



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	352151	ANSTO Lutetium (177Lu) Chloride Radiochemical Solution for injection vial
ARTG entry for	Medicine Registered	
Sponsor	Australian Nuclear Science and Technology Organisation T/A ANSTO	
Postal Address	Locked Bag 2001, KIRRAWEE DC, NSW, 2232 Australia	
ARTG Start Date	11/01/2022	
Product Category	Medicine	
Status	Active	
Approval Area	Drug Safety Evaluation Branch	



Medicine under additional monitoring

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

Products

1 . ANSTO Lutetium (177Lu) Chloride Radiochemical Solution for injection vial

Product Type	Single Medicine Product	Effective Date	24/01/2022
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Permitted Indications
 No Permitted Indications included on Record

Indication Requirements
 No Indication Requirements included on Record

Standard Indications
 No Standard Indications included on Record

Specific Indications

Lutetium (177Lu) chloride is a radiopharmaceutical precursor, and it is not intended for direct use in patients. For the treatment of non resectable or metastatic neuroendocrine tumours (NETS) expressing somatostatin subtype 2 receptors when coupled with a suitable carrier molecule.

Warnings
 See Product Information and Consumer Medicine Information for this product

Additional Product information

This product is included in the Black Triangle Scheme

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
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Vial	Glass Type I Clear	14 Days	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Not recorded
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Pack Size/Poison information

Pack Size
2 mL

Poison Schedule
exempt from scheduling - Appendix A; prescription medicine

Components

1 . ANSTO Lutetium (177Lu) Chloride Radiochemical Solution for injection vial

Dosage Form	Solution
Route of Administration	Intravenous
Visual Identification	Clear, colourless solution

Active Ingredients

lutetium (177Lu) chloride	10 GBq/mL
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Other Ingredients (Excipients)

dilute hydrochloric acid
purified water

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