LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Nitroglycerin Abcur
(glyceryl trinitrate)

Asp no: 2013-0647

This module reflects the scientific discussion for the approval of Nitroglycerin Abcur. The procedure was finalised at 2014-04-28. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Nitroglycerin Abcur, 1 mg/ml, solution for infusion, is a generic application made according to Article 10(1) of Directive 2001/83/EC. The applicant, Abcur AB applies for a marketing authorisation in Sweden through a National Procedure.

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Nitroglycerin BioPhausia, 1 mg/ml, solution for infusion/concentrate for solution for infusion, authorised in Sweden since 1991, with BioPhausia AB, Stockholm, as marketing authorisation holder.

For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Nitroglycerin is presented in the form of a solution for infusion containing 1 mg of glyceryl trinitrate which corresponds to 1.96% mg of the glyceryl trinitrate glucose trituration . The excipients are glucose monohydrate, hydrochloric acid and water for injection.

The finished product is filled into glass vials of type II.

II.2 Drug Substance

Glyceryl trinitrate has a monograph in the Ph Eur but glyceryl trinitrate glucose trituration doesn't have any monograph in the Ph Eur.

Glyceryl trinitrate glucose trituration is a white, crystalline odourless powder which is freely soluble in water. The structure of "drug substance" has been adequately proven and its physico-chemical properties sufficiently described.

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

Nitroglycerin solution for infusion is formulated using excipients described in the current Ph Eur. All raw materials used in the product are of vegetable origin/has 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 aqueous solubility, 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, with no special storage precautions.

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

Bioequivalence studies are not required since Nitroglycerin Abcur is a solution for infusion intended for intravenous administration containing the same active substance as the reference product. Bioequivalence with Nitroglycerin BioPhausia can be concluded.

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 Nitroglycerin Abcur, 1 mg/ml, solution for infusion, is recommended for approval.

VI. APPROVAL

Nitroglycerin Abcur, 1 mg/ml, solution for infusion, was approved in the national procedure on 2014-04-28.

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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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