LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Innohep, solution for injection, pre-filled syringe 8000 anti Xa IU
Innohep, solution for injection, pre-filled syringe 12 000 anti Xa IU
Innohep, solution for injection, pre-filled syringe 16 000 anti Xa IU
(tinzaparin sodium)

Asp no: 2014-0574, 2014-0575 and 2014-0576

This module reflects the scientific discussion for the approval of Innohep. The procedure was finalised on 2015-04-22. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Innohep, 8000 anti-Xa IU, 12 000 anti-Xa IU and 16 000 anti-Xa IU, solution for injection, pre-filled syringe, is an extension application made according to Article 8(3) of Directive 2001/83/EC, known active substance. The active substance tinzaparin sodium is the same as in Innohep, 20 000 anti-Xa IU/ml, solution for injection, marketed by LEO Pharma AB since 1994. No Public Assessment Report is available for Innohep, 20 000 anti-Xa IU/ml, solution for injection.

The applicant LEO Pharma AB applies through the National Procedure in Sweden.

For approved indications, see the Summary of Product Characteristics.

For recommendations to the marketing authorisation not falling under Article 21a/22 of Directive 2001/83 and conditions to the marketing authorisation pursuant to Article 21a or 22 of Directive 2001/83/EC to the marketing authorisation, please see section VI.

II. QUALITY ASPECTS

II.1 Drug Substance

The structure of the drug substance has been adequately proven and its physico-chemical properties are sufficiently described.

The manufacture of the drug substance has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The drug substance specification includes relevant tests and the limits for impurities and degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies support the shelf-life of the drug substance.

II.2 Medicinal Product

The medicinal product is formulated using excipients listed in section 6.1 in the Summary of Product Characteristics.

The manufacturing process has been sufficiently described and critical steps identified.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies have been performed and data presented support the shelf life and special precautions for storage claimed in the Summary of Product Characteristics, sections 6.3 and 6.4.

III. NON-CLINICAL ASPECTS

III.1 Introduction

The non-clinical pharmacodynamics, pharmacokinetics and toxicology of tinzaparin are considered well known. Innohep showed low toxicity in the non-clinical studies performed and the most important finding seen were bleedings at the high doses used.

III.2 Ecotoxicity/environmental risk assessment

Tinzaparin is a carbohydrate and therefore considered unlikely to result in significant risk to the environment.

III.3 Discussion on the non-clinical aspects

There are no concerns regarding the use of Innohep from a non-clinical point of view.

IV. CLINICAL ASPECTS

IV.1 Introduction

Innohep is indicated for;
”Behandling av djup ventrombos och lungemboli när trombolytisk behandling eller kirurgi inte är aktuell hos vuxna.
Patienter med cancersjukdom: Förlängd behandling av symtomatisk venös tromboembolism samt prevention av återfall hos vuxna.
Trombosprofylax vid allmän och ortopedisk kirurgi hos vuxna.
Trombosprofylax - antikoagulation vid extrakorporeal cirkulation av blod under hemodialys och hemofiltration hos vuxna.”

IV.2 Pharmacokinetics

There are no new pharmacokinetic data and none are required for this type of application.
The pharmacokinetic characteristics of Innohep are well known.

IV.3 Clinical efficacy and safey

The clinical experience with Innohep is well established, and no new data has been submitted, and is not needed for this application. From a clinical perspective the application is recommended for approval.

V. USER CONSULTATION

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PIL was Swedish.
The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The benefit/risk ratio is considered positive and Innohep, 8000 anti Xa IU, 12 000 anti Xa IU and 16 000 anti Xa IU, solution for injection, pre-filled syringe is recommended for approval.

List of recommendations not falling under Article 21a/22 of Directive 2001/83 in case of a positive benefit risk assessment

N/A

List of conditions pursuant to Article 21a or 22 of Directive 2001/83/EC

N/A

VII. APPROVAL

Innohep, 8000 anti Xa IU, 12 000 anti Xa IU and 16 000 anti Xa IU, solution for injection, pre-filled syringe was approved in the national procedure on 2015-04-22.

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Public Assessment Report – Update

Scope	Procedure number	Product Information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached
						Y/N (version)

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