LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Tobramycin + Dexamethasone Tubilux Pharma (Tobramycin + Dexamethasone)

SE/H/745/01/DC

This module reflects the scientific discussion for the approval of Tobramycin + Dexamethasone Tubilux Pharma. The procedure was finalised at 2010-09-29. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Tubilux Pharma S.p.A has applied for a marketing authorisation for Tobramycin + Dexamethasone Tubilux Pharma, 3 mg/ml + 1 mg/ml eye drops, suspension. The application for marketing authorisation was a hybrid application submitted under Article 10(3), of Directive 2001/83/EC as amended. The reference medicinal product is Tobradex 0,1 % + 0,3 % eye drops, suspension, with marketing authorisation holder S.A. ALCON Couvreur N.V, approved in Italy since January 1993. The product contains Tobramycin and Dexamethasone as active substances. For approved indications see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Tobramycin + Dexamethasone Tubilux Pharma is presented in the form of eye drops containing 3 mg/ml tobramycin and 1 mg/ml dexamethasone. The excipients are disodium edetate, hydroxyethyl cellulose, benzalkonium chloride, purified water, sodium chloride, sodium sulphate, tyloxapol, sulphuric acid and/or sodium hydroxide. The suspension is filled in polyethylene bottles.

II.2 Drug Substance

Dexamethasone and tobramycin and have monographs in the Ph.Eur. The structures of the drug substances have been adequately proven and the physico-chemical properties are sufficiently described. The route of synthesis has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The active substances specifications include 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 periods.

II.3 Medicinal Product

Tobramycin + Dexamethasone Tubilux Pharma 3 mg/ml + 1 mg/ml eye drops, suspension is formulated using excipients described in the current Ph Eur, except for tyloxapol which is controlled according to acceptable USP specifications. All raw materials used in the product are of vegetable origin.

The product development has taken into consideration the physico-chemical characteristics of the active substance, such as poor aqueous solubility.

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, 3 years, 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

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 Tobramycin + Dexamethasone Tubilux Pharma, 3 mg/ml + 1 mg/ml eye drops, suspension is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Tobramycin + Dexamethasone Tubilux Pharma, 3 mg/ml + 1 mg/ml eye drops, suspension was successfully finalised 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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