Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

innohep 14,000 IU in 0.7 ml, Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tinzaparin sodium 20,000 anti-Factor Xa IU/ml.

Excipients with known effect: Sodium metabisulphite
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for Injection.

Product imported from Greece:
Colourless or slightly yellow aqueous solution.

4 CLINICAL PARTICULARS

As per PA0046/060/011

5 PHARMACOLOGICAL PROPERTIES

As per PA0046/060/011

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium metabisulphite
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

Do not store above 25°C.
For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Prefilled variable dose graduated syringe with a plastic needle safety device.
Syringe contains 0.7ml 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

LTT Pharma Limited
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Worcestershire B98 0RE,
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/134/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th January 2015.

10 DATE OF REVISION OF THE TEXT