TRANSLATION FROM THE POLISH LANGUAGE

PRESIDENT

OF THE OFFICE FOR REGISTRATION OF MEDICINAL PRODUCTS, MEDICAL DEVICES AND BIOCIDAL PRODUCTS

Warsaw, 12 May 2015

No. UR/RD/0249/15

The National Centre for Nuclear Research
ul. Andrzeja Sołtana 7
05-400 Otwock

DECISION

Pursuant to Article 7 section 2 in relation with Article 15 section 1 point 2 and pursuant to Article 18a section 4 of the Act of 6th September 2001 –Pharmaceutical Law (Journal of Laws of 2008, No. 45, item 271, as amended) is issued:

Marketing Authorisation No 22500

Product Name:
Poltechnet

Commonly Used Name:
Natrii Pertechnetatis (^{99m}Tc) fission formation solution iniectabilis

Pharmaceutical Form, Strength and Active Substance Dose:
Radionuclide generator, 8.0-175 GBq

Method of Administration:
intravenous use
ocular use

Digitally signed by Bolea Petru
Date: 2023.07.11 09:49:07 EEST
Reason: MoldSign Signature
Location: Moldova

Procedure Number:
SE/H/1365/001/DC

Marketing Authorization Holder:
Narodowe Centrum Badań Jądrowych
ul. Andrzeja Sołtana 7
05-400 Otwock

Name and Address of Manufacturer where the Batch is Released:
Narodowe Centrum Badań Jądrowych
ul. Andrzeja Sołtana 7
05-400 Otwock

Place of Manufacture, where the Batch Inspection Takes Place:

Narodowe Centrum Badań Jądrowych
ul. Andrzeja Sołtana 7
05-400 Otwock

Full Qualitative Composition:

Active substances:

Sodium Molybdate (^{99}Mo)
Sodium Pertechnetate (^{99m}Tc)

Excipients:

Sodium Chloride
Water for injection

Packaging Size:

Approved:

1 generator + vials for elution (16 vials with eluent + 16 evacuated vials (for eluent))

Declared:

1 generator + vials for elution (16 vials with eluent + 16 evacuated vials (for eluent))

- **Code: 5909991225445**

Packaging Type:

Radionuclide generator:
Colorless glass (type I) column with filling, closed with rubber stoppers and protected with alumninium caps; connected by complex of metal needles with colorless glass (type I) vials filled with bacteriostatic agent; placed in a lead protective container.
Set for elution:
Colorless glass (type I) vial closed with a rubber stopper and aluminium cap, placed in a lead protective container.

Storage and Transportation Requirements:

Generator:
Do not freeze.
Eluate:
No special requirements
Set for elution:
No special requirements

Validity Period:

Generator:
21 days from manufacturing date.
Eluate:
12 hours after elution
Set for elution:
1 year

Availability:

Medicinal product to be applied in hospital health service - Lz.

Frequency of periodic safety update reports submission:
Not applicable

This Marketing Authorisation is valid till 11.06.2020.

In conformity with Article 107 § 4 of the Administrative Procedure Code, it is waived from giving the reasons for this decision.

Instruction:

Within 14 days of the date of service of this decision, pursuant to Article 127 § 3 and Article 129 § 2 of the Act of 14th June 1960 the Administrative Procedure Code (Journal of Laws of 2013, No. 267), the Party is entitled to file an appeal against this decision and submit thereof with the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

A red round official seal with Poland's emblem, reading:
President of the Office for Registration of Medicinal Products,
Medical Devices and Biocidal Products

A stamp, reading:
p.p. the President
VICEPRESIDENT
For Medical Devices
/ - / *Signature illegible*
Sebastian Migdalski

Copies to:

1. The party's plenipotentiary
2. File copy