LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Zolpidem Vitabalans
(zolpidem tartrate)

SE/H/969/01/DC

This module reflects the scientific discussion for the approval of Zolpidem Vitabalans. The procedure was finalised at 2011-03-16. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Vitabalans Oy has applied for a marketing authorisation for Zolpidem Vitabalans, film-coated tablet, 10 mg, claiming essential similarity to Stilnoct, film-coated tablet, 10 mg marketed in Sweden by Sanofi-Aventis Oy. The product contains zolpidem tartrate as active substance. For approved indications see the Summary of Product Characteristics. The reference product used in the bio-equivalence study is Stilnoct, film-coated, 10 mg tablet marketed by Sanofi-Aventis Oy in Finland.

II. QUALITY ASPECTS

II.1 Introduction

Zolpidem Vitabalans is presented in the form of film-coated tablets containing 10 mg of zolpidem tartrate. The excipients in the tablet core are cellulose microcrystalline, calcium hydrogen phosphate dehydrate, silica colloidal anhydrous, sodium starch glycolate, magnesium stearate. The tablet coating contains polydextrose, hypromellose, titanium dioxide and macrogol..The tablets are packed in PVC/Al blisters.

II.2 Drug Substance

Zolpidem tartrate has a monograph in the European Pharmacopoeia (Ph.Eur.).

Zolpidem tartrate is a white or almost white, hygroscopic, crystalline powder which is slightly soluble in water, sparingly soluble in methanol, practically insoluble in methylene chloride. The structure of zolpidem tartrate has been adequately proven and its physico-chemical properties sufficiently described. The route of synthesis has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The active substance specification and the analytical methods applied are in line with the European Pharmacopoeia monograph for zolpidem tartrate.

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

II.3 Medicinal Product

Zolpidem Vitabalans, film-coated tablet, 10 mg, is formulated using excipients described in the current Ph Eur, except for polydextrose a tablet coating component is of FCC (Food Chemical Codex) standard. 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 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

To support the application, the applicant has submitted one single-dose bioequivalence study performed under fasting conditions. The study design is considered acceptable. AUC_{0-t} and C_{max} the 90% confidence interval for the ratio of the test and reference products fell within the conventional acceptance range of 80.00-125.00%. Based on the submitted bioequivalence study, Zolpidem Vitabalans is considered bioequivalent with Stilnoct.

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 language used for the purpose of user testing the PIL was Czech.

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 Zolpidem Vitabalans, 10 mg, film-coated tablet is recommended for approval.

VI. APPROVAL

Decentralised procedure for Zolpidem Vitabalans, 10 mg, film-coated tablet, was successfully finalised on 2011-03-16.

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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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