endolucin beta

EndolucinBeta®

Radiopharmaceutical Precursor

Lu

Active substance:
non-carrier-added (n.c.a.) Lutetium-177 (^{177}Lu) chloride
40 GBq/mL radiopharmaceutical precursor, solution.

EU Marketing Authorization, Active US DMF

itm
PASSION FOR PRECISION

endolucin beta

EndolucinBeta® is a high quality radiopharmaceutical precursor for targeted cancer treatments using Radiopharmaceutical Therapy (RPT) and contains the active substance ^{177}Lu chloride as a non-carrier-added radioisotope.

The use of n.c.a. ^{177}Lu is superior to c.a. for radiolabeling purposes, capable of achieving significantly higher radiopharmaceutical molar activity and significantly simplifies the pre and post treatment waste management process. 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.

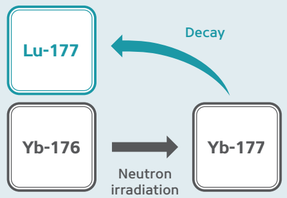
Using ^{177}Lu in its pure form enables the specific radioactivity to be greatly increased by up to 6 times. As a result, this superior characteristic creates favorable preconditions for efficient radiolabeling of biomolecules such as peptides and antibodies. With ITM, you can choose the day of calibration at one of 7 days within shelf life precisely to your needs.

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

EndolucinBeta® is GMP certified and has EU Marketing Authorization. Active US DMF is available for reference.

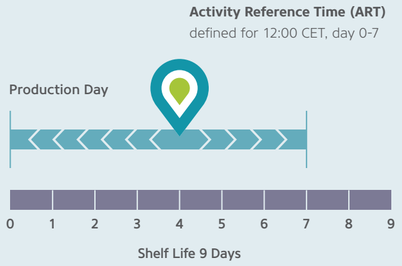
PRODUCTION ROUTE

Using the indirect production route by taking ^{176}Yb as starting material we are able to offer n.c.a. ^{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.



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

NON-CARRIER-ADDED vs. CARRIER-ADDED ^{177}Lu

- **EndolucinBeta® displays superior characteristics** when compared to the carrier-added (c.a.) radioisotope.
- The specific activity of n.c.a. ^{177}Lu is up to **6 times higher** than of c.a. ^{177}Lu.
- 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.
- EndolucinBeta® provides the **highest achievable radionuclidic purity.**

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 radiolabeling of carrier molecules. For further details, see EndolucinBeta Summary of Product Characteristics (SmPC).

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)-labeled medicinal products prepared by radiolabeling with EndolucinBeta®, refer to the Summary of Product Characteristics / package leaflet of the particular medicinal product to be radiolabeled.

Undesirable effects
Adverse reactions following the administration of a Lutetium (^{177}Lu)-labeled medicinal product prepared by radiolabeling 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 radiolabeled. 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* radiolabeling. 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

Get all components and services from one supplier!

Radiopharmaceuticals

Radioisotopes + Targeting Molecules

iQS–Theranostics Synthesizer

Quality Control Solution

iQS® Ga-68 Fluidic Labeling Module

Reagent Sets + Cassettes

endolucin beta

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 radio-labeling 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

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)

About the ITM Group

ITM, a leading radiopharmaceutical biotech company, is dedicated to providing a new generation of radiomolecular precision thera-peutics and diagnostics for hard-to-treat tumors. We aim to meet the needs of cancer patients, clinicians and our partners through excellence in development, production and global supply. With improved patient benefit as the driving principle for all we do, ITM advances a broad precision oncology pipeline, including two phase III studies, combining the company's high-quality radioisotopes with a range of targeting molecules. By leveraging our nearly two decades of pioneering radiopharma expertise, central industry position and established global network, ITM strives to provide patients with more effective targeted treatment to improve clinical outcome and quality of life.

Our contact

Phone: **+49 89 329 8986-6000**
Email: **sales@itm-radiopharma.com**
Web: **www.itm-radiopharma.com**

Distributed by ITM Pharma Solutions GmbH
Lichtenbergstrasse 1
85748 Garching/Munich, Germany

Produced by ITM Medical Isotopes GmbH, a company of the ITM Group.

itm
PASSION FOR PRECISION

Version 10.0, 09/2025