LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report

Scientific discussion

Sumatriptan Aurobindo
(sumatriptan succinate)

SE/H/686/01-02/DC

This module reflects the scientific discussion for the approval of Sumatriptan Aurobindo. The procedure was finalised at 2007-12-20 (Day 210). For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Aurobindo Pharma Ltd has applied for a marketing authorisation for Sumatriptan Aurobindo tablet, 50 mg and 100 mg claiming essential similarity to Imigran Sprint, dispersible tablet, 50 mg and 100 mg marketed in the EU by GlaxoSmithKline. The product contains sumatriptan succinate as active substance. For approved indications see the Summary of Product Characteristics. The reference product used in the bio-equivalence study is Imigran Radis, tablet, 100 mg marketed by GlaxoSmithKline in UK.

II. QUALITY ASPECTS

II.1 Introduction

Sumatriptan Aurobindo is presented in the form of tablets containing 69.98 or 139.96 mg of sumatriptan succinate which corresponds to 50 or 100 mg of sumatriptan. The excipients are croscarmellose sodium, polysorbate 80, anhydrous calcium hydrogen phosphate, microcrystalline cellulose, sodium hydrogen carbonate and magnesium stearate. The tablets are packed in polyamide/PVC/aluminium blister packs.

II.2 Drug Substance

Sumatriptan succinate has a monograph in the Ph Eur. The drug substance is a white powder which is freely soluble in water. The structure of sumatriptan succinate has been adequately proven and its physico-chemical properties sufficiently described. Relevant information on polymorphism and chirality 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 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

Sumatriptan Aurobindo tablets are formulated using excipients described in the current Ph Eur. All raw materials used in the product are of vegetable 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

Based on the submitted bioequivalence study Sumatriptan Aurobindo/Bluefish is considered bioequivalent with Imigran Radis. Linearity between 50 and 100 mg has been observed and no food interaction is present. Study Sum-05/06 was performed in fasting conditions. The results of study Sum-05/06 with the 100 mg formulation can be extrapolated to the 50 mg strength, according to conditions in Note for Guidance on the Investigation of Bioavailability and Bioequivalence CPMP/EWP/QWP/1401/98, section 5.4. The clinical and analytical site APL Research Center was inspected by WHO in 2005 and was found GCP compliant.

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 testing of the package leaflet has been performed.

The risk/benefit ratio is considered positive and Sumatriptan Aurobindo, 50 mg and 100 mg tablets is recommended for approval.

The Applicant has committed to update the pharmacovigilance system by February 2008.

VI. APPROVAL

The Decentralised procedure for Sumatriptan Aurobindo, tablets, 50 mg and 100 mg was successfully finalised on Day 210 (2007-12-20).

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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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