LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Esomeprazol Hospira
(esomeprazole)

SE/H/1304/01/DC

This module reflects the scientific discussion for the approval of Esomeprazol Hospira. The procedure was finalised at 2014-07-03. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Hospira UK Limited has applied for a marketing authorisation for Esomeprazol Hospira, 40mg, powder for solution for infusion/injection, claiming essential similarity to Nexium, 40 mg, pulver till injektions-/infusionsvätska, lösning, marketed in Sweden by AstraZeneca AB. The product contains esomeprazole as active substance. For approved indications see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Esomeprazol Hospira is presented in the form of a powder for solution for injection-infusion containing 42.5 mg of esomeprazole sodium, which corresponds to 40 mg of esomeprazole. The excipients are disodium edetate (dihydrate) and sodium hydroxide. The powder for solution for injection-infusion is filled in glass vials.

II.2 Drug Substance

Esomeprazole sodium does not have a monograph in the Ph Eur.

Esomeprazole sodium is a white to cream coloured powder which is freely soluble in water. The structure of esomeprazole sodium has been adequately proven and its physico-chemical properties sufficiently described. Relevant information on 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.

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

II.3 Medicinal Product

Esomeprazol Hospira, powder for solution for injection-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, such as stability.

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 in the original container.

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

Both Esomeprazol Hospira and the reference product are to be administered as aqueous intravenous solutions. Both products also contain the same active substance in the same concentration. The qualitative composition of Esomeprazole Hospira is the same as the reference product. In accordance with the Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1) no bioequivalence studies are required.

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 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 Esomeprazol Hospira, 40mg, powder for solution for infusion/injection, is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Esomeprazol Hospira, 40 mg, powder for solution for infusion/injection, was successfully finalised on 2014-07-03.

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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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