LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Poltechnet
(sodium molybdate [99Mo] / sodium pertechnetate [99mTc])

SE/H/1365/01/DC

This module reflects the scientific discussion for the approval of Poltechnet. The procedure was finalised on 2015-01-21. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Poltechnet, 9.1– 200 GBq[^{99}Mo] /8.0- 175 GBq[^{99m}Tc], radionuclide generator, is a hybrid application made according to Article 10(3) of Directive 2001/83/EC. The applicant,Narodowe Centrum Badań Jądrowych (National Centre for Nuclear Research), applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and AT, BG, CZ, DK, ES, LT, PL, PT, RO and SI as concerned member states (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Drytec, 2.5 – 100 GBq, radionuclide generator, authorised in DK since 1995, with GE Healthcare Limited, as marketing authorisation holder.

For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Poltechnet is presented in the form of a radionuclide generator containing 9.1 – 200 GBq of the parent isotope sodium molybdate (^{99}Mo) and 8.0 – 175 GBq of sodium pertechnetate (^{99m}Tc) as daughter nuclide. The daughter nuclide technetium-99m is eluted from the generator as sodium pertechnetate with 0.9 % sodium chloride solution. The excipients are sodium chloride and water for injection. The generator consists of a sterile glass column filled with alumina on which molybdenum-99 is adsorbed. The column is placed inside a lead shielding. The eluate is filled in glass vials closed with rubber stoppers and aluminium cap, placed in a lead shielded container.

II.2 Drug Substance

The drug substances sodium molybdate (^{99}Mo) and sodium pertechnetate (^{99m}Tc) have a monograph in the Ph Eur.

The structure of sodium molybdate (^{99}Mo) and sodium pertechnetate (^{99m}Tc) 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 not been conducted due to the short half-life. The data provided are sufficient to confirm the shelf life.

II.3 Medicinal Product

Poltechnet radionuclide generator is formulated using excipients described in the current Ph Eur. No excipients of human or animal origin are used.

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 not been performed due to the short half life. However, the data presented support the shelf life claimed in the SPC.

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 clinical studies or bioequivalence studies included in the application. The absence of bioequivalence studies is acceptable since the applied product is a radionuclide generator to be administered as an intravenous solution containing the same active substance as the currently authorised product.

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 Polish.

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 Poltechnet, 9.1– 200 GBq[^{99}Mo] /8.0- 175 GBq[^{99m}Tc], radionuclide generator, is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Poltechnet, 9.1– 200 GBq[^{99}Mo] /8.0- 175 GBq[^{99m}Tc], radionuclide generator, was successfully finalised on 2015-01-21.

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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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