isotopia
Nuclear Medicine

Lutetium-177 Chloride

Precision radiotherapy, global reliability

Rev D. August 2025

Lu-177: Precision and reliability in targeted radiotherapy

Lutetium-177 (Lu-177) offers a powerful radionuclide solution for treating prostate cancer and neuroendocrine tumors.

As a beta-emitting isotope, Lu-177 delivers localized radiation to cancer cells while minimizing damage to surrounding healthy tissue, making it a key component in cancer treatments.

Reliable global supply chain

At Isotopia, we produce high-purity Lu-177, non-carrier-added **(n.c.a**), and carrier-added **(c.a)** in GMP certified facilities, ensuring these products meet regulatory approved specifications for safety and efficacy.

Our extensive supply of critical starting materials, surplus irradiation capacity located around the globe, and our robust, commercial-scale manufacturing processes provide a stable, continuous supply of isotopes to our pharmaceutical customers, enabling healthcare providers worldwide to confidently deliver cutting-edge, patient-centered therapies.

Gold standard service – Complete and attentive support, direct communication with our professional team of experts.

Supplying all phases — from preclinical to commercial

Supply to all phases of pharmaceutical development from preclinical to commercial applications

Supply chain robustness built into all aspects of isotope manufacturing:
Substantial precursor supply, multi-site irradiation capacity, global isotope production facility footprint.

Shorter time from irradiation to patient

- Save pre-calibration costs and reach more patients
- De-risk the logistics
- Backup and surplus between all manufacturing sites

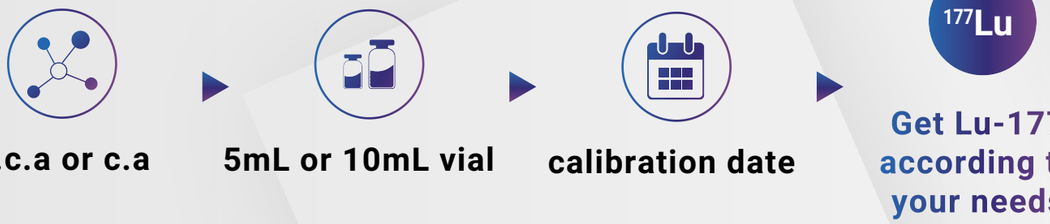
High Quality

- Full compliance with cGMP regulations
- US FDA DMF
- Health Canada MF*
- EU Marketing Authorization available*
- Certified Type A package for safe global shipping
- Authorized Manufacturer, Importer, Distributor, Exporter (MIDE)

**Applicable for n.c.a only*

10 mL Vial | 5 mL Vial (V Shape) | Plexiglass | Shield | Shield Cover

Tell us what you need



About Isotopia

Since 2006, Isotopia Molecular Imaging has been at the forefront of innovation in nuclear medicine, transforming patient care through cutting-edge solutions.

Driven by our scientific expertise and commitment to solving unmet medical needs, we develop, produce, and supply advanced diagnostic and therapeutic radioactive isotopes and cold kits worldwide.

With strategically located production facilities in Israel, the USA, and Austria, we ensure a reliable supply chain that minimizes patient risk and guarantees uninterrupted access to life-extending treatments.

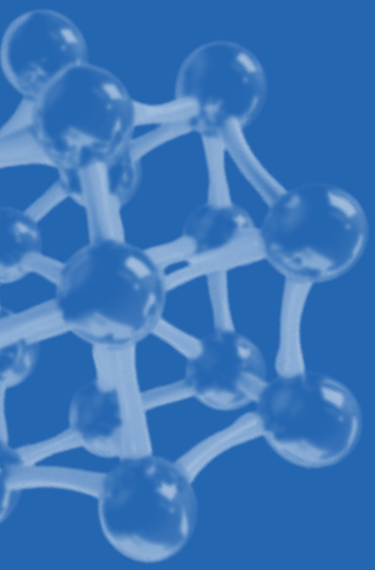
Our unwavering focus on consistency and sustainability empowers healthcare professionals to deliver uninterrupted, high-quality care where it's needed most.

Lutetium (Lu-177) Specifications

Chemical Form	$LuCl_3$ in HCl 0.04N
Packaging	10 mL molded vial closed with fluorotec septum and open top crimp seal 5 mL V-shaped vial closed with fluorotec septum and open top crimp seal

Test	Specification	
	n.c.a	c.a
Appearance	Clear, colorless solution	Clear, colorless solution
pH	1.0 – 2.0	1.0 – 2.0
Identification A (Gamma spectrometry)	Gamma photons with 208 KeV and 113 KeV present	Gamma photons with 208 KeV and 113 KeV present
Identification B (pH)	1.0 – 2.0	1.0 – 2.0
Identification C (iTLC)	The retardation factor of the principal peak in the chromatogram obtained in the test for radiochemical purity is 0.4 to 0.7	The retardation factor of the principal peak in the chromatogram obtained in the test for radiochemical purity is 0.4 to 0.7
Specific Activity (by ICP-OES at end of production)	>3000 GBq/mg (>81 Ci/mg)	>740 GBq/mg (>20 Ci/mg)
Chemical Purity (by ICP- OES at end of shelf life)	Cu ≤ 1.0 µg/GBq Fe ≤ 0.5 µg/GBq Pb ≤ 0.5 µg/GBq Zn ≤ 1.0 µg/GBq Yb ≤ 1.0 µg/GBq	Cu ≤ 1.0 µg/GBq Fe ≤ 0.5 µg/GBq Pb ≤ 0.5 µg/GBq Zn ≤ 1.0 µg/GBq
Radionuclidic Purity (Gamma spectrometry at end of shelf life)	^{175}Yb ≤ 0.1%	^{177m}Lu ≤ 0.07%
	The total radioactivity due to other radionuclides impurities ≤ 0.01%	The total radioactivity due to other radionuclides impurities ≤ 0.01%
Radiochemical Purity (by iTLC)	[^{177}Lu]lutetium(III) ion ≥ 99%	[^{177}Lu]lutetium(III) ion ≥ 99%
Bacterial endotoxins	< 35 EU/mL	< 35 EU/mL
Sterility	Sterile (by autoclaving)	Sterile (by autoclaving)

Name of the medicinal Product: Lutetium (177Lu) chloride Billev 51.8 GBq/mL radiopharmaceutical precursor, solution **Qualitative and quantitative composition:** 1 mL solution contains 51.8 GBq lutetium (177Lu) chloride on activity reference time (ART) corresponding to maximum 12.6 micrograms of lutetium (177Lu) (as chloride). The ART is defined as the end of production. The minimal specific activity is 3000 GBq/mg lutetium (177Lu) at the ART. **List of excipients:** Hydrochloric acid, diluted **Therapeutic indications:** Lutetium (177Lu) chloride Billev is a radiopharmaceutical precursor, and it is not intended for direct use in patients. It is to be used only for the radiolabelling of carrier molecules that have been specifically developed and authorised for radiolabelling with lutetium (177Lu) chloride. **Contraindications**: Hypersensitivity to the active substance or to any of the excipients listed; established or suspected pregnancy or when pregnancy has not been excluded. **Interaction with other medicinal products and other forms of interaction:** No interaction studies of lutetium (177Lu) chloride with other medicinal products have been performed. For information concerning interactions associated with the use of lutetium (177Lu)–labelled medicinal products refer to the Summary of Product Characteristics/Package Leaflet of the medicinal product to be radiolabelled. **Undesirable effects:** Adverse reactions following the administration of a lutetium (177Lu)-labelled medicinal product prepared by radiolabelling with Lutetium (177Lu) chloride Billev will be dependent on the specific medicinal product being used. Such information will be supplied in the Summary of Product Characteristics/Package Leaflet of the medicinal product to be radiolabelled. List of adverse reactions: very common (≥ 1/10): Anaemia, Thrombocytopenia, Leukopenia, Lymphopenia, Nausea, Vomiting, Alopecia; common (≥ 1/100 to < 1/10): Refractory cytopenia with multilineage dysplasia (Myelodysplastic syndrome), Neutropenia; uncommon (≥ 1/1,000 to < 1/100): Acute myeloid leukaemia; Not known (cannot be estimated from the available data): Pancytopenia, Carcinoid crisis, Tumour lysis syndrome, Dry mouth; In general: Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. The radiation dose resulting from therapeutic exposure may result in higher incidence of cancer and mutations. In all cases, it is necessary to ensure that the risks of the radiation are less than from the disease itself. **Marketing Authorisation Holder:** Billev Pharma ApS, Slotsmarken10, 2970 Hørsholm, Denmark **Marketing Authorisation numbers:** EU/1/22/1680/001, EU/1/22/1680/002, EU/1/22/1680/003, EU/1/22/1680/004, EU/1/22/1680/005, EU/1/22/1680/006 **General classification for supply:** prescription **Date of revision of the text:** 12.2022



isotopia
Nuclear Medicine

Isotopia Molecular Imaging LTD
39 Alexander Yanai St, Segula Industrial Park
Petach Tikva 4927735 | Tel +972 3 913 0314
Info@isotopia-global.com | isotopia-global.com

Isotopia USA Inc.
17075 Oak Ridge Rd
Westfield, IN 46074, USA
InfoUSA@isotopia-global.com | isotopia-global.com