# 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 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 is the date shown on the container and outer carton of the product as marketed 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 and other handling**

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**

IMED Healthcare Ltd.,
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/251/002

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 21st November 2025

**10 DATE OF REVISION OF THE TEXT**