: Non-Promotional

Certification Type: Examination Only

Audience: Healthcare Professionals

Additional Audience:

Intended Use: External Use

Method of Dissemination: Pro-active

Material Owner: Katharina Ecsy

I have examined the final form of the material and in my belief it is in accordance with the requirements of the relevant regulations relating to advertising and this Code, and is a fair and truthful representation of the facts.

Role	Signature
Arunesh Sil - Medical	Date: 26-Jul-2021 21:40:33 GMT+0000