LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Lecrolyn sine
(sodium cromoglicate)

SE/H/1402/01/DC

This module reflects the scientific discussion for the approval of Lecrolyn sine. The procedure was finalised on 2015-02-24. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Lecrolyn sine, 40 mg/ml, eye drops, solution, is a hybrid application made according to Article 10(3) of Directive 2001/83/EC. The applicant, Santen Oy, applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and DK, EE, FI, IS, LT 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 Lomudal, 40 mg/ml, eye drops, solution in single-dose container authorised in Sweden since 1992, with Sanofi-Aventis AB as marketing authorisation holder.

II. QUALITY ASPECTS

II.1 Introduction

Lecrolyn sine is presented in the form of eye drops, solution containing 40 mg/ml of sodium cromoglicate. The excipients are disodium edetate, glycerol, polyvinyl alcohol and water for injections. The eye drops are filled in multidose dropper containers.

II.2 Drug Substance

Sodium cromoglicate has a monograph in the Ph Eur.

Sodium cromoglicate is a white or almost white, hygroscopic, crystalline powder which is soluble in water but practically insoluble in ethanol (96%). The structure of sodium cromoglicate has been adequately proven and its physico-chemical properties sufficiently described. Relevant information on polymorphism is presented. The route of synthesis has been adequately described.

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

Lecrolyn sine, 40 mg/ml, eye drops, solution is formulated using excipients described in the current Ph Eur. None of the excipients used in the manufacturing is of animal or human origin.

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, when stored below 25°C/do not freeze.

III. 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

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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 Lecrolyn sine, 40 mg/ml, eye drops, solution, is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Lecrolyn sine, 40 mg/ml, eye drops, solution, was successfully finalised on 2015-02-24.

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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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