LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Pentocur
(Thiopental sodium)

SE/H/1206/01/DC

This module reflects the scientific discussion for the approval of Pentocur. The procedure was finalised at 2012-10-03. 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

Abcur AB has applied for a marketing authorisation for Pentocur, powder for solution for injection, claiming essential similarity to Pentothal Natrium, powder for solution for injection marketed in Sweden by Hospira Enterprises B.V. The product contains thiopental sodium as active substance. For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Pentocur is presented in the form of powder for solution for injection, containing 0.5 g or 1.0 g of thiopental sodium and sodium carbonate. The powder is filled in vials.

II.2 Drug Substance

Thiopental sodium and sodium carbonate is a mixture of the sodium derivative of thiopental and anhydrous sodium carbonate. The mixture is described in the Ph.Eur. (monograph 212). The drug substance manufacturer holds a Certificate of Suitability (CEP) for the sterile substance. No re-test date is given on the CEP. The manufacturing process of the sterile drug substance has been acceptably described and validated.

II.3 Medicinal Product

The drug product is a yellowish-white powder for solution for injection. The drug product is supplied in glass vials containing 0.5 g or 1.0 g powder. The drug product contains no additional excipients but anhydrous sodium carbonate which is added to the drug substance as a buffer in the time of its manufacture.

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, 3 years at no special storage conditions.

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

No bioequivalence study for Pentocur has been conducted. However, since Pentocur is to be administered as an aqueous intravenous solution a bioequivalence study is not 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 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 PL 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 Pentocur, powder for solution for injection is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Pentocur, powder for solution for injection was successfully finalised on 2012-10-03.

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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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