LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report

Scientific discussion

Oxaliplatin Vianex 5 mg/ml
Oxaliplatin

SE/H/960/01/MR

This module reflects the scientific discussion for the approval of Oxaliplatin Vianex 5 mg/ml powder for solution for infusion. The procedure was finalised on 27 October 2010, day 90 of the procedure. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Vianex S.A., Greece has applied for a marketing authorisation for Oxaliplatin Vianex 5 mg/ml powder for solution for infusion claiming essential similarity to Eloxatine 5 mg/ml powder for solution for infusion previously marketed in Sweden/ the EU by sanofi-aventis AB, Sweden. The product contains oxaliplatin as active substance. For approved indications see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Oxaliplatin Vianex 5 mg/ml is presented in the form of a powder for solution for infusion. The only excipient is lactose monohydrate. The product is filled in glass injection vials.

II.2 Drug Substance

The active substance oxaliplatin has a monograph in the Ph.Eur.

Oxaliplatin is a white to almost white, crystalline powder which is slighty soluble in water. The structure of oxaliplatin has been adequately proven and its physico-chemical properties sufficiently 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

Oxaliplatin Vianex 5 mg/ml powder for solution for infusion is formulated using excipients described in the current Ph Eur. The only excipient is lactose monohydrate. The raw material 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 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

As the product after reconstitution is an aqueous solution for intravenous infusion, a bioequivalence study is not necessary to demonstrate essential similarity to the originator product.

IV.2 Discussion on the clinical aspects

Since this product from a quality point of view has been shown to be essentially similar to 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 Danish.
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 Oxaliplatin Vianex 5 mg/ml powder for solution for infusion is recommended for approval.

VI. APPROVAL

The Mutual Recognition Procedure for Oxaliplatin Vianex 5 mg/ml powder for solution for infusion was successfully finalised on 2010-10-27.

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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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