

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

innohep 10,000 IU in 0.5 ml, solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tinzaparin sodium 20,000 anti-Factor Xa IU/mL

Excipient(s) with known effect

Sodium metabisulfite (E223) and sodium

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 PA0046/060/010

5 PHARMACOLOGICAL PROPERTIES

As per PA0046/060/010

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium metabisulfite

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 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.

6.5 Nature and contents of container

1 ml prefilled variable dose graduated syringe made of colourless glass assembled with a needle, sealed with a plunger stopper, a needle shield protective cap and a plastic needle safety device.

Syringe contains 0.5 ml 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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/265/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th January 2018

10 DATE OF REVISION OF THE TEXT

October 2019