LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report

Scientific discussion

Mometason Apofri
(mometasone furoate monohydrate)

Asp no:2013-0039

This module reflects the scientific discussion for the approval of Mometason Apofri. The procedure was finalised at 2014-03-06. 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

The application for Mometason Apofri, 50 microgram/dose, nasal spray, suspension, is a hybrid application made according to Article 10(3) of Directive 2001/83/EC. The applicant, Apofri AB, applies through the Swedish National Procedure.

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Nasonex, 50 microgram/dose, nasal spray, suspension authorised in Sweden since 1997, with Merck Sharp & Dohme BV as marketing authorisation holder.

II. QUALITY ASPECTS

II.1 Introduction

Mometason Apofri is presented in the form of nasal spray, suspension, containing 50 microgram/dose of mometasone furoate (in the form of mometasone furoate monohydrate). The excipients are microcrystalline cellulose, carmellose sodium, glycerol, citric acid monohydrate, sodium citrate, polysorbate 80, benzalkonium chloride and purified water. The nasal spray is filled in white plastic bottles with a spray pump.

II.2 Drug Substance

Mometasone furoate monohydrate does not have a monograph in the Ph Eur.

Mometasone furoate monohydrate is a white to almost white powder which is practically insoluble in water. The structure of the drug substance 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 under ICH conditions have been conducted and the data provided are sufficient to confirm the retest period.

II.3 Medicinal Product

Mometason Apofri, nasal spray, suspension, is formulated using excipients described in the current Ph Eur. None of the raw materials used in the product are of human or animal origin.

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 under ICH conditions have been performed and data presented support the shelf life claimed in the SPC, with no special storage precautions.

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

Mometason Apofri 50 μg/actuation, nasal spray suspension is intended to act locally. Mometasone furoate is minimally absorbed when administered as an intranasal spray with a bioavailability of ≤0.1% after a single intranasal dose of 400 μg. Any part of the intranasal dose swallowed and absorbed undergoes extensive first-pass metabolism to multiple metabolites, which are excreted in the bile and in the urine.

The developed product presents the same composition (qualitative and quantitative) as the reference product Nasonex. No bioequivalence studies have been conducted.

Given that mometasone is a locally applied, locally acting drug with very low bioavailability, the lack of bioequivalence studies is acceptable. Evaluation of equivalence between Mometason Apofri and Nasonex is based on quality data.

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 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 Mometason Apofri, 50 microgram/dose, nasal spray, suspension is recommended for approval.

VI. APPROVAL

Mometason Apofri, 50 microgram/dose, nasal spray, suspension, was approved in the national procedure on 2014-03-06.

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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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Internet: www.mpa.se E-mail: registrator@mpa.se