

endolucin[®]
beta

- ✓ GMP CERTIFIED
- ✓ REGISTERED



No-carrier-added
Lutetium (^{177}Lu) chloride

endolucin[®]
beta

EndolucinBeta® is an innovative radiopharmaceutical precursor for targeted radionuclide therapies and contains the active substance ¹⁷⁷Lu chloride as a no-carrier-added radioisotope.

The use of no-carrier-added (n.c.a.) ¹⁷⁷Lu is excellent for the efficacy and quality of therapeutic radiopharmaceuticals. The production route of EndolucinBeta® takes advantage of highly enriched Ytterbium-176 as starting material, thereby providing the highest specific activity and an unprecedented level of radionuclidic purity.

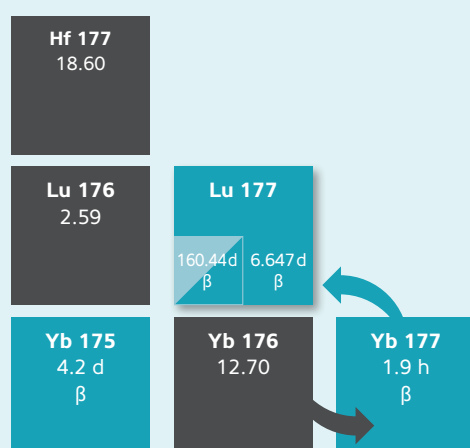
Using ¹⁷⁷Lu in its pure form enables the specific radioactivity to be greatly increased by up to 6-times. As a result, the superior performance creates favorable preconditions for efficient radiolabeling of biomolecules such as peptides and antibodies.

With us, you can choose the day of calibration at one of 7 days within shelf life, right according to your needs.

Through our reliable, longstanding partnerships with nuclear reactors we can guarantee security of supply and daily availability of EndolucinBeta®. We strive for excellence in establishing an innovative, fully-integrated n. c. a. ¹⁷⁷Lu platform, setting new standards.

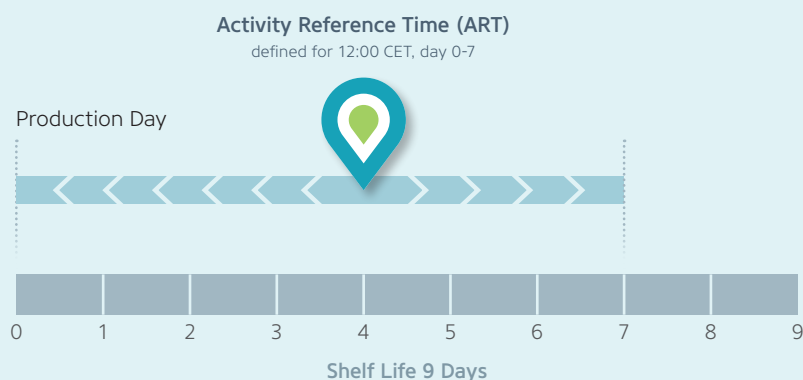
EndolucinBeta® is GMP certified and received EU Marketing Authorization.

PRODUCTION ROUTE



Using the indirect production route by taking ¹⁷⁶Yb as starting material we are able to offer no-carrier-added ¹⁷⁷Lu with superior characteristics when compared to the carrier-added radioisotope.

DEFINITION OF ART



ART (Activity Reference Time):
Date and time to which the activity-dependent parameters relate.

NO-CARRIER-ADDED VS. CARRIER-ADDED ¹⁷⁷Lu

EndolucinBeta® displays **superior characteristics** when compared to the carrier-added radioisotope.

The specific activity of n. c. a. ¹⁷⁷Lu is up to **6 times higher** than of the c. a. isotope.

Due to its slower decrease of specific activity EndolucinBeta® offers **favorable preconditions** for an **efficient radiolabeling reaction** over its entire shelf-life of 9 days after production.

Furthermore, EndolucinBeta® provides the **highest achievable radionuclidic purity**. In comparison to the c.a. isotope EndolucinBeta® contains no metastable ^{177m}Lu and does not require any costly logistics and storage of contaminated radioactive waste.

KEY ADVANTAGES

- ◆ EU Marketing Authorization
- ◆ GMP certification
- ◆ Highest specific activity at ART $\geq 3,000$ GBq/mg
- ◆ No contamination with long-lived ^{177m}Lu
- ◆ Choose the day of ART according to your needs
- ◆ Sterile / Endotoxin-tested
- ◆ Cost effective and environmentally sustainable waste management

Take advantage of our one-stop-shop offering: Get all components and services from one supplier!



Radioisotopes +
Biomolecules



iQS® Ga-68 Fluidic
Labeling Module

iQS®-Theranostics
Synthesizer



Consumables



Quality Control Solution

PRECISELY FOR ME.



SELY FOR ME.



Excipient

Hydrochloric acid solution

Therapeutic indications

EndolucinBeta® 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 authorized for radiolabelling with Lutetium (¹⁷⁷Lu) chloride.

Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Established or suspected pregnancy or when pregnancy has not been excluded.

For information on contraindications to particular Lutetium (¹⁷⁷Lu)-labelled medicinal products prepared by radiolabelling with EndolucinBeta®, refer to the Summary of Product Characteristics/package leaflet of the particular medicinal product to be radiolabelled.

Undesirable effects

Adverse reactions following the administration of a Lutetium (¹⁷⁷Lu)-labelled medicinal product prepared by radiolabelling with EndolucinBeta® 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.

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.

Special warnings and precautions for use

EndolucinBeta® contains a radioactive substance.

Read the package leaflet before use.

For administration after *in vitro* radiolabelling. Store in the original package in order to avoid unnecessary radiation exposure.

Storage of radiopharmaceuticals should be in accordance with national regulation on radioactive materials.

Any unused medicinal product or waste material must be disposed of in accordance with local requirements.

Keep out of the sight and reach of children.

Medicinal product subject to restricted medical prescription.

Marketing Authorization Holder

ITM Medical Isotopes GmbH

Lichtenbergstrasse 1

85748 Garching/Munich, Germany

A company of the ITM Group.

FIXED PARAMETERS

Characteristics	Acceptance Criteria	Characteristics	Acceptance Criteria
Element	Lutetium	Volume per vial	0.075–3.75 mL
Nuclide	¹⁷⁷ Lu	Radiolabeling yield	≥99.0 % (based on radiolabeling with ¹⁷⁷ Lu of DOTA-derivate, molar ratio 1:4)
Half-life	6.647 days	Packaging	Type I glass vial, closed with fluorotec® coated bromobutyl septum and center hole crimp cap
Decay mode	Beta decay	Shelf-life	9 days from production (filling of product)
Beta max. energy	0.498 MeV		
Main gamma radiation	112.9498 keV (6.17 %), 208.3662 keV (10.36 %)		
Chemical form	Lu ³⁺ in aqueous HCl solution		
Solvent	0.04 M HCl solution		

PHYSICAL DATA

Characteristics	Description
Content	Range: 3–150 GBq per vial at ART
ART	Specifiable to 12:00 (CET) of days 0–7 after production
Primary Packaging	Options: <ul style="list-style-type: none"> • vial 2 mL, conical bottom (Available for 3–80 GBq) • vial 10 mL, flat bottom (Available for 8–150 GBq)

RELEASE PARAMETERS

Characteristics	Acceptance Criteria	Method
Specific activity	≥ 3,000 GBq/mg at ART	ICP-MS
Radionuclidic purity	¹⁷⁵ Yb: ≤0.01 % Sum of others (the total radioactivity due to other radionuclidic impurities): ≤0.01 %	Gamma spectrometry, corrected to ¹⁷⁷ Lu activity at end of shelf life
Activity per vial	90 %–110 % of the declared ¹⁷⁷ Lu radioactivity at the date and time stated on the label (ART)	Dose calibrator
Radioactivity concentration	36–44 GBq/mL at ART	Dose calibrator/Weighing
Identity ¹⁷⁷ Lu	113 keV gamma line existing 208 keV gamma line existing	Gamma spectrometry
Identity chloride	White precipitate visible	Chloride detection reaction (Ph. Eur. 2.3.1)
pH	1–2	pH-strip
Appearance	Clear and colorless solution	Visual
Chemical purity	Fe ≤0.25 µg/GBq, Cu ≤0.5 µg/GBq, Zn ≤0.5 µg/GBq, Pb ≤0.5 µg/GBq, ¹⁷⁶ Yb ≤0.1 µg/GBq Sum of impurities ≤0.5 µg/GBq	ICP-MS, impurities content corrected to ¹⁷⁷ Lu activity at end of shelf-life
Radiochemical purity	≥99.0 % as ¹⁷⁷ LuCl ₃	TLC (Ph. Eur. 2.2.27)
Radiolabeling yield	≥99.0 % (based on radiolabeling with ¹⁷⁷ Lu of DOTA-derivate, molar ratio 1:4)	TLC (Ph. Eur. 2.2.27)
Bacterial endotoxins	≤20 EU/mL	Turbidimetric-kinetic (Ph. Eur. 2.6.14)
Sterility	Sterile (final autoclaving)	Direct inoculation (Ph. Eur. 2.6.1)

About the ITM Group

ITM Isotopen Technologien München AG is a privately owned biotechnology and radiopharmaceutical group of companies dedicated to the development, production and global supply of targeted diagnostic and therapeutic radiopharmaceuticals and radioisotopes for use in cancer treatment. ITM's main objectives are to significantly improve the treatment outcome and quality of life for cancer patients while at the same time reducing side effects and improving health economics through a new generation of Targeted Radionuclide Therapies in Precision Oncology.

Your contact:

Phone: +49 89 329 8986-600
 Email: info@itm.ag
 www.itm.ag
 ITM Isotopen Technologien München AG
 Lichtenbergstrasse 1
 85748 Garching/Munich, Germany

Produced by
ITM Medical Isotopes GmbH.

A company
 of the ITM Group.

