LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Ribodocel
(docetaxel)

SE/H/1052/01-02/DC

This module reflects the scientific discussion for the approval of Ribodocel. The procedure was finalised at 11 May 2011. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Alfred E. Tiefenbacher (GmbH & Co. KG) has applied for a marketing authorisation for Ribodocel 20 mg/1 ml and 80 mg/4 ml, concentrate for solution for infusion, claiming essential similarity to Taxotere, 20 mg/1 ml and 80 mg/4 ml, concentrate for solution for infusion marketed the EU by Aventis Pharma S.A. The product contains docetaxel as active substance. For approved indications see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Ribodocel is presented in the form of a concentrate for solution for infusion containing 20 mg or 80 mg of docetaxel anhydrous. The excipients are citric acid monohydrate, ethanol and polysorbate 80. The concentrate for solution for infusion is filled in glass vials.

II.2 Drug Substance

Docetaxel anhydrous does not yet have a monograph in the Ph Eur., although a monograph has been submitted for publication. Docetaxel trihydrate has a monograph in the Ph. Eur.

Docetaxel anhydrous is a white to off-white powder, which is insoluble in water and freely soluble in ethanol. The structure of docetaxel anhydrous has been adequately proven and its physico-chemical properties sufficiently described. Relevant information on 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/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

Ribodocel, concentrate for solution for infusion, is formulated using excipients described in the current Ph. Eur. All raw materials used in the product have demonstrated compliance with Commission Directive 2003/63/EC and the NfG on Minimising the risk of transmitting Animal Spongiform Encephalopathy Agents via human and veterinary medicinal products (EMEA/410/01).

The product development has taken into consideration the physico-chemical characteristics of the active substance, such as poor aqueous solubility and stability.

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 between 2 °C and 8 °C.

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

Ribodocel was developed to be essentially similar to the brand leader, Taxotere® with identical qualitative and quantitative composition in terms of active substance and same pharmaceutical form as the reference product. Given that the products are the same type of solution, contain the same concentrations of the same active substance and similar excipients, a bioequivalence study is not considered to be required. The assessment of similarity will have to rely on quality data.

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
A user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of a bridging report making reference to an authorized product containing docetaxel. The bridging report submitted by the applicant has been found acceptable.

The risk/benefit ratio is considered positive and Ribodocel 20 mg/1 ml and 80 mg/4 ml, concentrate for solution for infusion, is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Ribodocel 20 mg/1 ml and 80 mg/4 ml, concentrate for solution for infusion was successfully finalised on 11 May 2011.

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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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