LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

# Public Assessment Report
# Scientific discussion

# Sumatriptan Pfizer
# (sumatriptan succinate)

# SE/H/973/01-02/DC

**This module reflects the scientific discussion for the approval of Sumatriptan Pfizer. The procedure was finalised at 2011-02-10. For information on changes after this date please refer to the module 'Update'.**

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# I. INTRODUCTION

Pfizer AB has applied for a marketing authorisation for Sumatriptan Pfizer, tablets, 50 and 100 mg, claiming essential similarity to Imigran, film-coated tablet, 50 mg, marketed in DK 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, film-coated tablet, 100 mg, marketed by GlaxoSmithKline in UK.

# II. QUALITY ASPECTS

## II.1 Introduction

Sumatriptan Pfizer is presented in the form of tablets containing sumatriptan succinate which corresponds to 50 or 100 mg of the 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/Al blister.

## II.2 Drug Substance

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

Sumatriptan Pfizer tablet is formulated using excipients described in the current Ph Eur. None of the excipients present a risk of TSE/BSE as certified by the suppliers.
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

Sumatriptan has low bioavailability after oral administration (about 15%) with a large inter-individual variation although not adversely affected by concomitant food-intake. Tmax is reached at approximately 2 hours and is slightly delayed by the presence of food and during an acute migraine attack. The pharmacokinetics of sumatriptan is linear over the dose range 25-200 mg. The elimination half-life is about 2 h.

To support the application, the applicant has submitted one single-dose bioequivalence study comparing Sumatriptan Pfizer 100 mg tablets with Imigran Radis 100 mg film-coated tablets under fasting conditions. The study is performed by APL Research Center, Hyderabad, India during June and July 2006, and there are no identified issues regarding GLP/GCP. Bioequivalence was properly demonstrated for the primary pharmacokinetic parameters $C_{max}$ and $AUC_{0-t}$.

## 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 Sumatriptan Aurobindo SE/H/686/01-02/DC (lay-out) and Sumatriptan Bluefish SE/H/735/01-02/II/6 (content). The bridging report submitted by the applicant has been found acceptable.

The results of the conducted bioequivalence study can be extrapolated to other strengths since the criteria for biowaiver for additional strengths are fulfilled according to the Note for Guidance on the Investigation of Bioavailability and Bioequivalence.

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

# VI. APPROVAL

The Decentralised procedure for Sumatriptan Pfizer, tablets, 50 and 100 mg, was successfully finalised on 2011-02-10.

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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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