LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Prednisolon mibe
(prednisolone acetate)

SE/H/1317/01/DC

This module reflects the scientific discussion for the approval of Prednisolon mibe. The procedure was finalised at 2014-04-28. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Prednisolon mibe, eye drops, suspension, 10 mg/ml is a hybrid application made according to Article 10(3) of Directive 2001/83/EC. The applicant, mibe GmbH Arzneimittel applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and AT and DE as concerned member states (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Pred Forte, eye drops suspension, 1%, authorised in UK since 1988, with Allergan Ltd as marketing authorisation holder.
The reference product used in the CMS where the application is made is Inflanefran forte, Augentropfen, 10 mg/ml, authorised in Germany, with Allergan Pharmaceuticals Ireland as marketing authorisation holder. This is a European Reference product (ERP) in SE (RMS) and AT.

For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Prednisolon mibe is presented in the form of eye drops, suspension containing *10 mg/ml* of prednisolone acetate. In addition to other excipients it contains 0.06 mg benzalkonium chloride as preservative. The eye drops, suspension *is* filled in bottle with LDPE dropper applicator.

II.2 Drug Substance

Prednisolone acetate has a monograph in the Ph Eur.

Prednisolone acetate is white or almost white, crystalline powder and it is practically insoluble in water, slightly soluble in ethanol (96%) and in methylene chloride.
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

Prednisolone acetate 10 mg/ml, eye drops, suspension 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, such as poor aqueous solubility, polymorphism, stability.

The manufacturing process of Prednisolone acetate 10 mg/ml, eye drops, suspension is a non-standard pharmaceutical process, involving preparation sterile prednisolone acetate,

compounding step, sterile filtration, micronisation and filling of bulk solution under aseptic conditions.

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 25 ºC.

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

Since this product has been shown to be essentially similar and refer to a product approved based on a full application, no further pharmacokinetic data have been submitted or no such data are warranted for an eye drop.

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 English.
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 Prednisolon mibe, eye drops, suspension, 10 mg/ml is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Prednisolon mibe, eye drops, suspension, 10 mg/ml was successfully finalised on 2014-04-28.

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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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