LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

# Public Assessment Report
# Scientific discussion

# Pilexam
# (tranexamic acid)

# SE/H/1327/01/DC

**This module reflects the scientific discussion for the approval of Pilexam. The procedure was finalised at 2013-10-29. For information on changes after this date please refer to the module 'Update'.**

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# I. INTRODUCTION

The application for Pilexam, 100 mg/ml solution for injection, is a generic application made according to Article 10(1) of Directive 2001/83/EC. The applicant, Pilum Pharma AB, applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and DK and NO as concerned member states (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Cyklokapron, 100 mg/ml, solution for injection, authorised in Sweden since 1969, with Pfizer AB as marketing authorisation holder.

For approved indications, see the Summary of Product Characteristics.

# II. QUALITY ASPECTS

## II.1 Introduction

Pilexam is presented in the form of a solution for injection containing 100 mg of tranexamic acid. The only excipient is water. The solution for injection 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 practically insoluble in ethanol. The structure of tranexamic acid has been adequately proven and its physico-chemical properties sufficiently described. Relevant information on is presented. The route of synthesis has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

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 under ICH conditions have been conducted and the data provided are sufficient to confirm the retest period.

## II.3 Medicinal Product

Pilexam is formulated using excipients described in the current Ph. Eur. All raw materials used in the product has demonstrated compliance with Commission Directive 2003/63/EC and the NfG on Minimising the risk of transmitting Animal Spongiform Encephalopathy Agents via human and veterinary medicinal products (EMEA/410/01).

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

The applied product is to be administered as an aqueous intravenous solution containing the same active substance as the currently authorised product. Water is the only excipient in both the applied product and the reference product. 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).

The pharmacokinetic documentation is sufficient.

## 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
A user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of a bridging report making reference to Tranexamic acid 100 mg/ml solution for injection, UK/H/5039/001/DC (bridging of content) and Encapia 200 mg film coated tablets, NL/H/2497/001/DC (bridging of layout). The bridging report submitted by the applicant has been found acceptable.

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

# VI. APPROVAL

The Decentralised procedure for Pilexam, 100 mg/ml, solution for injection, was successfully finalised on 2013-10-29.

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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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