LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Vancosan
(vancomycin hydrochloride)

SE/H/975/01-02/DC

This module reflects the scientific discussion for the approval of Vancosan.The procedure was finalised at 2011-03-10. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

CNP Pharma GmbH has applied for a marketing authorisation for Vancosan, 500 and 1000 mg, powder for solution for infusion claiming essential similarity to Vancomycin FarmaPlus 500 and 1000 mg, powder for solution for infusion marketed Norway by FarmaPlus AS. The product contains vancomycin hydrochloride as active substance. For approved indications see the Summary of Product Characteristics. The reference product used in the bio-equivalence study is Vancomycin FarmaPlus 500 and 1000 mg, powder for solution for infusion marketed by FarmaPlus AS in Norway.

II. QUALITY ASPECTS

II.1 Introduction

The finished product Vancosan powder for solution for infusion contain lyophilised Vancomycin hydrochloride powder as the only component. The product is presented in two strengths: 500 mg or 1000 mg vancomycin (with regards to the free base). The powder is packaged in colourless glass vials with grey bromobutyl rubber stoppers, sealed with aluminium/polypropylene caps.

II.2 Drug Substance

The active pharmaceutical ingredient Vancomycin hydrochloride is a white or almost white, hygroscopic powder freely soluble in water. The drug substance is described in a monograph published in the European Pharmacopeia.

Vancomycin hydrochloride is obtained from manufacturers that hold a Certificate of Suitability issued by the European Directorate for the Quality of Medicines (EDQM). The certificates verify that the substance is suitably controlled by the current version of the monograph *Vancomycin hydrochloride* no. 1058 of the European Pharmacopeia.

The manufacturers have declared the use of materials of animal origin in the manufacturing process. It has been confirmed that the materials comply with the Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMEA/410/01 as revised).

The release specification includes relevant tests and the limits for impurities/degradation products have been justified. All tests of the specification are performed using validated analytical methods.

The stability of the drug substance has been evaluated by the EDQM. A suitable re-test period has been set in accordance with the Certificates of Suitability.

II.3 Medicinal Product

The finished product contains lyophilised Vancomycin hydrochloride powder as the only component.

Physico-chemical characteristics of the drug substance, such as solubility, hygroscopic properties and stability in aqueous solutions, were taken into consideration during product development.

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 release and shelf-life specifications are considered appropriate to control the quality of the finished product in relation to its intended purpose. All analytical methods have been successfully validated.

Stability studies under ICH conditions have been performed and the data presented support the shelf-life claimed in the Summary of Characteristics (SmPC). Sufficient stability data have also been presented regarding reconstituted solutions prepared with diluents specified in the SmPC.

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

Vancosan is to be administered as an aqueous intravenous solution containing the same active substances in the same concentrations as the currently authorised product. No bioequivalence studies are required for this type of product according to Note for guidance on the investigation of bioavailability and bioequivalence (CPMP/EWP/QWP/1401/98 and the applicant has submitted none.

IV.2 Discussion on the clinical aspects

Since this product has been shown to be essentially similar 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 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 "Vancosan, 500 and 1000 mg, powder for solution for infusion" is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Vancosan, 500 and 1000 mg, powder for solution for infusion was successfully finalised on 2011-03-10.

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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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