LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report

Scientific discussion

Venlafaxin Pfizer
(venlafaxine hydrochloride)

SE/H/1363/01-03/DC

This module reflects the scientific discussion for the approval of Venlafaxin Pfizer. The procedure was finalised at 2014-12-19. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Venlafaxin Pfizer, is a generic application made according to Article 10(1) of Directive 2001/83/EC. The applicant, Pfizer AB, applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and AT, CY, DK, EL and FI as concerned member states (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Efexor Depot, 75 mg, prolonged release capsules authorised in SE since 1997, with Pfizer AB as marketing authorisation holder.

For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Venlafaxin Pfizer is presented in the form of hard depot capsules containing 42.4 mg, 84.9 mg or 169.7 mg of venlafaxine hydrochloride which corresponds to 37.5 mg, 75 mg or 150 mg of the active entity venlafaxine. The excipients are microcrystalline cellulose, ethyl cellulose, hypromellose, talc, gelatin, iron oxide black, iron oxide red, iron oxide yellow, titanium dioxide, propylene glycol, simethicone, sodium hydroxide and shellac. The capsules are packed in blisters or bottles.

II.2 Drug Substance

Venlafaxine hydrochloride has a monograph in the Ph. Eur.

Venlafaxine hydrochloride is a white to almost white powder which is freely soluble in water. The structure of venlafaxine hydrochloride 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/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

Venlafaxin Pfizer, hard depot capsules are formulated using excipients described in the current Ph. Eur., except for the iron oxides which are controlled according to acceptable in house specifications. All raw materials used in the product have demonstrated compliance with Commission Directive 2003/63/EC and the NfG on Minimising the risk of transmitting Animal Spongiform Encephalopathy Agents via human and veterinary medicinal products (EMEA/410/01).

The product development has taken into consideration the physico-chemical characteristics of the active substance, such as polymorphism.

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, when stored below 30 °C.

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

No bioequivalence study was submitted with this application. This is acceptable since the applied product and the innovator product are identical.

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 Efexor depot capsule, hard, SE/H/0936/001-003/R/001. This bridging has been found acceptable.

The risk/benefit ratio is considered positive and Venlafaxin Pfizer, prolonged release capsule, hard, 37.5 mg, 75 mg and 150 mg is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Venlafaxin Pfizer, prolonged release capsule, hard, 37.5 mg, 75 mg and 150 mg was successfully finalised on 2014-12-19.

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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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