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Autoridade Nacional do Medicamento
e Produtos de Saúde I.P.

Summary Public Assessment Report

Generics

Fluoxetina Aurobindo

20 mg, 60mg Capsules, hard

(fluoxetine hydrochloride)

PT/H/1137/001-002/DC

Date: 11-11-2014

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Generics

Fluoxetina Aurobindo
Fluoxetin hydrochloride, 20 mg, 60 mg, capsules, hard.

This is a summary of the public assessment report (PAR) for Fluoxetina Aurobindo. It explains how Fluoxetina Aurobindo was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Fluoxetina Aurobindo.

For practical information about using Fluoxetina Aurobindo, patients should read the package leaflet or contact their doctor or pharmacist.

What is Fluoxetina Aurobindo and what is it used for?

Fluoxetina Aurobindo is a 'generic medicine'. This means that Fluoxetina Aurobindo is similar to a 'reference medicine' already authorised in the European Union (EU) called Prozac
Fluoxetina Aurobindo contains fluoxetin and is used to treat major depressive episodes, obsessive-compulsive disorder and bulimia nervosa in adults and moderate to severe major depressive disorder, if the depression does not respond to psychological therapy after 4-6 sessions in children and adolescents.

How does Fluoxetina Aurobindo work?

Fluoxetina Aurobindo belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level. Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.

How is Fluoxetina Aurobindo used?

The pharmaceutical form of Fluoxetina Aurobindo is capsules, hard and the route of administration is oral.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Fluoxetina Aurobindo have been shown in studies?

Because Fluoxetina Aurobindo is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Prozac. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Fluoxetina Aurobindo?

Because Fluoxetina Aurobindo is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Fluoxetina Aurobindo approved?

It was concluded that, in accordance with EU requirements, Fluoxetina Aurobindo has been shown to have comparable quality and to be bioequivalent to Prozac. Therefore, the INFARMED, I.P. decided that, as for Prozac, the benefits are greater than its risk and recommended that it can be approved for use.

Other information about Fluoxetina Aurobindo

The marketing authorisation for Fluoxetina Aurobindo was granted on 11-11-2014.

The full PAR for Fluoxetina Aurobindo can be found on the website www.infarmed.pt/infomed . For more information about treatment with Fluoxetina Aurobindo, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in MM-YYYY.

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Public Assessment Report

Scientific discussion

Fluoxetina Aurobindo

20 mg, 60mg Capsules, hard

(fluoxetine hydrochloride)

PT/H/1137/001-002/DC

This module reflects the scientific discussion for the approval of Fluoxetina Aurobindo. The procedure was finalised at 15-07-2013. For information on changes after this date please refer to the module 'Update'.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have agreed in granting a marketing authorisation for Fluoxetina Aurobindo 20 mg and 60 mg capsules, hard, from Aurobindo.
The product is indicated for*:* the treatment of major depressive episodes, obsessive-compulsive disorder and bulimia nervosa (adults) and moderate to severe major depressive episode, if depression is unresponsive to psychological therapy after 4–6 sessions. Antidepressant medication should be offered to a child or young person with moderate to severe depression only in combination with a concurrent psychological therapy (Children and adolescents aged 8 years and above*)*.
A comprehensive description of the indications and posology is given in the SmPC.

The originator product is Prozac, registered since 1989-08-09 by Lilly Portugal - Produtos Farmacêuticos, Lda.

The marketing authorisation has been granted pursuant to Article 10.1 of Directive 2001/83/EC.

This type of application refers to information that is contained in the pharmacological-toxicological and clinical part of the dossier of the authorisation of the reference product. A reference product is a medicinal product authorised and marketed on the basis of a full dossier, i.e. including chemical, biological, pharmaceutical, pharmacological-toxicological and clinical data. This information is not fully available in the public domain. Authorisations for generic products are therefore only allowed once the data protection time of the dossier of the reference product has expired. For this kind of application, it has to be demonstrated that the pharmacokinetic profile of the product is similar to the pharmacokinetic profile of the reference product. This generic product can be used instead of its reference product.

II. QUALITY ASPECTS

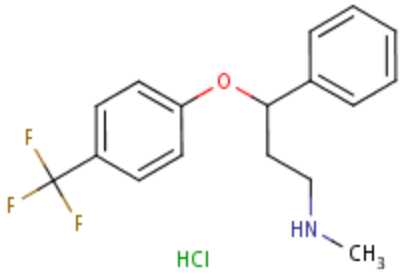
II.1 Introduction

Fluoxetina Aurobindo is 20 mg capsules, hard is an opaque green cap/yellow body, size "4" hard gelatin capsule filled with white to off-white powder and imprinted with 'J' on opaque green cap and '96' on yellow body with black ink. Fluoxetine Aurobindo 60 mg capsules, hard is an opaque green cap/yellow body, size "1" hard gelatin capsule filled with white to off-white powder and imprinted with 'J' on opaque green cap and '95' on yellow body with black ink.
Each tablet contains 20 mg or 60 mg of fluoxetin.

Fluoxetine Aurobindo capsules are available in clear PVC/PVdC -Aluminium foil blister pack and HDPE bottle pack with polypropylene closure.

The excipients are starch, pregelatinised (maize starch), cellulose, microcrystalline, Silica, colloidal anhydrous, iron oxide yellow (E172), Patent blue V (E131), titanium dioxide (E171), gelatine, sodium lauryl sulphate.*Printing ink:*shellac, propylene glycol, black iron oxide (E172), potassium hydroxide

II.2 Drug Substance



Fluoxetine hydrochloride

The chemical-pharmaceutical documentation and Expert Report in relation to fluoxetine hydrochloride are of sufficient quality in view of the present European regulatory requirements.

II.3 Medicinal Product

The documentation provided complies with relevant EU guidelines and directives. Manufacture is performed in accordance with cGMP and consistency in quality and homogeneity is demonstrated.

The finished product specification is based on relevant development and stability studies. The development of the product has been described, the choice of excipients is justified and their functions explained.
Appropriate validation data have been provided for the analytical methods. Batch analyses data support the proposed finished product specification.

The conditions used in the stability studies are according to the ICH stability guideline. The control tests and specifications for drug product are adequately drawn up.

The proposed shelf-life of 24 months for the drug product with no special storage requirements is considered acceptable

III. NON-CLINICAL ASPECTS

The pharmacodynamic, pharmacokinetic and toxicological properties of fluoxetin are well known. As fluoxetin is a widely used, well-known active substance, the applicant has not provided additional studies and further studies are not required. An overview based on literature review is, thus, appropriate.

Environmental Risk Assessment (ERA)

An Environmental Risk Assessment has not been performed as the product is intended for generic substitution. A disposal advice has been added to the SmPC.

IV. CLINICAL ASPECTS

To support the present application, the applicant has submitted as report one bioequivalence study (Study No.: 362-11) in healthy, adult, male, human subjects under fasting conditions. The test product was Fluoxetine Aurobindo 60 mg capsules (1x60mg) and the Reference product was Prozac 20 mg capsules (3x20 mg). The study was performed at AXIS Clinicals Limited 1-121/1, Miyapur, Hyderabad-500049, India.
The study was performed regarding GCP and GLP. The Protocol Study was approved by an Independent Ethics Committee.

Pharmacovigilance system
The Summary of the Applicant´s Pharmacovigilance System is acceptable according the new legislation for pharmacovigilance applied in the European Union (EU) which replaced Volume 9A of the Rules Governing Medicinal Products in the EU.

Risk Management Plan
The current application is a generic version of an already authorized reference product.
The RMP version 2.0 from 04-03-2014 was accepted.

V. 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 ***Fluoxetine Accord (SE/H/753/01/DC)***. The bridging report submitted by the applicant has been found acceptable.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Based on the review of the data on quality, safety and efficacy, the RMS considered that the application for Fluoxetina Aurobindo 20 mg and 60 mg, capsules, hard is approvable