LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report

Scientific discussion

Ondansetron Hexal, 2 mg/ml, solution for injection

(Ondansetron hydrochloride dihydrate)

Asp.no 2004-1304

This module reflects the scientific discussion for the approval of Ondansetron Hexal 2mg/ml, solution for injection. Please note that the marketing authorisation was first approved with the name "Ondansetron Epipharm" and therefore this name is used throughout the document. The procedure was finalised at 2007-08-31. For information on changes after this date please refer to the module 'Update'.

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.mpa.se E-mail: registrator@mpa.se

I. INTRODUCTION

Epipharm AB has applied for a marketing authorisation for Ondansetron Epipharm, 2 mg/ml, solution for injection claiming essential similarity to Zofran, 2 mg/ml, solution for injection, marketed in Sweden by GlaxoSmithKline. The product contains ondansetron hydrochloride dihydrate as active substance. For approved indications see the Summary of Product Characteristics. No bioequivalence study has been performed since the dosage form is solution for injection. The composition is similar to the reference product on the Swedish market and the products are considered to be pharmaceutically equivalent.

II. QUALITY ASPECTS

II.1 Introduction

Ondansetron Epipharm is presented in the form of solution for injection containing 2mg/ml ondansetron as ondansetron hydrochloride dihydrate. The excipients are sodium chloride, sodium citrate dihydrate, citric acid monohydrate and water for injections. The solution is filled into 2 ml or 4 ml glass ampoules.

II.2 Drug Substance

Ondansetron hydrochloride dihydrate has a monograph in the Ph Eur. The drug substance manufacturers hold European Certificates of Suitability.

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

Ondansetron Epipharm 2mg/ml solution for injection 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, with the storage restriction, store in the outer carton, sensitive to 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

As the product is to be administered as an aqueous intravenous solution, no difference in absorption rate or bioavailability between the two products is expected. Consequently, no bioequivalence study is required.

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 testing of the package leaflet has not been performed. The justification for absence of user testing is acceptable.

The risk/benefit ratio is considered positive and Ondansetron Epipharm 2mg/ml solution for injection is recommended for approval.

VI. APPROVAL

Ondansetron Epipharm, 2mg/ml, solution for injection, was approved in the national procedure on 2007-08-31.

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

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)

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.mpa.se E-mail: registrator@mpa.se