LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Statraxen
(tranexamic acid)

Asp no: 2013-1592

This module reflects the scientific discussion for the approval of Statraxen. The procedure was finalised on 2014-12-04. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Statraxen, 100 mg/ml, solution for injection, is a generic application made according to Article 10(1) of Directive 2001/83/EC. The applicant, Stasisport Pharma, applies for a marketing authorisation in Sweden through the National Procedure.

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Cyklokapron, 500mg/5ml, solution for injection authorised in UK since 1987, with Pfizer Limited as marketing authorisation holder.

For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Statraxen is presented in the form of solution for injection containing 100 mg/ml of tranexamic acid. The excipients are sodium hydroxide, hydrochloric acid and water for injection. The solution is filled in glass ampoules.

II.2 Drug Substance

Tranexamic acid has a monograph in the Ph Eur.

Tranexamic acid is a white or almost white crystalline powder which is freely soluble in water and in glacial acetic acid, practically insoluble in acetone and in ethanol. The structure of tranexamic acid has been adequately proven and its physico-chemical properties sufficiently described. Relevant information on chirality is presented. The route of synthesis has been adequately proven.

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

Stability studies confirm the retest period.

II.3 Medicinal Product

Statraxen 100 mg/ml solution for injection is formulated using excipients described in the current Ph Eur. None of the raw materials used in the product are a risk TSE.

The product development has taken into consideration the physico-chemical characteristics of the active substance.
The manufacturing process has been sufficiently described and critical steps identified. Results from the process validation studies confirm that the process is under control and ensure both batch to batch reproducibility and compliance with the product specification.

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 under ICH conditions have been performed and data presented support the shelf life claimed in the SPC, with no special storage precautions.

III. NON-CLINICAL ASPECTS

III.1 Discussion on the non-clinical aspects

Since this product has been shown to be essentially similar and refer to a product approved based on a full application with regard to preclinical data, no further such data have been submitted or are considered necessary.

IV. CLINICAL ASPECTS

IV.1 Pharmacokinetics

No bioequivalence studies have been conducted. The applied product is to be administered as an aqueous intravenous solution containing the same active substance as the currently authorised product. None of the excipients are known to interact with the drug substance. For this type of product, no bioequivalence studies are required according to the Guideline on the investigation of Bioequivalence (CHMP/QWP/EWP/1401/98 Rev. 1).

IV.2 Discussion on the clinical aspects

Since this product has been shown to be essentially similar and refer to a product approved based on a full application with regard to clinical efficacy/safety data, no further such data have been submitted or are considered necessary.

V. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

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 English.
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.

The risk/benefit ratio is considered positive and Statraxen, 100 mg/ml, solution for injection is recommended for approval.

VI. APPROVAL

Statraxen, 100 mg/ml, solution for injection was approved in the national procedure on 2014-12-04.

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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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