IPAR

PUBLIC ASSESSMENT REPORT FOR A MEDICINAL PRODUCT FOR HUMAN USE

Scientific discussion

Easofen Max Strength 400 mg Film-coated Tablets

Ibuprofen

PA PA0126/060/002

The Public Assessment Report reflects the scientific conclusion reached by the Irish Medicines Board (IMB) at the end of the evaluation process and provides a summary of the grounds for approval of a marketing authorisation for a specific medicinal product for human use. It is made available by the IMB for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of Directive 2001/83/EC, as amended. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the IMB leading to the approval of the medicinal product for marketing in Ireland.

I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the IMB has granted a marketing authorisation for Ibuprofen 400 mg film-coated tablets from Clonmel Healthcare Limited on 9th September 2011 as an adjunct in the treatment of rheumatoid arthritis, osteoarthritis, ankylosing sponylitis, acute articular and periarticular disorders, fibrositis, cervical spondylitis, low back pain, and painful musculo-skeletal conditions.

This application for a marketing authorisation was submitted in accordance with Article 10c of Directive 2001/83/EC and is referred to as an 'informed consent' application. This means that the Marketing Authorisation Holder for Melfen 400 mg film-coated tablets, an authorised medicinal product in Europe, has permitted the applicant to refer to their dossier to obtain an authorisation for Ibuprofen 400 mg film-coated tablets. Ibuprofen 400 mg film-coated tablets have the same qualitative and quantitative composition in terms of the active substance and the same pharmaceutical form as Melfen 400 mg Film-coated tablets.

This product is available on prescription only

The Summary of Product Characteristics for (SmPC) for this medicinal product is available on the IMB's website at www.imb.ie

Name of the product	Easofen Max Strength
Name(s) of the active substance (INN)	Ibuprofen
Pharmacotherapeutic classification (ATC code)	M01AE01
Pharmaceutical form and strength	400 mg film-coated tablets
Marketing Authorisation Number(s) in Ireland (PA)	126/60/2
Marketing Authorisation Holder	Clonmel Healthcare Limited

II QUALITY ASPECTS

II.1. Introduction

This application is for Ibuprofen 400 mg film-coated tablets.

II.2 Drug substance

The active substance is ibuprofen, an established active substance described in the European Pharmacopoeia, and is manufactured in accordance with the principles of Good Manufacturing Practice (GMP).

The active substance specification is considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.3 Medicinal product

P.1 Composition

The product is a round, white, biconvex film-coated tablet, 12 mm in diameter.

Each film-coated tablet contains 400 mg of ibuprofen.

The tablet cores also contain maize starch, sodium starch glycolate (type A) and magnesium stearate. The film-coating contains hypromellose, macrogol 400 and macrogol 6000.

P.2 Pharmaceutical Development

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of good manufacturing practice (GMP) at suitably qualified manufacturing sites.

The manufacturing process has been validated according to relevant European/ICH guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients/*Ancillary Substances)*

All ingredients comply with Ph. Eur.

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for coated tablets, and the tests and control limits are considered appropriate for this type of product.

The analytical methods used are described in sufficient detail and are supported by validation data.

Batch analytical data for a number of batches from the proposed production sites have been provided, and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.6 Packaging material

The product is presented as blisters consisting of 9 μm aluminium foil with 50 g/m2 sulphate paper and 250 μm white opaque PVC.

Evidence has been provided that the blisters comply with EU legislation for packaging materials used with foodstuffs.

P.7 Stability of the Finished Product

Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines, and demonstrate the stability of the product for 5 years when stored at a temperature not exceeding 25 °C. The tablets should be stored in the original package in order to protect from light.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects

The important quality characteristics of the product are well-defined and controlled. Satisfactory chemical and pharmaceutical documentation has been provided, assuring consistent quality of Ibuprofen 400 mg film-coated tablets.

III NON-CLINICAL ASPECTS

III.1 Introduction

This active substance is the same as that present in Melfen 400 mg film-coated tablets on the European market. No new preclinical data have been submitted. As such, no pre-clinical assessment has been made on the application. This is acceptable for this type of application.

IV CLINICAL ASPECTS

IV.1 Introduction

Ibuprofen is a well known active substance with established efficacy and tolerability. This medicinal product is the same as Melfen 400 mg film-coated tablets on the European market

The content of the SmPC approved during the national procedure is in accordance with that accepted for the reference product Melfen 400 mg film-coated tablets.

V OVERALL CONCLUSIONS

BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Ibuprofen 400 mg film-coated tablets are the same as Melfen 400 mg film-coated tablets. Melfen 400 mg film-coated tablets is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

The HPAR, on the basis of the data submitted considered that Ibuprofen 400 mg film-coated tablets was the same as the reference product and therefore granted a marketing authorisation.

VI REVISION DATE

September 2011.