LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Vinorelbin Hospira
Vinorelbine tartrate

SE/H/577/01/MR

This module reflects the scientific discussion for the approval of Vinorelbine Hospira. Please note that the marketing authorisation was first approved with the name "Vinorelbine Mimer" and therefore this name is used throughout the document. The procedure was finalised at 2006-05-23. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Mimer Medical has applied for a marketing authorisation for Vinorelbin Mimer, 10 mg/ml concentrate for solution for infusion claiming essential similarity to Navelbine 10mg/ml concentrate for solution for infusion marketed in Sweden by Pierre Fabre. The product contains vinorelbine tartrate as active substance and is indicated for the treatment of non-small cell lung cancer (stage 3 or 4) and as single agent to patients with metastatic breast cancer (stage 4), where treatment with anthracycline- and taxane containing chemotherapy has failed or is not appropriate.

No bioequivalence study has been performed which is acceptable since this is a dosage form intended for infusion. The innovator's and the generic formulations are similar containing the same quantitative and qualitative amounts of the drug substance and the same excipient, water for injection.

II. QUALITY ASPECTS

II.1 Introduction

Vinorelbin Mimer is presented in the form of concentrate for solution for infusion containing 10 mg/ml of vinorelbine (as tartrate). The excipient is water for injections. The concentrate for solution for infusion is filled in clear Type 1 glass vials of 2 ml and 5 ml resulting in packages of 10mg/1ml and 50mg/5ml.

II.2 Drug Substance

Vinorelbine tartrate has a monograph in the Ph Eur. Information on vinorelbine tartrate has been supplied in the form of an ASMF.

Vinorelbine tartrate is a white to off white amorphous, very hygroscopic powder. The substance is freely soluble in water from which it is lyophilized and partially soluble in methanol. It is insoluble in aprotic solvents. The structure of vinorelbine tartrate 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/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

Vinorelbin Mimer 10mg/ml concentrate for solution for infusion is formulated using excipients described in the current Ph Eur. No raw materials of human or animal origin are used in the product. The product development has taken into consideration the physico-chemical characteristics of the active substance.

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 restrictions, store in a refrigerator (2°C - 8°C), do not freeze. Store the vial 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 refers 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 Vinorelbin Mimer concentrate for solution for infusion 10 mg/ml and the reference product Navelbine concentrate for solution for infusion 10 mg/ml 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 refers 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 been performed.

The risk/benefit ratio is considered positive and Vinorelbin Mimer, 10 mg/ml, concentrate for solution for infusion 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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