Direct Healthcare Professional Communication

22 May 2023

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

(Minor updates to Direct Healthcare Professional Communication dated 02 August 2021)

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 in the UK, the product is provided with two needle guard safety systems: ERIS and PREVENTIS.
- Clexane pre-filled syringes with both ERIS and PREVENTIS safety systems are 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:

- 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.
- Extended treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of its recurrence in patients with active cancer.
- 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 both Clexane device presentations available in the UK (ERIS and PREVENTIS) and highlight the differences in their needle guard safety systems (protective sleeve to cover the needle).

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, is provided within each box of syringes. It is also 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 are clearly marked to differentiate from Clexane stock containing the ERIS device. To allow clear differentiation, the enclosed Patient Information Leaflet in each carton of Clexane syringes will indicate whether they contain the ERIS or PREVENTIS needle guard safety system. For both devices, to assist with recognition of the correct drug dose, colour coding of cartons and syringe labels is used to indicate the different strengths of Clexane.

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 ▼

You can report via:

- the Yellow Card website (www.mhra.gov.uk/yellowcard)

- the free Yellow Card app available from the Apple App Store or Google Play Store
  some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals
- Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing 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 [such as gene and tissue therapy]) 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,

Debbie Woods
Head of Medical
General Medicines UK and Ireland