LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific Discussion

Cipralex, oral drops, solution, 20 mg/ml (escitalopram oxalate)

SE/H/278/06/E05

This module reflects the scientific discussion for the approval of Cipralex, oral drops, solution 20 mg/ml. The procedure was finalised at 2007-07-17. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

H. Lundbeck A/S has applied for a marketing authorisation for Cipralex, oral drops, solution 20 mg/ml. The active substance escitalopram oxalate is the same as in Cipralex tablets, marketed by "H. Lundbeck A/S since December 2001. For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Cipralex is presented in the form of oral drops containing 25.551 mg/ml of escitalopram oxalate which corresponds to 20 mg/ml of escitalopram. The excipients are propyl gallate, anhydrous citric acid, ethanol 96%, sodium hydroxide and purified water.
The oral solution is filled into brown glass bottle with dropper applicator (polyethylene), and child-proof screw cap (polypropylene).

II.2 Drug Substance

Escitalopram oxalate does not have a monograph in the Ph Eur.

Escitalopram oxalate is a white to slightly yellow crystalline powder which is soluble in water, sparingly soluble in ethanol, freely soluble in methanol and insoluble in heptane. The structure of ecitalopram oxalate 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 and 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

Cipralex oral drops are formulated using excipients described in the current Ph Eur. All raw materials used in the product are of vegetable origin.

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

See public assessment report Cipralex tablets, 5, 10, 15 and 20 mg.

IV. CLINICAL ASPECTS

IV.1 Introduction

See public assessment report Cipralex tablets, 5, 10, 15 and 20 mg.

IV.2 Pharmacokinetics

No bioequivalence study is required, since this application concerns a new strength of the earlier approved Cipralex, oral drops solution, 10 mg/ml.

IV.3 Pharmacodynamics

See public assessment report Cipralex tablets, 5, 10, 15 and 20 mg.

IV.4 Clinical efficacy

See public assessment report Cipralex tablets, 5, 10, 15 and 20 mg.

IV.5 Clinical safety

See public assessment report Cipralex tablets, 5, 10, 15 and 20 mg.

IV.6 Discussion on the clinical aspects

See public assessment report Cipralex tablets, 5, 10, 15 and 20 mg.

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 Cipralex, oral drops, solution 20 mg/ml was recommended for approval.

Since this was a repeat use procedure, the applicant committed to submit a type II variation to include requested changes to the SmPC and PIL.

VI. APPROVAL

The Mutual recognition procedure for Cipralex, oral drops solution 20 mg/ml was successfully finalised on 2007-07-17.

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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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