LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Valsartan Sandoz
(Valsartan)

SE/H/813/01-04/DC

This module reflects the scientific discussion for the approval of Valsartan Sandoz. The procedure was finalised at 2010-04-28. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Sandoz A/S, Denmark has applied for a marketing authorisation for Valsartan Sandoz, film-coated tablets, 40, 80, 160 and 320 mg claiming essential similarity to Diovan, capsules, 80 mg marketed in the EU by Novartis Pharma GmbH. The product contains valsartan as active substance. For approved indications see the Summary of Product Characteristics. No bioequivalence studies have been performed.

II. QUALITY ASPECTS

II.1 Introduction

Valsartan Sandoz is presented in the form of film-coated tablets containing 40, 80, 160 or 320 mg of valsartan. The excipients are microcrystalline cellulose, crospovidone, magnesium stearate, colloidal anhydrous silica and different coating premixes containing hypromellose, titanium dioxide, macrogol, iron oxide yellow, iron oxide red or iron oxide black. The film-coated tablets 40, 80 and 160 mg are packed in PVC/PVdC/Al blister packs (Duplex or DPX), PVC/PE/PVdC/Al blister packs (Triplex or TPX) or PA/Al/PVC/Al blister packs (Alu/Alu). For the 320 mg strength the packaging is PVC/PVdC/Al blister packs (Duplex or DPX) or PA/Al/PVC/Al blister packs.

II.2 Drug Substance

Valsartan has a monograph in the Ph Eur, valid from January 2010.

Valsartan is a white or almost white, hygroscopic powder which is practically insoluble in water, freely soluble in anhydrous ethanol, sparingly soluble in methylene chloride. The structure of valsartan 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.

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

II.3 Medicinal Product

Valsartan Sandoz is formulated using excipients described in the current Ph Eur, except for the iron oxides, which are controlled according to acceptable in house specifications. 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 poor aqueous solubility and hygroscopic properties.

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 30 °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 preclinical data, no further such data have been submitted or are considered necessary.

IV. CLINICAL ASPECTS

IV.1 Pharmacokinetics

No bioequivalence studies have been performed. The applicant states that the products applied for are identical to the corresponding formulations of the originator.

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

A user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of a bridging report making reference to Diovan 320 mg (and a focus test on Diovan 160 mg), SE/406/06/II068, The layout is in accordance with the HEXAL AG, DE/H/769/DC, DE/H/859-860/DC, DE/H/717-719/MR, NL/H/355/01-03 and DE/H/1226-1227/001-003.
The bridging report submitted by the applicant has been found acceptable.

The risk/benefit ratio is considered positive and Valsartan Sandoz, film-coated tablets, 40, 80, 160 and 320 mg is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Valsartan Sandoz, film-coated tablets, 40, 80, 160 and 320 mg was successfully finalised on 2010-04-28.

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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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