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TRANSLATION FROM THE POLISH LANGUAGE

PRESIDENT

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

Warsaw, 12th August 2013

No. UR/RR/1308/13

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

DECISION

ln compliance with Art. 7 par. 2 and Art. 29 par. 2 of the act of 6th September 2001 Pharmaceutical Law (Journal of Laws of 2008, No. 45, item 271 as amended)

the period of validity of Marketing Authorisation No. R/3267 granted for the PoltechColloid medicinal product has been extended for an indefinite time

Product name:

PoltechColloid

Commonly used name:

Stanni colloidalis et technetii (^{99m}Tc) solutio iniectabilis

Pharmaceutical form, strength and active substance dose:

Kit for radiopharmaceutical preparation, 0.17 mg stannous chloride dihydrate

Method of administration:

Intravenous

Marketing Authorization Holder:

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

Name and address of manufacturer where the batch is released:

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

Place of manufacture, where the batch control takes place:

National Centre for Nuclear Research

ul. Andrzeja Sołtana 7

05-400 Otwock

Full qualitative composition:

Stannous chloride dihydrate

Sodium fluoride

Povidone

Nitrogen

Packaging size:

3 vials – code: 5909990326716

6 vials – code: 5909990326723

Packaging type:

10 ml glass vials with rubber stopper and an aluminium cap in a cardboard box.

Storage and transportation requirements:

Store in a refrigerator ($2^oC – 8^oC$).

During transportation (not longer than 7 days), temperature below 35°C is allowable.

Validity period:

The kit – 1 year

Shelf life after reconstitution and labelling with sodium pertechnetate (^{99m}Tc) solution:

up to 4 hours at a temperature below 25°C in a suitable radiation lead shield.

Availability category:

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

THE GROUNDS FOR THIS DECISION

Pursuant to Article 107 § 4 of the Administrative Procedure, formulation of grounds for this decision has been departed from since the party's claim has been accepted in its entirety.

Instruction:

Pursuant to Art. 127 § 3 and Art. 129 § 2 of the act of 14th June 1960 Code of Administrative Procedure (i.e. Journal of Laws of 2013, item 267), the party is entitled to apply to the President of The Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products for re-examination of its case within 14 days of this decision being served thereto.

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 Medicinal Products
/ - / *Signature illegible*
Marcin Kołakowski

Copies to:

1. The party's proxy: Dariusz Socha, National Centre for Nuclear Research
   ul. Andrzeja Sołtana 7, 05-400 Otwock
2. File copy