LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Baklofen Alternova
(previous Baklofen E Consult)
(baklofen)

Asp-nr: 2010-1354 and 1355

This module reflects the scientific discussion for the approval of Baklofen Alternova. The procedure was finalised at 2012-06-07. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

E CONSULT ApS has applied for a marketing authorisation for Baklofen Alternova (previous Baklofen E Consult) Tablet, 10 mg and 25 mg claiming essential similarity to Lioresal, tablet marketed in Sweden by Novartis Sverige AB. The product contains baclofen as active substance. For approved indications see the Summary of Product Characteristics.
The reference product used in the bioequivalence study is Lioresal, tablets marketed by Novartis Farma S.p.A., Italy.

II. QUALITY ASPECTS

II.1 Introduction

Baklofen Alternova is presented in the form of tablets containing 10 mg and 25 mg of baclofen respectively. The excipients are microcrystalline cellulose, maize starch, povidone, colloidal anhydrous silica and magnesium stearate. The tablets are packed in PVC/aluminium (Al) blisters and in HDPE containers.

II.2 Drug Substance

The active substance baclofen has a monograph in the Ph. Eur.

Baclofen drug substance is a white to creamy-white powder which is slightly soluble in water and soluble in dilute mineral acids and alkali hydroxides. The chemical structure of baclofen 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 of 5 years.

II.3 Medicinal Product

Baklofen Alternova tablets are formulated using excipients described in the current Ph. Eur. No ingredients of animal or human 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 lifes 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

Baclofen is rapidly and almost completely absorbed from the gastrointestinal tract with peak plasma concentrations occuring 0.5 to 3 hours after oral dose. The concentration of baclofen in CSF is approximately 12% of the plasmaconcentration. Baclofen is about 30% bound to plasma proteins. About 70 to 80% of a dose is excreted in urine mainly as unchanged drug. The terminal plasma half-life of baclofen is about 3 to 4 hours.

One study was submitted to support the application. The study was a standard single dose (25 mg tablet), two periods, crossover, controlled bioequivalence study on 36 adult male and female healthy volunteers, under fasting conditions. Bioequivalence has been demonstrated between test and reference formulations for the 25 mg strength under fasting conditions.

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 Danish.
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 results of the conducted bioequivalence study can be extrapolated to other strengths since the criteria for biowaiver for additional strengths are fulfilled according to the Guideline on the Investigation of Bioequivalence.

The risk/benefit ratio is considered positive and Baklofen Alternova (previous Baklofen E Consult) Tablet, 10 mg and 25 mg are recommended for approval.

VI. APPROVAL

Baklofen Alternova (previous Baklofen E Consult) Tablet, 10 mg and 25 mg were approved in the national procedure on 2012-06-07.

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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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