Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Clexane 6,000 IU (60 mg) /0.6 ml Solution for Injection in pre-filled syringes

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pre-filled syringe contains enoxaparin sodium 6,000 IU anti-Xa activity (equivalent to 60 mg) in 0.6 ml water for injections.

For the full list of excipients, see section 6.1.

Enoxaparin sodium is a biological substance obtained by alkaline depolymerization of heparin benzyl ester derived from porcine intestinal mucosa.

3 PHARMACEUTICAL FORM

Solution for injection in pre-filled syringes.

Product imported from Belgium
Clear, colourless to yellowish solution, pH value 5.5-7.5.

4 CLINICAL PARTICULARS

As per PA0540/097/006

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/097/006

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

SC injection
Do not mix with other products.

IV (Bolus) Injection (for acute STEMI indication only):
This medicinal product must not be mixed with other medicinal products except those mentioned in SmPC section 4.2 of PA0540/097/006.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.
Diluted solution
Diluted solution should be used immediately

6.4 Special precautions for storage

Do not store above 25 °C. Do not freeze.

6.5 Nature and contents of container

Solution for injection in glass pre-filled syringes fitted with an injection needle (without an automatic safety system).
Supplied in packs of 10 pre-filled syringes.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Pre-filled syringes are ready for immediate use. For method of administration see SmPC section 4.2 of PA0540/097/006.
Use only clear, colourless to yellowish solutions.
Pre-filled syringes are supplied without an automatic safety system. The instructions for use are presented in the package leaflet.
Each syringe is for single use only. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/477/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th November 2021

10 DATE OF REVISION OF THE TEXT