itm
MEDICAL ISOTOPES

PASSION FOR PRECISION


DMF submitted

# GeGant®

## $^{68}$Ge/$^{68}$Ga GENERATOR

$^{68}$Ga as radiopharmaceutical precursor, not intended for direct use in patients.

# Easy and direct labeling of targeting molecules for PET imaging.

$^{68}$Ga PET imaging is an excellent approach for healthcare professionals looking for precise localization in diagnostic imaging. With the new $^{68}$Ge/$^{68}$Ga Generator GeGant® we have set another milestone in order to improve the availability of Gallium-68 ($^{68}$Ga) labeled targeting molecules. Radiolabeled with a tumor-specific targeting molecule, Gallium-68 is used for Targeted Radionuclide Diagnostics in Precision Oncology.

GeGant® shows a breakthrough of $^{68}$Ge ≤ 0.001% of total radioactivity and is available in sizes from 1 GBq to 4 GBq, making it the largest $^{68}$Ge/$^{68}$Ga Generator on the market.


**$^{68}$Ge/$^{68}$Ga Generator with a breakthrough of $^{68}$Ge ≤ 0.001% of total radioactivity in sizes from 1 GBq to 4 GBq.**

GeGant® allows fast and convenient onsite production of $^{68}$Ga for radiolabling of disease-specific targeting molecules.

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## KEY ADVANTAGES

- The generator is available in sizes from 1 GBq to 4 GBq
- Breakthrough of $^{68}Ge \leq 0.001\%$ of total radioactivity
- Fast and convenient labeling of disease-specific targeting molecules for PET imaging
- Low acidic eluent (0.05 M HCl)

**PRECISELY FOR ME.**

## PHYSICAL DATA

| **Mother nuclide** | **$^{68}$Ge** |
|---|---|
| Half-life | 270.95 days |
| Decay mode | Electron capture |
| Decay energy | 106 keV |
| **Daughter nuclide** | **$^{68}$Ga** |
| Half-life | 67.71 min |
| Decay mode | Beta plus decay (89 %), Electron capture (11 %) |
| Decay energy | E $(\beta^{+})_{max}$ = 1.9 MeV Gamma: 511 keV (178 %, annihilation) |

## RELEASE SPECIFICATION

| | |
|---|---|
| Appearance | Clear and colourless solution |
| Identity A (Radionuclidic Identity) | Energy line 511 keV and 1077 keV extant |
| Identity B (Half-life) | Half-life: 62-74 min |
| Identity C (pH) | pH ≤ 2 |
| Identity D (Radioactivity) | Percentage or radioactive fraction in A3 ≥ 90% |
| Identity E (Chloride test) | Formation of a white precipitate |
| Elution yield | $^{68}$Ga ≥ 60% of target activity corrected to calibration date[1] |
| Radiochemical purity | $^{68}Ga^{3+}$ ≥ 95% of total radioactivity due to $^{68}$Ga |
| Elemental impurities | Fe ≤ 10 µg/GBq<br>Zn ≤ 10 µg/GBq |
| $^{68}$Ge Breakthrough | $^{68}$Ge ≤ 0.001% of total radioactivity |
| Radionuclidic purity | $^{68}$Ga ≥ 99.9% of total radioactivity |
| Bacterial endotoxins | ≤ 20 EU/ml |
| Sterility | Sterile |

[1]Calibration date: Date/time of the loading of $^{68}$Ge/$^{68}$Ga Generator with $^{68}$Ge solution

$^{68}$Ga is a radiopharmaceutical precursor and it is not intended for direct use in patients. It is to be used only for the radiolabeling of targeting molecules that have been specifically developed and authorized for radiolabeling with $^{68}$Ga.

Distribution of this brochure only allowed in countries, in which the generator has Marketing Authorization or is not considered as a pharmaceutical.

### 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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**ITM Medical Isotopes GmbH.**

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