LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Line extensions

Scientific discussion

Entact, oral drops, solution, 20 mg/ml
(Escitalopram oxalate)

SE/H/279/06/DC

This module reflects the scientific discussion for the approval of Entact, oral drops, solution 20 mg/ml. The procedure was finalised at 2006-12-11. 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 Entact, oral drops, solution 20 mg/ml. The active substance escitalopram oxalate is the same as in Entact, film-coated tablet 5 mg, 10 mg, 15 mg and 20 mg, marketed by H. Lundbeck A/S since 2001 and as in Entact, oral drops, solution 10 mg/ml, marketed by H. Lundbeck A/S since 2003. The product is indicated for the treatment of major depressive episodes, panic disorder with or without agoraphobia, social anxiety disorder (social phobia) and generalised anxiety disorder.

II. QUALITY ASPECTS

II.1 Introduction

Entact is presented in the form of oral drops containing 25.551 mg/ml of escitalopram oxalate which corresponds to 20 mg/ml of the escitalopram. The excipients are propyl gallate, anhydrous citric acid, ethanol (96%), sodium hydroxide and purified water. The oral drops are filled in 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. Information on the drug substance has been supplied in the form of an ASMF.

Escitalopram oxalate is a white to slightly yellow crystalline powder which is freely soluble in methanol, soluble in water, sparingly soluble in ethanol (96%) and insoluble in heptane. The structure of the drug substance 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

Entact oral drops is 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.

III. NON-CLINICAL ASPECTS

Not applicable as this application concerns a new strength of Entact oral drops, an earlier approved product with a known active substance.

IV. CLINICAL ASPECTS

Not applicable as this application concerns a new strength of Entact oral drops, an earlier approved product with a known active substance.

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 Entact, oral drops, solution 20 mg/ml is recommended for approval.

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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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