LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Akistan
(latanoprost)

SE/H/1095/01/DC

This module reflects the scientific discussion for the approval of Akistan. The procedure was finalised at 2012-03-05. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Pharmaselect International Beteiligungs GmbH has applied for a marketing authorisation for Akistan, 50 micrograms/ml, eye drops, solution claiming essential similarity to Xalatan, 50 microgram/ml, eye drops, solution Sweden 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

Akistan is presented in the form of eye drops containing 50 micrograms/ml of latanoprost. The excipients are benzalkonium chloride, sodium chloride, sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, purified water, sodium hydroxide and/or phosphoric acid. The eye drop solution is filled in dropper containers of polyethylene with screw cap and tamper evident overcap of polypropylene.

II.2 Drug Substance

Latanoprost does not have a monograph in the Ph Eur.

Latanoprost is a colourless to yellowish oily substance which is freely soluble in acetone, ethanol, ethyl acetate and has very low solubility in water. The structure of latanoprost has been adequately proven and its physico-chemical properties sufficiently described. Relevant information on 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

Akistan eye drop solution is formulated using excipients described in the current Ph Eur, except for benzalkonium chloride 10 % which is controlled according to an acceptable in house specification. No excipients of human/animal origin are used.

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, when stored in a refrigerator (2-8°C) and 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
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 Akistan, 50 micrograms/ml, eye drops, solution, is recommended for approval.

Follow-up measure:
The applicant has made a commitment to perform a migration study with the labelled container and present a study protocol until March 30th, 2012.

VI. APPROVAL

The Decentralised procedure for Akistan, 50 micrograms/ml, eye drops, solution was successfully finalised on 2012-03-05.

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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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