



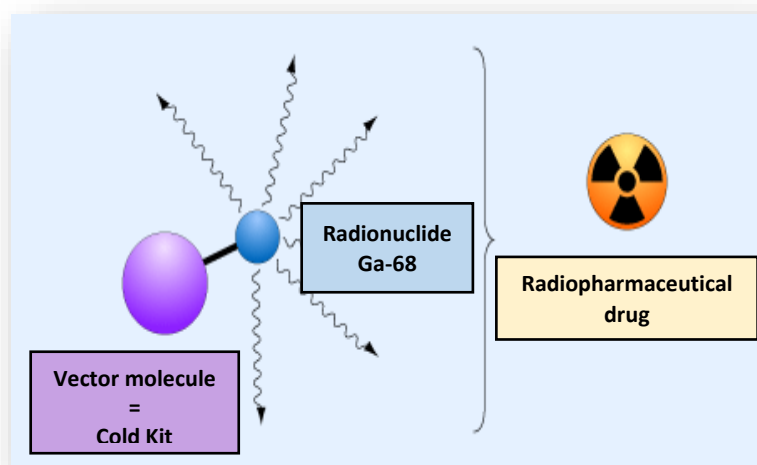
## Technical information sheet

The indication for which Germanium-68/Gallium-68 generator has been accepted is the following:

*The eluate (Gallium chloride ( $^{68}\text{Ga}$ ) solution) is used for the *in vitro* radiolabelling of specific vector molecules that have been specifically developed and authorised for radiolabelling with this radionuclide for positron emission tomography (PET) diagnostic imaging.*

The Germanium-68/Gallium-68 generator facilitates the routine use of Gallium-68 for PET imaging in radiopharmacy.

A radiopharmaceutical product consists of a radionuclide, a radioactive element called a “hot” tracer, and a “cold” (non-radioactive) vector molecule called a vector. The vector molecule can be provided in the form of “cold kits” and will then be combined with the appropriate quantity of Gallium-68 from the generator before being injected into the patient to carry out the examination.



The innovation of the Germanium-68/Gallium-68 generator is having been specifically designed, due to its technical properties, to be combined with cold kits in order to get closer to the best practice in nuclear medicine using Technetium-99 generators (another diagnostic radionuclide used very easily with cold kits for SPECT imaging).

This innovation is based on three unique aspects:

1. An innovative elution mechanism delivering a very small and always fixed amount of eluate: 1.1 ml of a Gallium ( $^{68}\text{Ga}$ ) chloride solution for radiolabelling (European Pharmacopoeia).
2. A unique chromatographic column: dry, on which the Germanium-68 ( $^{68}\text{Ge}$ ) is adsorbed.

3. A ready-to-use system integrating the eluent pouch which is pre-connected to the inside of the generator.

These characteristics make it possible, among other things, to:

- Simplify and reduce the steps for the preparation of radiopharmaceuticals;
- Ensure their reproducibility and maintain their specifications throughout the lifetime of the generator;
- Ensure operator safety;
- Enable hospitals to control costs.

For further information on Germanium-68/Gallium-68 generator please consult the SmPC (Summary of Product Characteristics) of the product available on our website [www.ire.eu](http://www.ire.eu)

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#### **About IRE ELiT**

IRE ELiT, founded by the Institute for Radioelements (Fleurus) in 2010 to develop new diagnostic and therapeutic applications in the area of radiopharmaceuticals, is the IRE's innovation subsidiary.

In 2017, IRE ELiT allocated 16.2% of its turnover to R&D, a percentage which has constantly increased since the company's creation. In 2017 and this year, in 2018, several million euros have been and will be invested to support its production capacity, which it plans to double and then quadruple.

IRE ELiT employed over 40 people at the end of 2017.

Further information at [www.ire.eu](http://www.ire.eu)

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