LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Oxymimer
(oxytocin)

SE/H/961/01-02/DC

This module reflects the scientific discussion for the approval of. The procedure was finalised 2010-09-07. 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 Oxymimer solution for injection and infusion, 8,3 microgram/ml and 16,7 micrograms/ml, claiming essential similarity to Syntocinon, 5 and 10 IU/ml solution marketed in UK by Alliance Pharmaceuticals Ltd. The product contains oxytocin as active substance. For approved indications see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Oxymimer are presented in the form of a solution for injection and infusion containing 8,3 or 16,7 microgram of oxytocin which corresponds to 5 or 10 IU respectively. The excipients are chlorobutanol hemihydrate, acetic acid and water for injections. The solution is filled in transparent glass ampoules.

II.2 Drug Substance

Oxytocin has a monograph in the Ph Eur.

Oxytocin is a white or almost white fluffy powder which is very soluble in water. The structure of oxytocin 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

Oxymimer solution for injection and infusion 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 below 25 °C.

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 clinical efficacy/safety data, no further such data have been submitted or are considered necessary.

IV. CLINICAL ASPECTS

IV.1 Pharmacokinetics

Following injection oxytocin is distributed throughout the extracellular fluid. Oxytocin has a plasma half-life only of about few minutes, which is decreased in late pregnancy and during lactation. Its rapid removal from plasma is accomplished largely by the kidney and the liver. Only small amounts are excreted in urine unchanged.

According to „Note for guidance on the investigation of bioavalability and bioequivalence“ (CHMP/EWP/QWP/1401/98), the applicant is not requested to produce a bioequivalence study if the product is to be administered as an aqueous intravenous solution containing the same active substance in the same concentration as the currently authorised product. Therefore comparative bioequivalence studies have not been performed with proposed Oxytocin injection 8,3 microgram/ml and 16,7 micrograms/ml, which is considered appropriate.

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 the application for Oxymimer solution for injection and infusion, 8,3 microgram/ml and 16,7 micrograms/ml is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Oxymimer solution for injection and infusion, 8,3 microgram/ml and 16,7 micrograms/ml was successfully finalised 2010-09-07.

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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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