LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Pantoprazol Campus
(pantoprazole sodium sesquihydrate)

This module reflects the scientific discussion for the approval of Pantoprazol Campus. The procedure was finalised at 2010-11-26. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

CampusPharma AB has applied for a marketing authorisation for Pantoprazol Campus, 40 mg, powder for solution for injection/infusion claiming essential similarity to Pantoloc, 40 mg, powder for solution for injection marketed in Sweden by Nycomed AB. The product contains pantoprazole sodium sesquihydrate as active substance. For approved indications see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Pantoprazol Campus is presented in the form of a powder for solution for injection/infusion containing pantoprazole sodium sesquihydrate which corresponds to 40 mg pantoprazole. The excipients are disodium edetate and sodium hydroxide. The powder is filled in glass vials.

II.2 Drug Substance

Pantoprazole sodium sesquihydrate has a monograph in the Ph Eur.

Pantoprazole sodium sesquihydrate is a white or almost white powder which is very soluble in methanol, freely soluble in water and ethanol and practically insoluble in methylene chloride. The structure of pantoprazole sodium sesquihydrate has been adequately proven and its physico-chemical properties sufficiently described. Relevant information on polymorphism and chirality 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. Batch analysis data for two more batches of drug substance tested by the product manufacturer is requested.

Stability studies under ICH conditions have been conducted and the data provided are sufficient to confirm the retest period.

II.3 Medicinal Product

Pantoprazol Campus, 40 mg, powder for solution for injection/infusion is formulated using excipients described in the current Ph. Eur. All raw materials used in the product are of vegetable origin.

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, with the storage precaution “Keep the vial in the outer carton in order to protect 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

Pantoprazole Campus 40 mg, powder for solution for injection/infusion is administered as an aqueous intravenous solution containing the same active substance in the same concentration as the reference product. Thus, in accordance with the Note for Guidance on the Investigation of Bioavailability and Bioequivalence (CPMP/EWP/QWP/1401/98), the applicant is not required to submit a bioequivalence study.

IV.2 Risk Management Plan

No specific risk management plan has been provided. No safety concerns requiring additional risk minimisation activities have been identified. Routine pharmacovigilance procedures are considered sufficient.

IV.3 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

User testing has not been performed.

User testing is not required for national applications in Sweden for medical products which are exclusively given by health care professionals at hospitals.

The risk/benefit ratio is considered positive and Pantoprazol Campus, 40 mg, powder for solution for injection/infusion is recommended for approval.

VI. APPROVAL

Pantoprazol Campus, 40 mg, powder for solution for injection/infusion was approved in the national procedure on 2010-11-26.

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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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