LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Naltrexon Abcur
(naltrexone hydrochloride)

ASP no: 2013-1584

This module reflects the scientific discussion for the approval of. The procedure was finalised on 2015-05-07. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Naltrexon Abcur, 50 mg, film-coated tablet, is a generic application made according to Article 10(1) of Directive 2001/83/EC. The applicant, Abcur AB, applies for a marketing authorisation in Sweden through the National Procedure.

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Nalorex, 50 mg, film-coated-tablet authorised in IT since 1987, with L.Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A. as marketing authorisation holder. The reference product is used as European reference product (ERP) and is thus not authorised in Sweden.

For approved indications, see the Summary of Product Characteristics.

For recommendations to the marketing authorisation not falling under Article 21a/22 of Directive 2001/83 and conditions to the marketing authorisation pursuant to Article 21a or 22 of Directive 2001/83/EC to the marketing authorisation, please see section VI.

II. QUALITY ASPECTS

II.1 Drug Substance

The structure of the drug substance has been adequately proven and its physico-chemical properties are sufficiently described.

The manufacture of the drug substance has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The drug 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 confirm the retest period.

II.2 Medicinal Product

The medicinal product is formulated using excipients listed in section 6.1 in the Summary of Product Characteristics.

The manufacturing process has been sufficiently described and critical steps identified.

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 have been performed and data presented support the shelf life and special precautions for storage claimed in the Summary of Product Characteristics, sections 6.3 and 6.4.

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 such further data have been submitted or are considered necessary.

IV. CLINICAL ASPECTS

IV.1 Pharmacokinetics

No bioequivalence study was submitted with this application. The proposed formulation is stated to be the same as the reference product. Thus, no bioequivalence study was performed, which is found acceptable.

IV.2 Discussion on the clinical aspects

Since this product has been shown to be essentially similar and refers to a product approved based on a full application with regard to clinical efficacy/safety data, no such further data have been submitted or are considered necessary.

IV.3 Risk Management Plan

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Naltrexon Abcur.

The MAH has suggested the following safety concerns:

Summary of safety concerns	
Important identified risks	• Acute opioid withdrawal
Important potential risks	• Liver toxicity • Use in patients with renal disorders
Missing information	• Use in pregnancy and lactation

RMS Comment
Safety concerns proposed are acceptable.
The safety concerns will be addressed with routine pharmacovigilance activities and no additional pharmacovigilance activities are suggested.
Routine risk minimisation measures and no additional risk minimisation measures are suggested, which are accepted.
Suggested safety concerns and risk management plan are accepted.
The RMP is approved

V. USER CONSULTATION

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PIL was Finnish.
The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the generic product Naltrexon Abcur is found adequate. There are no objections to approval of Naltrexon Abcur from a non-clinical and clinical point of view. The product information is acceptable.
The application is therefore recommended for approval.

List of recommendations not falling under Article 21a/22 of Directive 2001/83 in case of a positive benefit risk assessment

N/A

List of conditions pursuant to Article 21a or 22 of Directive 2001/83/EC

N/A

VII. APPROVAL

Naltrexon Abcur, 50 mg, film-coated tablet was approved in the national procedure on 2015-05-07.

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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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