IPAR

HEALTH PRODUCTS REGULATORY AUTHORITY

PUBLIC ASSESSMENT REPORT FOR A MEDICINAL PRODUCT FOR HUMAN USE

Scientific discussion

Imigran Migraine Relief 50mg Film-coated Tablets
SUMATRIPTAN
PA 678/110/1

The Public Assessment Report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) 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 HPRA 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 HPRA 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 HPRA has granted a marketing authorisation for Imigran Migraine Relief 50mg Film-coated Tablets, from Ivowen Limited on 29th July 2011 for the acute intermittent treatment of migraine.

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 Imigran Ftab 50 mg Film-coated Tablets, an authorised medicinal product in Europe, has permitted the applicant to refer to their dossier to obtain an authorisation for Imigran Migraine Relief 50mg Film-coated Tablets. Imigran Migraine Relief 50mg Film-coated Tablets have the same qualitative and quantitative composition in terms of actives substances and the same pharmaceutical form as Imigran Ftab 50 mg Film-coated Tablets.

This product is subject to prescription which may be renewed.
The Summary of Product Characteristics for (SPC) for this medicinal product is available on the HPRA's website at www.HPRA.ie.

Name of the product	Imigran Migraine Relief
Name of the active substance (INN)	Sumatriptan, as sumatriptan succinate
Pharmacotherapeutic classification (ATC code)	N02 C C01
Pharmaceutical form and strength	50mg Film-Coated Tablets
Marketing Authorisation Number(s) in Ireland (PA)	PA 678/110/1
Marketing Authorisation Holder	GlaxoSmithKline Consumer Healthcare (Ireland) Limited

II QUALITY ASPECTS

II.1. Introduction

This application is for Imigran Migraine Relief 50mg Film-coated Tablets.

II.2 Drug substance

The active substance is sumatriptan succinate, 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 pink, triangular, biconvex, film-coated tablet debossed ‘GS 1YM’ on one face and '50' on the other. It contains sumatriptan 50 mg (as sumatriptan succinate) and the following excipients in the tablet core: anhydrous calcium hydrogen phosphate, microcrystalline cellulose, sodium hydrogen carbonate, croscarmellose sodium and magnesium stearate.
The film-coating contains hypromellose, titanium dioxide (E171), triacetin and red iron oxide (E172).

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 in the core comply with Ph. Eur.; the film-coat is adequately controlled by the manufacturer’s specifications.

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for 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 site(s) 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 in double foil blister packs within an outer cardboard carton.

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 demonstrating the stability of the product for 3 years when stored at a temperature not exceeding 30 °C in the original packaging 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 Imigran Migraine Relief 50mg Film-coated Tablets.

III NON-CLINICAL ASPECTS

III.1 Introduction

This active substance has been available on the Irish market for sixteen years. Preclinical data have been superseded by clinical experience and therefore no preclinical assessment report is available.

This active substance is the same as that present in Imigran Ftab 50mg Film-Coated Tablets PA 1077/8/6 on the Irish 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

Sumatriptan succinate is a well known active substance with established efficacy and tolerability.

The content of the SPC approved during the national procedure is in accordance with that accepted for the reference product Imigran Ftab 50mg Film-Coated Tablets marketed by GSK.

V OVERALL CONCLUSIONS

Benefit/Risk Assment and Recommendation

Imigran Migraine Relief 50mg Film-coated Tablets are the same as Imigran Ftab 50 mg Film-coated Tablets. Imigran Ftab 50 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 HPRA, on the basis of the data submitted considered that Imigran Migraine Relief 50mg Film-coated Tab was the same as the reference product and therefore granted a marketing authorisation.