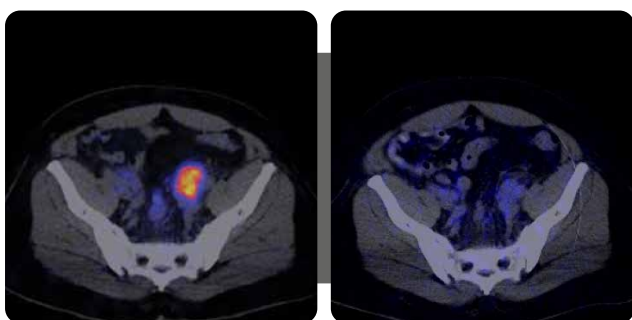




LUTETIUM-177 NON-CARRIER ADDED



A 68-year-old male diagnosed with metastatic prostate cancer before and after three cycles of treatment with Lu-PSMA. Images supplied by Steve Biko Academic Hospital.

LUTETIUM-177 N.C.A. NOW AVAILABLE GLOBALLY

Lutetium-177 n.c.a. utilises highly enriched Ytterbium-176 as a starting material. The result provides the highest specific activity and radionuclidic purity and a non-carrier added product that is suitable for radiolabelling biomolecules such as peptides and antibodies.

- Now produced by NTP Radioisotopes in South Africa
- Identical product from ANSTO in Australia
- Ongoing production by ITG in Germany
- Available 365 days per year
- Global security of supply



34 GEPNET PATIENTS TREATED WITH Lu-177 OCTREOTATE, CAPECITABINE & TEMOZOLOMIDE¹

Median progression free survival (PFS)
31 months (95%CI 21-33 mo)

Median overall survival (OS)
not reached with 90% surviving at 24
months follow up (range 21-30 mo)

58 NET PATIENTS WITH DISEASE PROGRESSION, TREATED WITH Lu-177 OCTREOTATE & 5-FU²

Overall survival rate at 2 years: 72.1%
Overall survival rate at 5 years: 52.1%
Median OS: not estimable at 60 months
(range 5-86 mo)



REFERENCES

1. Claringbold P et al. Cancer Biother Radiopharm 2012; 27(9):561-9
2. Kong G et al. Eur J Nucl Med Mol Imaging 2014. Published online: 21 May 2014 (doi:10.1007/s00259-014-2788-5)

Lutetium-177 is a radioisotope. It is not a registered medicine.

SUPERIOR QUALITY & RESULTS NON-CARRIER-ADDED VS CARRIER-ADDED

Non-carrier-added Lutetium-177 (Lu-177 n.c.a.) offers a number of advantages compared to the carrier-added version. Lu-177 n.c.a. has a specific activity that is up to 3 to 5 times higher, offering the best preconditions for efficient radiolabelling of biomolecules. Lu-177 n.c.a. also has a significantly longer shelf life (up to 9 days from dispensing) compared with the carrier-added variant. Lu-177 n.c.a. is produced through the irradiation of enriched Ytterbium-176 targets, resulting in the highest possible radionuclidic purity. Carrier-added Lutetium-177 contains up to 0.05% metastable Lutetium-177m, a long-lived radionuclide that has a half-life of 160.1 days and which requires costly management and storage of contaminated radioactive waste and waste water.

ADVANTAGES

- Specific activity of 3-5 times higher than Lu-177 c.a.
- Significantly longer shelf-life
- Sterile, endotoxin tested
- No contamination with long-lived Lu-177m (half-life 160.1 days)
- Global security of supply through the alliance and technical alignment of NTP Radioisotopes (South Africa), ANSTO (Australia) and ITG (Germany)



PRODUCT SPECIFICATIONS

Element	Lutetium
Nuclide	Lu-177
Half-life	6.647 days
Main mode of decay	Beta
Beta (β^-) energy	E (β^-)max = 0.498 MeV
Gamma radiation keV (%)	112.9498 (6.17%), 208.3662 (10.36%)
Chemical form	LuCl ₃
Diluent	0.04M HCl solution
Radioactivity concentration	40 GBq/mL at Calibration
Specific Activity	≥ 3000 GBq/mg at Calibration
Activity	3 – 40 GBq per vial at Calibration
Packaging	2mL V vial, closure with Bromobutyl stopper

PURITY

Parameter	Value
Radionuclidic purity	¹⁷⁵ Yb: ≤ 0.01 % at End of Shelf-life (EOS). Sum of others (the total radioactivity due to other radionuclidic impurities) ≤ 0.01% at EOS
Radiochemical purity	≥ 99.0% as ¹⁷⁷ LuCl ₃

ADDITIONAL PARAMETERS

Parameter	Value
Sterility	Sterile (autoclaving)
Bacterial endotoxins (LAL)	≤ 20 EU/ml
Storage	Room temperature
Calibration date and time	0 to 7 days after dispensing
Shelf life	Up to 9 days after dispensing



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