LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Brimonidine Brown
Brimonidine tartrate

SE/H/997/01/DC

This module reflects the scientific discussion for the approval of Brimonidine Brown. The procedure was finalised at 2011-06-08. 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

Brown and Burk UK Limited has applied for a marketing authorisation for Brimonidine Brown, eye drop solution 2 mg/ml claiming essential similarity to Alphagan®, 0.2% w/v (2mg/ml) eye drops marketed in Sweden by Allergan Ltd, UK .The product contains brimonidine tartrate as active substance. For approved indications see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Brimonidine Brown is presented in the form of a sterile eye drop solution containing 2 mg of brimonidine tartrate per ml. The excipients are benzalkonium chloride, citric acid monohydrate, poly(vinyl alcohol), sodium chloride, sodium citrate, water for injections and hydrochloric acid or sodium hydroxide for pH adjustment. The eye drop solution is filled in polyethylene bottles with polypropylene caps.

II.2 Drug Substance

Brimonidine tartrate does not have a monograph in the Ph Eur.

Brimonidine tartrate is a pale yellow to wheatish coloured powder which is sparingly soluble 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

Brimonidine Brown is formulated using excipients described in the current Ph Eur. No ingredients of human/animal origin are used in the product and 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) has been demonstrated.

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 and in-use time claimed in the SPC.

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 Brimonidine Brown, eye drop solution 2 mg/ml is recommended for approval.

VI. APPROVAL

The decentralised procedure for Brimonidine Brown, eye drop solution 2 mg/ml was successfully finalised on 2011-06-09.

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

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)

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