LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report

Scientific discussion

Flucorpus
(fludeoxyglucose [^{18}F])

Asp no: 2017-0801

This module reflects the scientific discussion for the approval of Flucorpus. The procedure was finalised on 2018-06-29. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Flucorpus, 2-60 GBq, Solution for injection, is a generic application made according to Article 10(1) of Directive 2001/83/EC. The applicant, Universitetssjukhuset Linköping, Röntgenkliniken US applies for a marketing authorisation in Sweden through a National Procedure.

European Reference Product (ERP)
A European Reference Product is used: [Fluor-18-FDG, 400 MBq – 210 GBq, solution for injection, authorised in DK since 1999, with PET & Cyclotron Unit, Rigshospitalet Copenhagen as marketing authorisation holder. The justification to use this product is based on information received from DK.

For approved indications, see the Summary of Product Characteristics.

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

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 is not isolated during the manufacturing of the drug product. However, the drug substance is controlled by the drug product specification.

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

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

There are no bioequivalence studies included in the application. The absence of bioequivalence studies is acceptable since the applied product is to be administered as an intravenous solution containing the same active substance as the currently authorised product. None of the excipients are known to interact with the drug substance. There are no objections to approval of Flucorpus, 2-60 GBq, Solution for injection from a pharmacokinetic point of view.

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.

IV.3 Risk Management Plan

The MAH has resubmitted an updated 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 Flucorpus.

Safety specification

Summary of safety concerns	
Important identified risks	• Hypersensitivity
Important potential risks	• Radiation risks (cancerogenity, mutagenity) • Use in pregnancy • Nursing mothers (lactation)
Missing information	None identified

Pharmacovigilance Plan
Routine pharmacovigilance is considered sufficient with regard to the benign safety profile of the product based on its well-established use.
No additional pharmacovigilance activities are proposed by the applicant, which is endorsed.

Risk minimisation measures
The safety information on the proposed product information is aligned to the Core Summary of Product Characteristics for Fludeoxyglucose (18F) (EMA WC500099826).
Sections V.1-V.3 are not applicable.

This is endorsed.

Summary of the RMP
The MAH has satisfactory responded to the questions raised and updated the RMP accordingly. The submitted Risk Management Plan, version 0.2 signed 180212 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 MPA;
- 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

A user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of a bridging report making reference to MetaTrace FDG solution for injection 3000 MBq/ml, UK/H/2656/001/MR. The bridging report submitted by the applicant has been found acceptable.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the generic product, Flucorpus is found adequate. There are no objections to approval of Flucorpus, from a non-clinical and clinical point of view. The product information is acceptable. The application is therefore recommended for approval.

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

N/A

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

N/A

VII. APPROVAL

Flucorpus, 2-60 GBq, Solution for injection, was approved in the national procedure on 2018-06-29.

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Public Assessment Report – Update

Procedure number*	Scope	Product Information affected	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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