FOOD AND DRUGS AUTHORITY GHANA

Public Assessment Report

PREBAXE 50 CAPSULES

Pregabalin Capsules 50 mg

AFH0156/22

Cipla Limited - Cipla House Peninsula Business Park Ganpatrao Kadam Marg Lower Parel Mumbai 400013, India

TABLE OF CONTENTS

1. Part 1 1
1.1 Introduction 1
1.2 Executive Summary 1
1.2.1 About the product 1
2. Part 2: All accepted presentations (including photo) 1
3. Part 3: Product information for the user (Patient Information Leaflet - PIL) – Enclosed PIL (Refer Annex 2) 1
4. Part 4: Information for the health care provider (Summary of Product Characteristics– SmPC) – 1
5. Part 5 Scientific Overview and Discussion 2
5.1 Introduction 2
5.2 Active Pharmaceutical Ingredient (API) 2
5.3 Finished Pharmaceutical Product (FPP) 2
5.4 Summary of product safety and efficacy 3
6. Part 6: Benefit/Risk Assessment 4
7. Part 7: Steps taken for registration. 4

Administrative info

Dosage Form	Capsule
Strength	50 mg
Applicant's Name & Postal Address	Cipla Limited - Cipla House Peninsula Business Park Ganpatrao Kadam Marg Lower Parel Mumbai 400013, India
Manufacturer's Name & Address	Cipla Ltd Unit I D7, MIDC Industrial Area, Kurkumbh 413 802 Tal Daund , Dist. Pune. India
Local Agent	Worldwide Healthcare Limited (WWHCL) -: 'Amenfi Plaza' Plot 53, Tema Motorway Indus. Area, Spintex Road, Accra –Ghana

1. Part 1

1.1 Introduction

Based on the review of the data on quality, safety and efficacy, the application for Prebaxe 50mg Capsule, indicated for the management of neuropathic pain associated with diabatic peripheral neuropathy, postherpetic neuralgia, adjunctive therapy for the treatment of partial- onset seizures in patients 17 years old age and older, fibromyalgia and neuropathic pain associated with spinal cord injury is approved.

1.2 Executive Summary

1.2.1 About the product

A comprehensive description of the indications and posology is given in the SmPC. This registration application concerns a generic application claiming essential similarity with the reference product, Lyrica.

The marketing authorization has been granted pursuant to section 118 of the Public Health Act, Act 857.

2. Part 2: All accepted presentations (including photo)

Enclosed Pack shots (Refer Annex 1)

3. Part 3: Product information for the user (Patient Information Leaflet - PIL) –

Enclosed PIL (Refer Annex 2)

4. Part 4: Information for the health care provider (Summary of Product Characteristics– SmPC) –

Enclosed SmPC (Refer Annex 3).

5. Part 5 Scientific Overview and Discussion

5.1 Introduction

Prebaxe 50mg capsule is a white to off white powder filled in size ‘’ ‘3’hard gelatin white opaque and white opaque capsule linear printed in black ink with 'Cipla 50 mg' on the cap and -’ ‘678’ on the body. The Capsule is packed in Aluminum blister with PVC/PE/PVDC film.

The excipients are:
Capsule content: Maize starch and talc.
Capsule shell: Gelatin, titanium dioxide, sodium lauryl sulphate and purified water.
Printing ink: Shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, , black iron oxide, potassium hydroxide and purified water.

5.2 Active Pharmaceutical Ingredient (API)

The active pharmaceutical ingredient is pregabalin, an established substance described in the United State Pharmacopeia (USP). The active substance is a white crystalline powder, sparingly soluble in water. The drug substance exhibits polymorphism which is adequately controlled.

Manufacturing process
The manufacturing process was presented with sufficient details. The active pharmaceutical ingredient has been adequately characterised and acceptable specifications have been adopted for solvents and reagents.

Quality control of drug substance
The pharmaceutical ingredient specification is considered adequate to control the quality. Batch analytical data demonstrating compliance with this specification have been provided.

Stability of drug substance
Stability data are provided on the active pharmaceutical ingredient of three batches stored at 25°C (excursions allowed between 15°C and 30°C in a tight container. The currently acceptable retest period is 60 months when stored.

5.3 Finished Pharmaceutical Product (FPP)

Pharmaceutical development

The product is an established pharmaceutical form, and its development is adequately described in accordance with the relevant FDA/ICH guidelines. The choice of excipients, packaging and manufacturing is justified. The main development studies concerned the characterisation of the reference product and the development of the manufacturing process. The product contains the same active ingredients at the same strengths as that of the reference product. The

physicochemical characteristics are similar to the reference product. Similarity has adequately been demonstrated.

Manufacturing process

The manufacturing process consists of dispensing of raw materials, sifting, blending and encapsulation. The manufacturing process has been validated according to relevant FDA/ICH guidelines. Process validation data on the product have been presented for at least three production scale batches in accordance with the relevant FDA guidelines.

Control of excipients

The excipients comply with the requirements of official compendia. The used colourants in the capsules are approved and ingredients comply with official compendia. These specifications are acceptable.

Quality control of the Finished Pharmaceutical Product

The finished product specifications are adequate to control the relevant parameters for the dosage form. The specification includes the following parameters: description, identification, water content, uniformity of dosage units, dissolution, related substance, assay, and residual solvents. Limits in the specification have been justified and are considered appropriate for adequate quality control of the product. Batch analytical data from at least three production scale batches from the proposed production site have been provided, demonstrating compliance with the specification.

Stability of drug product

Stability data on the product have been provided on three production scale batches stored at 30℃. The conditions used in the stability studies are according to the FDA/ICH stability guideline. The batches were stored in the proposed unit dose containers. All parameters remain within the specified limits. The proposed shelf-life of 24 months and storage conditions are justified.

Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies.

There are no substances of ruminant animal origin present in the product nor have any been used in the manufacturing of this product, so a theoretical risk of transmitting TSE can be excluded.

5.4 Summary of product safety and efficacy

Prebaxe 50mg capsule has been shown to conform to the same relevant standards of quality, efficacy and safety as those required of the comparator product. According to the submitted data on quality and bioavailability, Prebaxe 50mg capsule is pharmaceutically and therapeutically equivalent and thus interchangeable with the comparator product Lyrica for which benefits have been proven in terms of clinical efficacy. The clinical safety of Prebaxe 50mg capsule is considered acceptable when guidance and restrictions stated in the summary of product characteristics (SmPC) are considered. Refer to the SmPC for data on clinical safety.

Find below the summary of the bioequivalence results.

No bioequivalence study has been performed. The finished product contains active ingredients eligible for a BCS-based biowaiver. Accordingly, a request for a biowaiver was submitted with the required supporting data in line with the FDA guidance and criteria for biowaivers.

Comparability between the reference product and the test product regarding the qualitative and quantitative composition of the formulations have been sufficiently proven. In addition, comparable in vitro dissolution at a pH 1.2, 4.5 and 6.8 have been shown. Accordingly, the test capsule meets the criteria for a BCS based biowaiver and is, therefore, considered bioequivalent to the reference product.

6. Part 6: Benefit/Risk Assessment

Based on FDA's assessment of data on quality, bioequivalence, safety and efficacy the team of assessors considered that the benefit–risk profile of Prebaxe 50mg capsules was acceptable.

7. Part 7: Steps taken for registration.

The application was submitted through the regular application procedure.