LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Gabapentin Brown, film-coated tablet (gabapentin)

SE/H/1082/01-02/DC

This module reflects the scientific discussion for the approval of Gabapentin Brown. The procedure was finalised at 2011-10-11. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Brown&Burk UK Ltd has applied for a marketing authorisation for Gabapentin Brown, 600 mg and 800 mg, film-coated tablet claiming essential similarity to Neurontin, 600 mg and 800 mg, film-coated tablets marketed in UK by Pfizer Limited. The product contains gabapentin as active substance. For approved indications see the Summary of Product Characteristics. The reference product used in the bio-equivalence study is Neurontin, film-coated tablet, 600 mg marketed by Parke - Davis GmbH in DE and Neurontin, film-coated tablet, 800 mg marketed by Pfizer Ltd in UK.

II. QUALITY ASPECTS

II.1 Introduction

Gabapentin Brown is presented in the form of film-coated tablets containing 600 mg or 800 mg of gabapentin. The excipients are hydroxypropylcellulose, magnesium stearate and talc. The tablets are packed in PVC/PE/PVdC-aluminium blisters or in polypropylene containers.

II.2 Drug Substance

Gabapentin has a monograph in the Ph Eur.

Gabapentin is a white, crystalline powder which is freely soluble in water and in alkaline and acidic solutions. The structure of gabapentin has been adequately proven and its physico-chemical properties sufficiently described. Relevant information on polymorphism 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

Gabapentin Brown film-coated tablets are formulated using excipients described in the current Ph Eur, except for low substituted hydroxypropylcellulose which is controlled according to USP/NF. All raw materials used in the product are of vegetable/chemical origin.

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, 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

Bioequivalence was evaluated in two single-dose, two-way crossover studies under fasting conditions conducted at at Accutest Research Laboratories (India) Private Ltd. Study ARL/08/287 was conducted in 34 healthy volunteers, comparing Gabapentin Brown 800 mg, tablets with Neurontin, 800 mg, tablets. Study ARL/10/175 was conducted in 36 healthy volunteers, comparing Gabapentin Brown, 600 mg, tablets with Neurontin, 600 mg, tablets.

The study design was similar in both studies. Blood samples were collected pre-dose and up to 48 hours post-dose. The study design is considered acceptable. Plasma concentrations of gabapentin were determined with an adequately validated HPLC/MS/MS method. For AUC_{0-t} and C_{max} the 90% confidence interval for the ratio of the test and reference products fell within the conventional acceptance range of 80.00-125.00%.

Based on the submitted bioequivalence studies, Gabapentin Brown, 600 mg and 800 mg, tablets are considered bioequivalent with Neurontin, 600 mg and 800 mg, tablets.

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 Gabapentin Brown 100, 300 and 400 mg hard capsules, procedure number SE/H/1003/01-03/DC. The bridging report submitted by the applicant has been found acceptable.

The risk/benefit ratio is considered positive and Gabapentin Brown, 600 mg and 800 mg is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Gabapentin Brown, 600 mg and 800 mg was successfully finalised on 2011-10-11.

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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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