LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Colecalciferol Meda
(cholecalciferol)

SE/H/1368/01/DC

This module reflects the scientific discussion for the approval of Colecalciferol Meda. The procedure was finalised at 2014-06-12. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Colecalciferol Meda, tablet, 800 IU (20 microgram), is submitted in accordance with Article 10a of Directive 2001/83/EC, as a well-established use application. The applicant, Meda AB, applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and IS as concerned member state (CMS).

The application is a duplicate to the already approved product Divisun SE/H/1122/01/DC. A duplicate application is defined by reference to the first application with the same dossier (Module 1, 2, 3, 4 and 5) and the same legal basis according to CMDh. The trade name and the Marketing Authorisation Holder (MAH) might be different. The product information should be harmonised, including the same pack sizes for all duplicates.

For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Colecalciferol Meda is presented in the form of tablets containing colecalciferol (vitamin D_3) 800 IU (equivalent to 20 microgram vitamin D_3). The excipients are Pregelatinzed maize starch, Isomalt (E 953), Magnesium stearate, Sucrose, Sodium ascorbate, Triglycerides, medium chain, Silica, colloidal anhydrous, Sodium starch octenyl succinate (E 1450) and All-rac-alpha-tocopherol.

The tablets are packed in blisters and bottles.

II.2 Drug Substance

Colecalciferol has a monograph in the Ph Eur.

The structure of colecalciferol 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 includes relevant tests and the limits for impurities/degradation products have been justified. The analytical methods applied are suitably described and validated.

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

II.3 Medicinal Product

Colecalciferol Meda tablet is formulated using excipients described in the current Ph Eur.

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 have been performed and data presented support the shelf life claimed in the SPC.

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

There is no pharmacokinetic data specific for the currently applied product, which is acceptable due to the nature of the active substance. It is not considered necessary to compare the bioavailability of vitamin D from the current new product with that from existing vitamin D containing products on the market.

IV.2 Discussion on the clinical aspects

The product is intended to be a complement to dietary vitamin D_3, which might be highly variable, and a potential minor difference in *in vivo* release properties between different formulations would not be expected to lead to a different therapeutic profile. Moreover, as the absorption of vitamin D_3 is controlled by a number of physiological processes and factors, the true absorption of this partly endogenous substance may be difficult to determine in a bioavailability study.

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 Recikalc D-forte 500 mg/800 IU chewable tablets - SE/H/805/02/DC (bridging with regard to content) and Relifex 500 mg film-coated tablets - UK national procedure PL 19166/0060 – 0009 (bridging with regard to layout). The bridging report submitted by the applicant has been found acceptable.

The risk/benefit ratio is considered positive and Colecalciferol Meda, tablet, 800 IU (20 microgram) is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Colecalciferol Meda, tablet, 800 IU (20 microgram) was successfully finalised on 2014-06-12.

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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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