itm
MEDICAL ISOTOPES

PASSION FOR PRECISION

endolucin beta

✔ GMP CERTIFIED

✔ REGISTERED

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

endolucin beta

EndolucinBeta® 40 GBq/mL radiopharmaceutical precursor, solution.
Active substance: Lutetium (^{177}Lu) chloride.

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

The use of no-carrier-added (n.c.a.) ^{177}Lu 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.

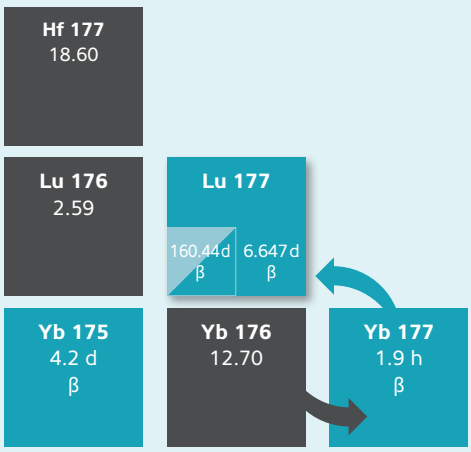
Using ^{177}Lu in its pure form enables the specific radioactivity to be greatly increased by up to 6-times. As a result, the superior performance creates favorable preconditions for efficient radiolabeling of biomolecules such as peptides and antibodies.

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. ^{177}Lu platform, setting new standards.

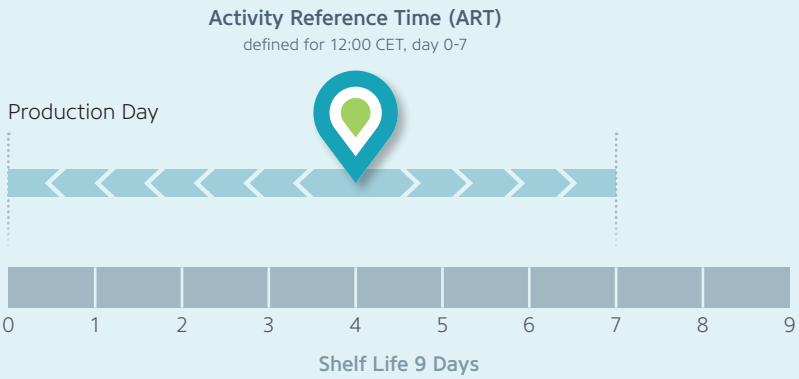
EndolucinBeta® is GMP certified and received EU Marketing Authorization.

PRODUCTION ROUTE



Using the indirect production route by taking ^{176}Yb as starting material we are able to offer no-carrier-added ^{177}Lu 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 ^{177}Lu

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

The specific activity of n. c. a. ^{177}Lu 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 ≥ 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 (^{177}Lu) 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 (^{177}Lu)-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 (^{177}Lu)-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
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A company of the ITM Group.

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FIXED PARAMETERS

Characteristics	Acceptance Criteria
Element	Lutetium
Nuclide	^{177}Lu
Half-life	6.647 days
Decay mode	Beta decay
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

Characteristics	Acceptance Criteria
Volume per vial	0.075–3.75 mL
Radiolabeling yield	≥ 99.0 % (based on radiolabeling with ^{177}Lu of DOTA-derivate, molar ratio 1:4)
Packaging	Type I glass vial, closed with fluorotec® coated bromobutyl septum and center hole crimp cap
Shelf-life	9 days from production (filling of product)

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: • **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.

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