

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Clexane Syringes 100mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Enoxaparin sodium 40mg (equivalent to 4,000 IU anti-Xa activity) in 0.4ml water for injections

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection

Product sourced from Spain:

Sterile clear pyrogen-free solution for injection contained in ready-to-use pre-filled syringes.

4 CLINICAL PARTICULARS

As per PA0540/097/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/097/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections.

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

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.

Any unused product should be discarded immediately after use.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Pre-filled syringes in packs of 10.

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

See “Posology and method of administration”.

Each syringe is for single use. Any unused product should be discarded.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/251/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th March 2012

10 DATE OF REVISION OF THE TEXT

December 2014