LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Latanoprost Actavis
(latanoprost)

SE/H/822/01/DC

This module reflects the scientific discussion for the approval of Latanoprost Actavis. Please note that the marketing authorisation was first approved with the name "Latanoprost Nucleus" and therefore this name is used throughout the document. The procedure was finalised at 2010-09-29. 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

Nucleus ehf. has applied for a marketing authorisation for Latanoprost Nucleus, eye drops, solution, 50µg/ml, claiming essential similarity to Xalatan, 50 µg/ml, eye drops solution, marketed in Sweden/ the EU by Pfizer AB. The product contains latanoprost as active substance. For approved indications see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Latanoprost Nucleus is presented in the form of eye drops, solution containing 50 micrograms of latanoprost. The excipients are benzalkonium chloride, disodium phosphate, anhydrous, sodium chloride, sodium dihydrogen phosphate monohydrate and water. The eye drop solution is filled in LDPE bottle with HDPE screw cap.

II.2 Drug Substance

Latanoprost does not have a monograph in the Ph Eur.

Latanoprost is a colourless to yellow viscous oil which is practically insoluble in water. The structure of latanoprost has been adequately proven and its physico-chemical properties sufficiently described. Relevant information on polymorphism and chirality 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

Latanoprost Nucleus eye drops, solution, is formulated using excipients described in the current Ph Eur BP. All raw materials used in the product 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 poor aqueous solubility and sorption to the container closure.

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 refrigerated (2-8°C) in the outer carton in order to protect from light.

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
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 Soleye 50 µg/ml eye drops, solution, NL/H/1382/001/DC. The bridging report submitted by the applicant has been found acceptable.

The risk/benefit ratio is considered positive and Latanoprost Nucleus, eye drops, solution, 50µg/ml, is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Latanoprost Nucleus, eye drops, solution, 50µg/ml was successfully finalised on 2010-09-29.

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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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