LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Prednisolon Unimedic
(prednisolone sodium phosphate)

Asp no: 2015-1341

This module reflects the scientific discussion for the approval of Prednisolon Unimedic The procedure was finalised on 2017-03-06. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Prednisolon Unimedic, 31.25 mg, rectal solution, is a hybrid application made according to Article 10(3) of Directive 2001/83/EC. The applicant, Unimedic AB applies for a marketing authorisation in Sweden through a National Procedure.

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Pred-Clysma, 31.25 mg rectal solution authorised in SE since 1963, with Bayer AB as marketing authorisation holder.

For recommendations to the marketing authorisation not falling under Article 21a/22 of Directive 2001/83 and conditions to the marketing authorisation pursuant to Article 21a or 22 of Directive 2001/83/EC to the marketing authorisation, please see section VI.

II. QUALITY ASPECTS

II.1 Drug Substance

The structure of the drug substance has been adequately proven and its physico-chemical properties are sufficiently described.

The manufacture of the drug substance has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

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

Stability studies confirm the retest period.

II.2 Medicinal Product

The medicinal product is formulated using excipients listed in section 6.1 in the Summary of Product Characteristics.

The manufacturing process has been sufficiently described and critical steps identified.

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 and special precautions for storage claimed in the Summary of Product Characteristics, sections 6.3 and 6.4.

III. NON-CLINICAL ASPECTS

III.1 Discussion on the non-clinical aspects

No new non-clinical studies on pharmacology, pharmacokinetics and toxicology have been submitted. As prednisolon is a widely used and well-known active substance this is considered to be acceptable.

IV. CLINICAL ASPECTS

IV.1 Pharmacokinetics

Since Prednisolon Unimedic 31.25 mg rectal solution can be claimed to be identical to the reference product PredClysma 31.25 mg rectal solution, no pharmacokinetic or clinical studies were performed within this application. This is acceptable.

IV.2 Pharmacodynamics, Clinical efficacy, Clinical safety

No new studies on pharmacodynamics, clinical efficacy or clinical safety have been submitted. Provided that essential similarity with the originator product is demonstrated, additional data is not necessary.

IV.3 Risk Management Plans

The Applicant has submitted a signed Summary of the Applicant's/Proposed Future MAH's Pharmacovigilance System. Provided that the Pharmacovigilance System Master File fully complies with the new legal requirements as set out in the Commission Implementing Regulation and as detailed in the GVP module, the MPA considers the Summary acceptable.

Risk Management Plan

The MAH has submitted a risk management plan (Version 1.0), in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Prednisolon Unimedic.

Safety specification

Summary table of safety concerns (RMP version 1.1)

Summary of safety concerns	
Important identified risks	• Disturbances of the endogenous cortisol balance (HPA) axis • Immunosuppression • Overdose
Important potential risks	• Pregnancy, lactation and fertility
Missing information	• None

Pharmacovigilance Plan

Routine pharmacovigilance is suggested and no additional pharmacovigilance activities are proposed by the applicant, which is endorsed.

Risk minimisation measures

Routine risk minimisation is suggested and no additional risk minimisation activities are proposed by the applicant, which is endorsed.

Summary of the RMP

The RMP is approved

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the RMS;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time, but via different procedures.

V. 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.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the hybrid product, Prednisolon, is found adequate. There are no objections to approval of Prednisolon, from a non-clinical and clinical point of view. The product information is acceptable.

The application is therefore recommended for approval.

List of recommendations not falling under Article 21a/22 of Directive 2001/83 in case of a positive benefit risk assessment

N/A

List of conditions pursuant to Article 21a or 22 of Directive 2001/83/EC

N/A

VII. APPROVAL

Prednisolon Unimedic, 31.25 mg, rectal solution was approved in the national procedure on 2017-03-06.

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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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