LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Fenoximetylpenicillin EQL Pharma (phenoxymethylpenicillin potassium)

SE/H/1265/01-02/DC

This module reflects the scientific discussion for the approval of Fenoximetylpenicillin EQL Pharma. The procedure was finalised at 2013-01-11. 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

EQL Pharma AB has applied for a marketing authorisation for Fenoximetylpenicillin EQL Pharma 800 mg and 1 g film-coated tablets claiming essential similarity to Kåvepenin 800 mg and 1 g film-coated tablets marketed in Sweden by Meda AB. The product contains phenoxymethylpenicillin potassium as active substance. For approved indications see the Summary of Product Characteristics. The reference product used in the bio-equivalence study is Kåvepenin 800 mg film-coated tablets marketed by Meda AB in Sweden.

II. QUALITY ASPECTS

II.1 Introduction

The product Fenoximetylpenicillin EQL Pharma is presented in the form of film-coated tablets tablets containing 800 mg or 1000 mg of the drug substance phenoxymethylpenicillin potassium. The excipients are microcrystalline cellulose, povidone, talc, colloidal silica and magnesium stearate. The coating contains hypromellose, macrogol and titanium dioxide. The tablets are packaged in a clear PVC/Aclar-Aluminium blister packs.

II.2 Drug Substance

The drug substance phenoxymethylpenicillin potassium is a white or almost white crystalline powder which is freely soluble in water. The substance is described in monograph no. 149 published in the European Pharmacopeia. The manufacturer of phenoxymethylpenicillin potassium holds a Certificate of Suitability which verifies that the drug substance is suitably controlled by this monograph.

The drug substance specification includes relevant tests and the limits for impurities/degradation products have been justified. The analytical methods are suitably described and validated.

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

II.3 Medicinal Product

Fenoximetylpenicillin EQL Pharma 800 mg and 1 g film-coated tablets are formulated using excipients described in the European Pharmacopeia. None of the excipents are produced from materials of human or animal origin.

The pharmaceutical development work has been sufficiently described. It has been demonstrated that the *in vitro* dissolution profiles of Fenoximetylpenicillin EQL Pharma and the reference product Kåvepenin are similar.

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 according to ICH standards have been performed and data presented support the shelf-life claimed in the Summary of Product Characteristics.

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

Bioequivalence was evaluated in one single-dose, two-way crossover study conducted in 32 healthy volunteers, comparing Fenoximetylpenicillin EQL Pharma, 800 mg, film-coated tablet with Kåvepenin, 800 mg, film-coated tablet under fasting conditions. The study was conducted at Lambda Therapeutic Research Ltd, Ahmedabad, India between 8th and 12th December 2011. Blood samples were collected pre-dose and up to 10 hours post-dose. The study design is considered acceptable. Plasma concentrations of phenoxymethylpenicillin were determined with an adequately validated HPLC/UV method. For 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, Fenoximetylpenicillin EQL Pharma is considered bioequivalent with Kåvepenin.

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 Swedish.

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 results of the conducted bioequivalence study can be extrapolated to other strengths since the criteria for biowaiver for additional strengths are fulfilled according to the Note for Guidance on the Investigation of Bioavailability and Bioequivalence.

The risk/benefit ratio is considered positive and Fenoximetylpenicillin EQL Pharma 800 mg and 1 g film-coated tablets, is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Fenoximetylpenicillin EQL Pharma 800 mg and 1 g film-coated tablets was successfully finalised on 2013-01-11.

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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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