LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Morfin Abcur
(morphine hydrochloride)

SE/H/1354/01/MR

This module reflects the scientific discussion for the approval of Morfin Abcur. The procedure was finalised at 2013-12-10. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Morfin Abcur, solution for injection, 10 mg/ml, is a generic application made according to Article 10(1) of Directive 2001/83/EC. The applicant, Abcur AB, applies through the Mutual recognition procedure with Sweden acting as reference member state (RMS) and IS and NO as concerned member states (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Morfin Meda 10 mg/ml solution for injection, authorised in Sweden since 1973, with Meda AB as marketing authorisation holder.

For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Morfin Abcur is presented in the form of solution for injection containing 10 mg/ml of morphine hydrochloride which corresponds to 7.6 mg/ml of morphine. The excipients are hydrochloric acid and water for injections. The solution for injection is filled in brown glass ampoules.

II.2 Drug Substance

Morphine hydrochloride has a monograph in the Ph Eur.

Morphine hydrochloride is a white or almost white crystalline powder which is soluble in water and glycerol, and slightly soluble in alcohol. The structure of morphine hydrochloride has been adequately proven and its physico-chemical properties sufficiently described. The route of synthesis has been adequately proven.

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

Morfin Abcur solution for injection is formulated using excipients described in the current Ph Eur.

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 in the outer carton in order to protect from light.

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

According to the Guideline on the investigation of Bioequivalence (CHMP/QWP/EWP/1401/98 Rev. 1) no bioequivalence study is necessary for parenteral solutions if the test product is to be administered as an aqueous intravenous solution containing the same active substance as the currently approved product. In addition, no bioequivalence studies are required for other parenteral routes, if the test product is of the same type of solution (aqueous or oily), contains the same concentration of the same active substance and the same excipients in similar amounts as the medicinal product currently approved. Moreover, a bioequivalence study is not required for an aqueous parenteral solution with comparable excipients in similar amounts, if it can be demonstrated that the excipients have no impact on the viscosity.

Morfin Abcur is a parenteral solution, intended for intravenous administration as well as administration via other parenteral routes, containing the same active substance in the same concentration as the currently authorised product. There are differences in excipients between the test and reference product. However, it is considered unlikely that the differences should significantly affect the viscosity of the solution or the bioavailability following intramuscular or subcutaneous injection.

Thus, the absence of bioequivalence studies is considered acceptable for this product.

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
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.

The risk/benefit ratio is considered positive and Morfin Abcur, 10 mg/ml, solution for injection, is recommended for approval.

VI. APPROVAL

The Mutual recognition procedure for Morfin Abcur, 10 mg/ml, solution for injection, was successfully finalised on 2013-12-10.

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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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