LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Glucose-Na-K Baxter 50 mg/ml

glucose monohydrate
magnesium chloride hexahydrate
potassium chloride
sodium acetate trihydrate
sodium chloride

SE/H/921/01/E/02

This module reflects the scientific discussion for the approval of Glucose-Na-K Baxter 50 mg/ml. The procedure was finalised on 2022-02-07. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, a marketing authorisation has been granted for Glucose-Na-K Baxter, 50 mg/ml, Solution for infusion.

The active substances are glucose monohydrate, magnesium chloride hexahydrate, potassium chloride, sodium acetate trihydrate and sodium chloride. A comprehensive description of the indication and posology is given in the SmPC.

For recommendations to the marketing authorisation not falling under Article 21a/22a/22 of Directive 2001/83/EC and conditions to the marketing authorisation pursuant to Article 21a/22a/ 22 of Directive 2001/83/EC to the marketing authorisation, please see section VI.

The application for Glucose-Na-K Baxter, 50 mg/ml, Solution for infusion, is submitted according to Article 10a of Directive 2001/83/EC. The applicant, Baxter Medical AB, applies through the Mutual Recognition Procedure (second wave Repeat Use) with Sweden acting as reference member state (RMS) and Germany as the concerned member state (CMS). The product was first approved through a National Procedure in Sweden.

For an application according to Article 10a, Well established-use (WEU), the applicant needs to demonstrate that the active substance of the medicinal product has been in well-established medicinal use for the claimed therapeutic indication within the Union for at least ten years, with recognised efficacy and an acceptable level of safety. The active substance is not considered a new active substance.

Potential similarity with orphan medicinal products

According to the application form and a check of the Community Register of orphan medicinal products there is no medicinal product designated as an orphan medicinal product for a condition relating to the indication proposed in this application.

II. QUALITY ASPECTS

II.1 Drug Substance

The structure of the drug substance has been adequately proven and its physico-chemical properties are sufficiently described.

The manufacture of the drug substance has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The drug substance specification includes relevant tests and the limits for impurities and degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies confirm the retest period.

II.2 Medicinal Product

The medicinal product is formulated using excipients listed in section 6.1 in the Summary of Product Characteristics.

The manufacturing process has been sufficiently described and critical steps identified.

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 have been performed and data presented support the shelf life and special precautions for storage claimed in the Summary of Product Characteristics, sections 6.3 and 6.4.

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 exposure 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.

Environmental Risk Assessment (ERA)
Since Glucose-Na-K Baxter 50 mg/ml is composed of glucose as energy nutrient together with electrolytes, no additional environmental risks are expected for the product.

IV. CLINICAL ASPECTS

Clinical efficacy
Electrolyte- and glucose-containing fluids are since many decades well-established in clinical practice and the wide-spread experience is documented in medical textbooks, clinical practice guidelines, and scientific reports. The data provided covers the topic sufficiently. It is therefore concluded that the efficacy of these products is well established.

Clinical safety
The conclusion reached from examination of all existing data is that the safety profile of the product is well characterised and the risks adequately minimised by the proposed product information.

Risk Management Plan

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Glucose-Na-K Baxter 50 mg/ml.

Safety specification

Important identified risks	None
Important potential risks	None
Missing information	None

Pharmacovigilance Plan
Routine pharmacovigilance is suggested and no additional pharmacovigilance activities are proposed by the applicant, which is endorsed.

Risk minimisation measures
Routine risk minimisation is suggested and no additional risk minimisation activities are proposed by the applicant, which is endorsed.

Summary of the RMP
The submitted Risk Management Plan, version 1.1 signed 14 November 2017 is considered acceptable.

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:
- At the request of the RMS;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time, but via different procedures.

V. USER CONSULTATION

The user test was assessed and accepted in SE/H/921/01-02/MR.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The benefit/risk for this well-established product was considered positive, and Glucose-Na-K Baxter, 50 mg/ml, Solution for infusion was therefore recommended for approval.

List of recommendations not falling under Article 21a/22a/22 of Directive 2001/83/EC in case of a positive benefit risk assessment

N/A

List of conditions pursuant to Article 21a/22a or 22 of Directive 2001/83/EC

N/A

VII. APPROVAL

The mutual recognition procedure for Glucose-Na-K Baxter 50 mg/ml, Solution for infusion was positively finalised on 2022-02-07.

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Public Assessment Report – Update

Procedure number*	Scope	Product Information affected (Yes/No)	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse

*Only procedure qualifier, chronological number and grouping qualifier (when applicable)

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