LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Lidocaine Accord
(lidocaine hydrochloride)

SE/H/1430/01-02/DC
AspNr. 2014-0466, 2014-0467

This module reflects the scientific discussion for the approval of Lidocaine Accord. The procedure was finalised on 2015-06-17. For information on changes after this date please refer to the module 'Update'.

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.mpa.se E-mail: registrator@mpa.se

I. INTRODUCTION

The application for Lidocaine Accord, 10 mg/ml and 20 mg/ml, solution for injection, is a generic application made according to Article 10(1) of Directive 2001/83/EC. The applicant, Accord Healthcare Ltd, applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and AT, BE, BG, CY, DE, DK, EE, ES, FI, FR, IT, LT, LV (only for 20 mg/ml), NL, NO, PL and PT as concerned member states (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Xylocain, 10 mg/ml, solution for injection and Xylocain, 20 mg/ml, solution for injection, authorised in Sweden since 1987, with AstraZeneca AB as marketing authorisation holder.

For approved indications, see the Summary of Product Characteristics.

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 confirm the retest period.

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 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 were included for this application. Lidocaine Accord 10mg/ml and 20mg/ml are solutions for parenteral administration, containing the same active substance in the same concentration and the same excipients as the reference product. Thus, the absence of bioequivalence studies is considered acceptable for this product.

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.

IV.3 Risk Management Plan

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Lidocaine Accord.

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Lidocaine Accord.

Safety specification

Summary table of safety concerns as approved in RMP

Important identified risks	Cardiac toxicity CNS toxicity Use in patients with hypersensitivity to local anaesthetic of the amide type or to any of the excipients
Important potential risks	Serious adverse reactions associated with local anaesthetic procedure Use in patients with acute porphyria Use during the pregnancy Genotoxicity/carcinogenicity of 2,6-dimethylaniline in short term intermittent use
Missing information	None

Pharmacovigilance Plan

Routine pharmacovigilance is suggested and no additional pharmacovigilance activities are proposed by the applicant, which is endorsed.

Risk minimisation measures

Routine risk minimisation is suggested and no additional risk minimisation activities are proposed by the applicant, which is endorsed.

V. 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 the content to Lidocaine Hydrochloride 1% and 2% w/v Solution for Injection leaflet that was assessed and accepted. RMS requested an update in some sections to approved Lidicaine Grindeks which was user tested and approved in SE/H/982. The bridging of layout was on the product Zoledronic acid Accord 4 mg/5 ml solution for injection, EMEA/H/C/2667. The bridging report submitted by the applicant has been found acceptable.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the generic product, Lidocaine Accord, is found adequate. There are no objections to approval of product name, from a non-clinical and clinical point of view. The product information is acceptable. The absence of bioequivalence studies is considered acceptable for this product.

The application is therefore 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

The Mutual recognition/Decentralised procedure for Lidocaine Accord, 10 mg/ml and 20 mg/ml, solution for injection, was positively finalised on 2015-06-17.

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

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)

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.mpa.se E-mail: registrator@mpa.se