LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Lidocaine Grindeks
(lidocaine)

SE/H/982/01/DC

This module reflects the scientific discussion for the approval of Lidocaine Grindeks. Please note that the marketing authorisation was first approved with the name "Lidocaine Mimer" and therefore this name is used throughout the document. The procedure was finalised at 2011-04-14. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Mimer Medical has applied for a marketing authorisation for “Lidocaine Mimer 20 mg/ml solution for injection” claiming essential similarity to Xylocain 20 mg/ml solution for injection marketed in Sweden by Astra Zencea AB. The product contains lidocaine hydrochloride as active substance. For approved indications see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Lidocaine Mimer is presented in the form of a solution for injection containing 20 mg/ml of lidocaine hydrochloride. The excipients are sodium chloride, sodium hydroxide and water for injections. The solution for injection is filled in clear colourless glass ampoules.

II.2 Drug Substance

Lidocaine hydrochloride has a monograph in the Ph Eur.

Lidocaine hydrochloride is a white or almost white crystalline powder which is very soluble in water and freely soluble in ethanol. The structure of lidocaine hydrochloride has been adequately proven and its physico-chemical properties sufficiently described. Relevant information on the drug substance 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

Lidocaine Mimer solution for injection 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, when stored protected from light.

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

Lidocaine Mimer is an aqueous solution for parenteral administration and it has the same qualitative and quantitative composition as the reference product Xylocain. Hence, a bioequivalence study is not needed.

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 Latvian.
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 “Lidocaine Mimer 20 mg/ml solution for injection” is recommended for approval.

VI. APPROVAL

The Mutual recognition/Decentralised procedure for “Lidocaine Mimer 20 mg/ml solution for injection” was successfully finalised on 2011-04-14.

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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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