LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Glucose-Na-K Baxter 50 mg/ml
Glucose-Na-K Baxter 50 mg/ml

(glucose monohydrate 55 or 110 mg/ml, sodium chloride 1 mg/ml, potassium chloride 1.5 mg/ml, magnesium chloride hexahydrate 0.3 mg/ml, sodium acetate trihydrate 3.1 mg/ml)

SE/H/921/01-02/MR

This module reflects the scientific discussion for the approval of Glucos Baxter Viaflo. Please note that the marketing authorisations were first approved with the names "Glucos Baxter Viaflo 50 mg/ml + Na 40 + K 20" and "Glucos Baxter Viaflo 100 mg/ml + Na 40 + K 20" and therefore these names are used throughout the document. The procedure was finalised at day 75, 2009-09-01. 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

Baxter Medical AB has applied for a marketing authorisation for Glucos Baxter Viaflo 50 mg/ml + Na 40 + K20 and 100 mg/ml + Na 40 + K20, solution for infusion. The active substances are Glucose monohydrate, Magnesium chloride hexahydrate, Potassium chloride, Sodium acetate trihydrate, and Sodium chloride. The products are used as energy, electrolyte and fluid replacement therapy. For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Glucos Baxter Viaflo 50 mg/ml + Na 40 + K 20 and 100 mg/ml + Na 40 + K 20 is presented in the form of solution for infusion containing glucose monohydrate, sodium chloride, potassium chloride, magnesium chloride hexahydrate and sodium acetate trihydrate. The excipients are hydrochloric acid for pH adjustment and water for injections as solvent. The solution is filled in flexible "Viaflo" plastic bags.

II.2 Drug Substance

All the active drug substances have a monograph in the Ph Eur.

The active substance specifications include relevant tests and limits. The analytical methods applied are according to the Ph Eur monographs.

No stability data has been submitted and this is considered acceptable due to the nature of the active ingredients. The stability of the ingredients is well-known and well-established.

II.3 Medicinal Product

Glucos Baxter Viaflo 50 mg/ml + Na 40 + K 20 and 100 mg/ml + Na 40 + K 20 is formulated using excipients described in the current Ph Eur. All raw materials used in the product 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 relevant characteristics.

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 below 25ºC.

III. NON-CLINICAL ASPECTS

The novelty of this drug product lies in its primary packaging material which is already registered and marketed as container for other solutions for infusion in most of European countries. The Viaflo container passes the European Pharmacopoeia (EP) tests described in the current edition of the EP monograph 3.2.2.1. For this application, an additional safety study was conducted investigating extractives following storage of the actual Glucos Baxter Viaflo 50 mg/ml + Na 40 + K 20 at two different temperatures. Five main extractives were detected and the available toxicological data for each of them was reviewed. Even if the cited publications mainly refer to oral and not intravenous administration of the extractives, or data presented only on structurally similar compounds (i.e. euracamide), the preclinical safety margin is considered sufficient. The risk of acute or chronic toxicity or mutagenic, carcinogenic or teratogenic effects at the predicted exposure levels are considered negligible for all detected extractives in the Viaflo system under the proposed conditions and duration of clinical use. The products are approvable from a preclinical point of view.

IV. CLINICAL ASPECTS

IV.1 Clinical efficacy

There are enough experiences with these kinds of products in clinical practice. The data found in current text books and in published literature are extensive and covers the area sufficiently. It is therefore concluded that the efficacy of these products have been well established.

IV.2 Clinical safety

The conclusion reached from examination of all existing data is that the products are safe when used as energy, electrolyte and fluid replacement therapy in accordance with the recommendations of the proposed Summary of Product Characteristics and by sufficiently trained medical professionals.

IV.3 Risk Management Plan

Pharmacovigilance System

The Assessor considers that the Pharmacovigilance system as described by the applicant fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

Risk Minimisation Plan

This is a well established product, and routine pharmacovigilance activities are considered sufficient.

Periodic Safety Update Report (PSUR)

The product has a well established use and PSUR submission scheme should be 3 yearly PSUR after approval.

V. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

User testing of the package leaflet has not been performed, but an acceptable bridging to a test for a similar product has been made.

The risk/benefit ratio is considered positive and Glucos Baxter Viaflo 50 mg/ml + Na 40 + K20 and Glucos Baxter Viaflo 100 mg/ml + Na 40 + K20, solution for infusion, are recommended for approval.

VI. APPROVAL

The Mutual recognition procedure for Glucos Baxter Viaflo 50 mg/ml + Na 40 + K 20 solution for infusion and Glucos Baxter Viaflo 100 mg/ml + Na 40 + K 20 solution for infusion was successfully finalised on 2009-09-01.

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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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