LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Kudeq
(celecoxib)

SE/H/1077/01-02/DC

This module reflects the scientific discussion for the approval of Kudeq. The procedure was finalised at 26 January 2012. For information on changes after this date please refer to the module 'Update'.

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.mpa.se E-mail: registrator@mpa.se

I. INTRODUCTION

Pfizer AB has applied for a marketing authorisation for Kudeq, 100 mg and 200 mg, capsule, hard claiming essential similarity to Celebra, 100 mg and 200 mg capsule, hard marketed in Sweden by Pfizer AB. The product contains celecoxib as active substance. For approved indications see the Summary of Product Characteristics. No bioequivalence study has been submitted, since Kudeq and the reference product are identical and have an identical Module 3.

II. QUALITY ASPECTS

II.1 Introduction

Kudeq is presented in the form of hard capsules containing 100 mg or 200 mg of celecoxib respectively. The excipients are lactose monohydrate, sodium laurilsulfate, povidone, croscarmellose sodium and magnesium stearate. The capsule shells contain gelatine, titanium dioxide E171, sodium laurilsulfate and sodium monolaurate. The capsules are printed with ink containing indigo carmine aluminium lake E132 (100 mg only), iron oxide E172 (200 mg only), shellac and propylene glycol.
The capsules are packed in clear or opaque PVC/aluminium blister.

II.2 Drug Substance

Celecoxib has a monograph in the Ph Eur.

Celecoxib is a white or almost white, crystalline powder which is practically insoluble in water. The structure of celecoxib has been adequately proven and its physico-chemical properties sufficiently described. Relevant information on polymorphism 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

Kudeq hard capsules are formulated using excipients described in the current Ph Eur, except for the colouring agents yellow iron oxide E172 and indigocarmine aluminium lake E132, used as pigments in the printing ink, which meet Directive 95/45/EC requirements for purity. The raw materials used in the product are of vegetable origin or 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 for example the poor aqueous solubility.

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

Kudeq and the reference product are identical and have an identical Module 3, the active pharmaceutical ingredient used, the manufacturing process and manufacturing site for the finished dosage form being the same. A bioequivalence study has therefore not been provided in this application, which is acceptable.

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 the product Celebra. Celebra´s leaflet was assessed and accepted in SE/H/198/01-02/II/46. The bridging report submitted by the applicant has been found acceptable.

The risk/benefit ratio is considered positive and Kudeq, 100 mg and 200 mg, capsule, hard is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Kudeq, 100 mg and 200 mg, capsule, hard was successfully finalised on 26 January 2012.

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

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)

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.mpa.se E-mail: registrator@mpa.se