

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

innohep 4,500 IU, solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tinzaparin sodium 10,000 anti-Factor Xa IU/ml

Excipient(s) with known effect: Sodium (in total < 23 mg/mL).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

Product imported from Belgium:

Colourless or slightly yellow aqueous solution.

4 CLINICAL PARTICULARS

As per PA0046/060/007

5 PHARMACOLOGICAL PROPERTIES

As per PA0046/060/007

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium acetate trihydrate

Sodium hydroxide (for pH adjustment)

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 portion of the contents not used at once should be discarded. The liquid may turn yellow in storage but this does not affect product quality.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Prefilled unit dose syringe made of colourless glass assembled with a stainless steel needle, sealed with a plunger stopper made of chlorobutyl rubber, a needle shield protective cap made of styrene butadiene rubber (latex-free) and a plastic needle safety device.

Syringe contains 0.45 ml of solution. Supplied in packs of 10 syringes.

6.6 Special precautions for disposal

Do not use if cloudiness or particles are visible in the liquid. 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

PPA0465/499/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd March 2023

10 DATE OF REVISION OF THE TEXT