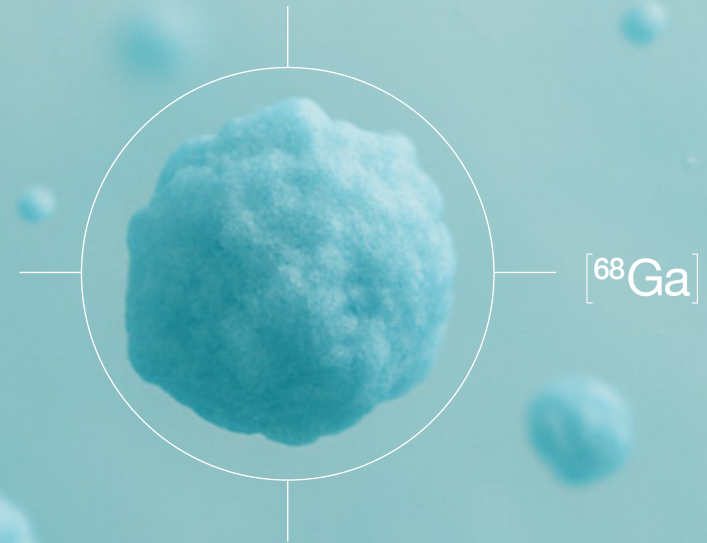




IRE ELIT key player in Gallium-68 generator production

Gallium-68 [^{68}Ga] has become a transformative tool in oncology imaging, providing significant benefits in both diagnosis and treatment planning. Its growing role is attributed to its production versatility, novel radiopharmaceuticals, and regulatory advancements.^[1]



^[1] Expanding Role for Gallium-68 PET Imaging in Oncology Janke Kleynhans,PhD,*ThomasEbenhan, PhD and Mike Machaba Sathekge,MD,PhDz.



I. Gallium-68^[68Ga] is key

With several FDA and EMA-approved imaging agents already commercially available and hundreds of clinical trials underway investigating the use of Ga-68 labeled radiopharmaceuticals for the diagnosis of various types of disease.^[2]

Ga-68 is a prime isotope for your needs today and your plans for tomorrow.

[2] www.clinicaltrials.gov





02. Gallium-68 makes possible



PROMPT AND FLEXIBLE
SCALABILITY

Ga-68 tracers offer a **cost-effective solution**, allowing hospitals to adopt in-house production without major upfront investments.

The availability of **ready-to-use kits** simplifies the preparation of Ga-68 radiopharmaceuticals, reducing infrastructure and cost barriers for smaller facilities.

Increasing availability of Ga-68 radiopharmaceuticals can be accomplished by adding additional generators.^[3]



TRACERS WITH PROVEN
EFFICACY AND ACCURACY
TO LIMIT FALSE POSITIVES^[3]

Data for currently approved Ga-68 labeled tracers* delivers confidence for both **practitioners** and their **patients**.

* Refer to SmPC on the national health authorities websites



DEPENDABLE AND CONVENIENT
ACCESS ON-DEMAND

Ga-68 can be obtained using compact and readily available generators, which makes the isotope locally accessible.^[3]

With streamlined workflows, tailored dosing, and reduced dependence on external suppliers, Ga-68 brings **operational efficiency** to a new level.^[3]

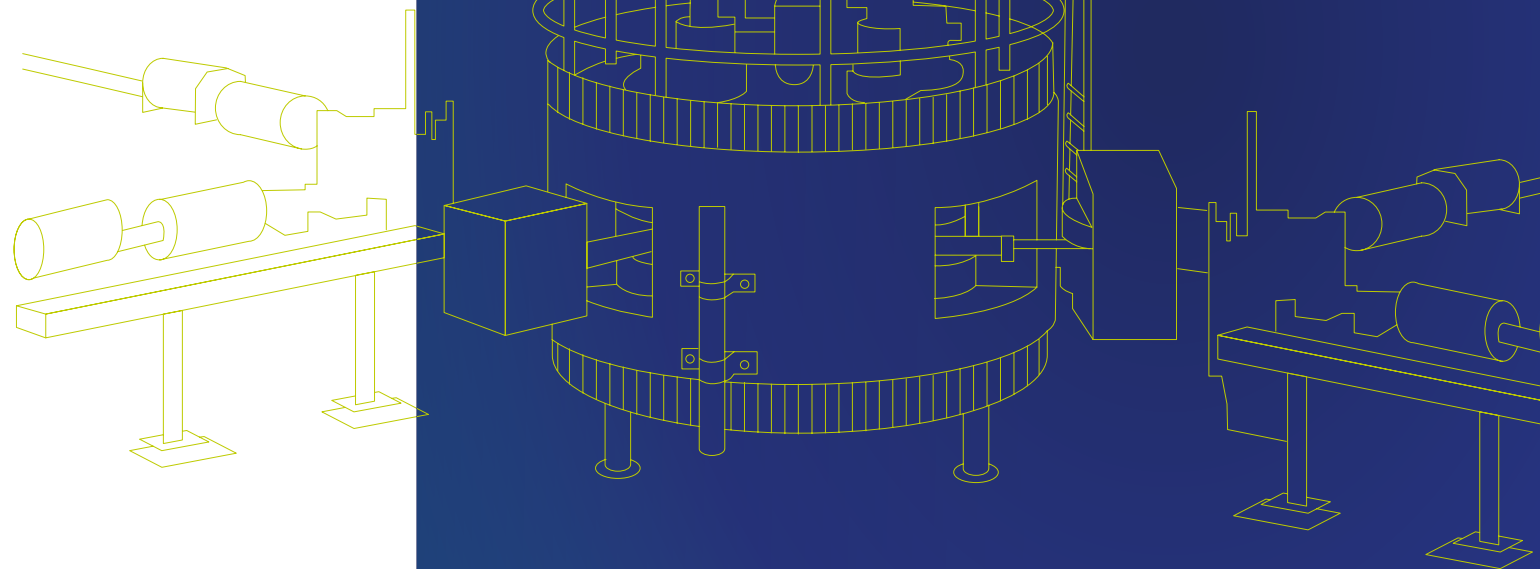
^[3] Marketing research project (for IRE ELiT)
nov 2024-The MarkeTech Group



03. Current availability

IRE ELiT has significantly expanded its production capacity, introducing **high-activity generators** to meet growing global demand.

At IRE ELiT we have also optimized our supply chain and reinforced our manufacturing capabilities, resulting in a stable and reliable supply. These strategic efforts have not only addressed prior concerns but have also ensured that the market is **now adequately served without any disruptions**, facilitating the continued use of Ga-68 in medical imaging worldwide.



Additionally, there are no significant issues with the supply of Germanium-68, the key precursor for Ga-68 production, as industry-wide efforts have secured consistent access to high-quality Ge-68. A notable development in this context is **IRE's recent investment in a 30 MeV cyclotron**, which enables us to produce our own Ge-68 and secure control over the global supply chain. This strategic move not only strengthens IRE ELiT's ability to meet its own needs but also positions the company as a key player in ensuring the continued availability of Ge-68, reinforcing the stability of the entire Ga-68 generator market.

With its proven **clinical reliability, operational flexibility, and cost-effectiveness**, Ga-68 is the solution for healthcare providers seeking **innovation and growth**.^[3]

^[3] Marketing research project (for IRE ELiT)
nov 2024-The MarkeTech Group

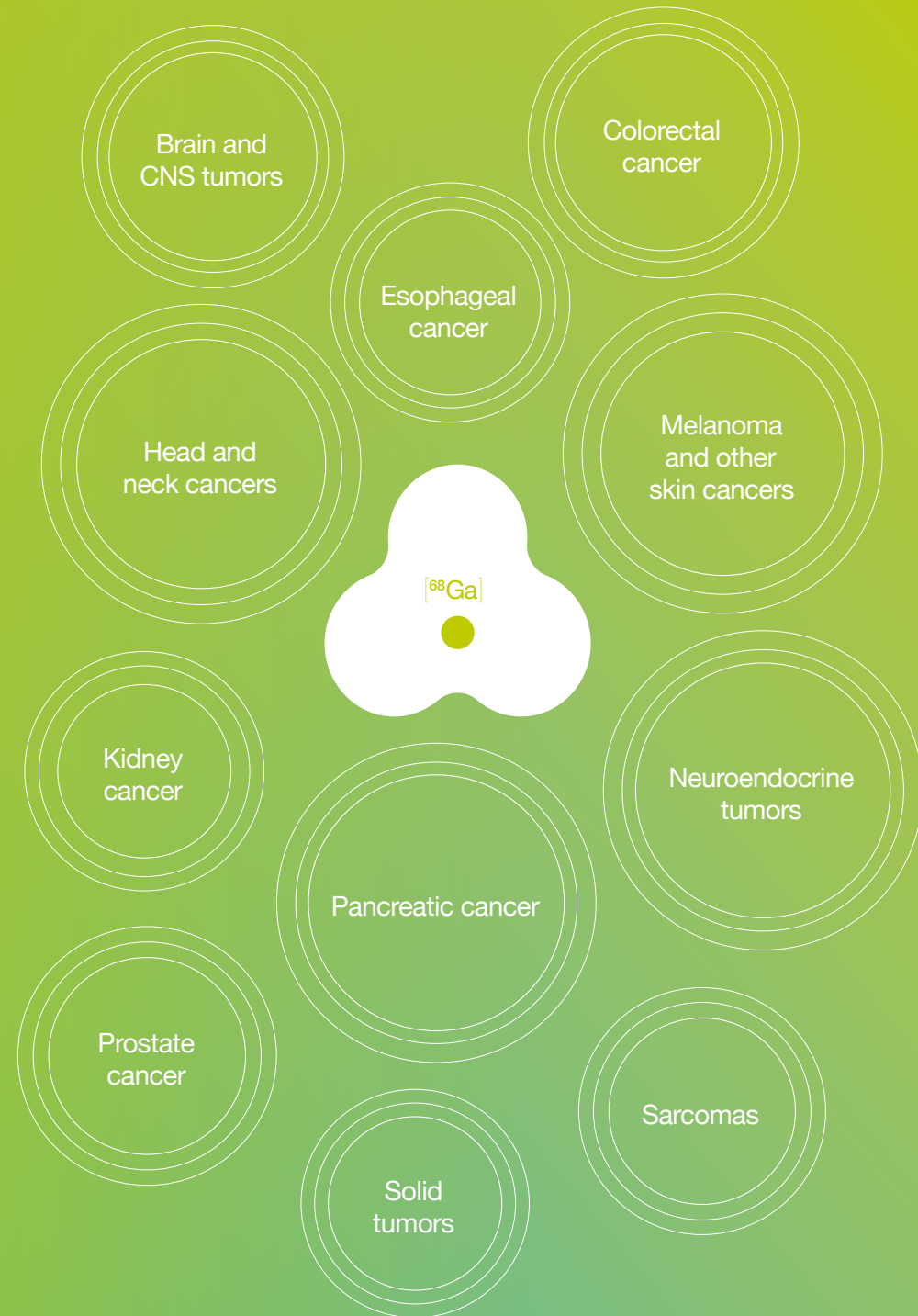


04. Ongoing clinical research involving Ga-68^[2]

Various **clinical trials** investigating Ga-68 use in FAPIs (Fibroblast Activation Protein Inhibitors) are currently underway.^[2]

These studies demonstrate potential for imaging tumors that do not respond well to conventional tracers like FDG (fluorodeoxyglucose).^[1]

As of January 2024, numerous Ga-68 radiopharmaceuticals and theranostic pairs utilizing novel ligands are currently under **investigation for use in several indications.**^[2]



[1] Expanding Role for Gallium-68 PET Imaging in Oncology
Janke Kleynhans, PhD,*ThomasEbenhan, PhD, and Mike
Machaba Sathekge, MD, PhDz

[2] www.clinicaltrials.gov

II.

Galli Ad

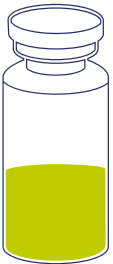
Ge-68 / Ga-68 Generator

Galli Ad is manufactured and tested under **cGMP compliance**, adhering to stringent regulatory standards to ensure safety, efficacy, and reliability for pharmaceutical use according to European Pharmacopoeia specifications.



01. Galli Ad is the unique **ready to use** generator of the market

→ Gallium chloride eluate for **PET radiolabelling** applications



The eluate from the generator (gallium chloride solution) is indicated for in vitro radiolabelling of various kits for radiopharmaceutical preparation developed and approved for radiolabelling with such solution to be used for positron emission tomography (PET) imaging.

→ **Kits compatible** with Galli Ad[®]



Galli Ad[®] has been approved for the reconstitution of approved kits, such as: SOMAKIT[™], LOCAMETZ[®], ILLUCCIX[®] and ISOPROTRACE[®]*.

* For more information, please refer to the Summary of Product Characteristics (SmPC) for each product.

→ Perfectly designed for **cold-kit-based** method: similar to Tc-99m generator



→ Galli Ad[®] is also **compatible** for automated use with synthesis modules



02. Features

01 A dry type generator

The Germanium-68 (Ge-68) is adsorbed onto a unique chromatographic dry-type TiO₂ column made of very pure inorganic material.

→ Reduced risk of **impurities** and **microbiological contamination**.

→ **Stability** of specifications over time.

02 Aspiration mechanism for elution

The Galli Ad generator is the only generator which works **by suction** (via vacuum application) as against by positive pressure.



03 Ready-to-use system with a pre-connected sterile eluent bag

→ Minimum **450 elutions** available.

→ No additional cost for eluent bags.

04 Lowest elution volume with 1.1 mL of Gallium [⁶⁸Ga] chloride solution

→ **High radioactive** concentration of the eluate.

→ **No fractionation steps** of the eluate.

→ Easy dilution and pooling of eluates.

05 Optimized radioprotection with a specific double lead/tungsten shielding

→ **Minimizing simultaneously** both the shielding thicknesses and the operator exposure to external radiation.

03. Specifications

Generator



CHEMICAL FORM	$^{68}\text{GaCl}_3$ in 0.1M HCl (Gallium Chloride solution)
AVAILABLE ACTIVITY	20-30-40-50 mCi (0.74-1.11-1.48-1.85 GBq)
ELUENT	Sterile 0.1 M HCl
ELUTION VOLUME	1.1 mL
ELUTION TIME	3 min
ELUTION YIELD	>70% at release, >55% end of life
TIME BETWEEN TWO ELUTIONS	3 hours
SHIELDING	Equivalent to 50 mm lead thickness
AVERAGE SURFACE RADIATION DOSE RATE	< 0.054 $\mu\text{Sv/h}$ per MBq of ^{68}Ge (e.g., 1.85 GBq generator: max 100 $\mu\text{Sv/h}$)
SHELF LIFE	Min 450 elutions or 1 year
DIMENSIONS	220 mm (W) * 210 mm (D) * 230 mm (H)
WEIGHT	16.5 kg

Eluate



BREAKTHROUGH	< 0.001% throughout the generator's life
RADIOCHEMICAL PURITY	$\geq 95\%$
CHEMICAL PURITY (Al, Cu, Fe, Ni, Pb, Zn, Ga, Ti)	$\leq 10 \mu\text{g} / \text{GBq}$
pH	< 2
ENDOTOXIN	< 0.5 EU/mL
MICROBIOLOGICAL QUALITY	Sterile
APPEARANCE	Clear, colorless solution
HALF-LIFE	About 68 min

SmPC available here: <https://www.ire.eu/en/our-activities/ire-elit/galli-ad>

04. Services & accessories



Premium services

Lead time:
8 weeks maximum
between order
and delivery

Free dismantling
of expired
generators

Initial
training

Technical
assistance
and **expertise**
when needed



Consumables

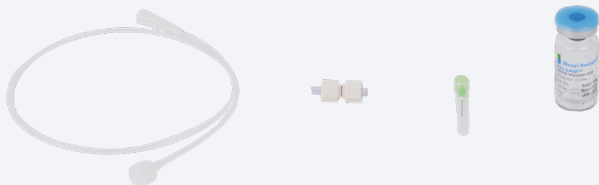
STERILE TUBING
Ref.: 1155.03 or
1155.05 (Vygon)

**MALE MALE
LUER-LOCK
CONNECTOR**
Ref.: 893.00
(Vygon)

STERILE NEEDLES
0.8X16MM 21G 5/8"
Ref.: AN*2116R1
(Terumo)

**10ML STERILE
EVACUATED VIALS
(CE MARKED)**
Ref.: SVV-10A
(Huayi)

These consumables are suitable, tested by IRE ELIT and described in the SmPC. A sample kit is delivered with the generator. IRE ELIT can supply these consumables directly, or you have the option to order them independently.



Generators range



Galli Demo [BLUE]
A cold generator designed
for training, laboratory
testing, setup, and
footprint assessment
in your lab.

Galli R&D [GREEN]
A chemical-grade
generator, not for
human use, designed
for preclinical work,
experimentation.
Activity on demand.

Galli Ad [WHITE]
A GMP pharmaceutical-
grade generator approved
in some European
countries (Marketing
Authorisation) and
registered in the US with
DMF #031715 (access
letter available on demand).
*See specifications on
previous pages.*

04. Services & accessories

Accessories



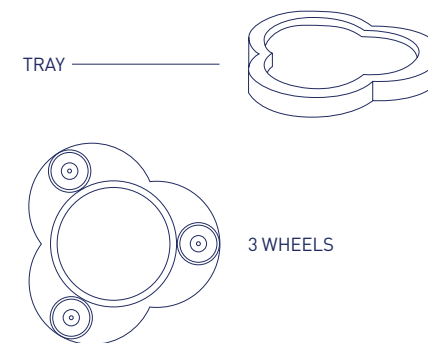
Galli Cap

Galli Cap is an actuator that has to be placed on the top of the IRE ELIT $^{68}\text{Ge}/^{68}\text{Ga}$ generator and that allows, thanks to the control touch screen to which it is connected, a remote activation of the generator on/off button. It is a system that allows the monitoring of the remaining activity in ^{68}Ga and its regrowth since the last elution. It provides a history of elutions since the generator was switched on, as well as various use indicators (in time and number of elutions) and alerts the user when a cleaning elution needs to be performed or when the generator needs to be replaced. It facilitates the handling of the generator and improves the radiation protection of the users.



Galli Mov

Galli Mov is a rolling support designed for IRE ELIT's $^{68}\text{Ge}/^{68}\text{Ga}$ generators. Tightly fitting to the generator base, it allows to move it in the hotcell without having to lift it.



Galli Up

Galli Up is a device that allows stacking two IRE ELIT generators in a cell to optimize workspace efficiency. Using two generators ensures continuous and stable activity, allowing an increase in the number of doses administered daily.

Galli Up has been designed for use exclusively with IRE ELIT generators.





SmPC

Name of the medicinal product GalliAd / Galli Ad, 0.74 - 1.85 GBq, radionuclide generator

Qualitative and quantitative composition The radionuclide generator contains germanium (^{68}Ge) as mother nuclide which decays to the daughter nuclide gallium (^{68}Ga). The germanium (^{68}Ge) used for the production of the ($^{68}\text{Ge}/^{68}\text{Ga}$) generator is carrierfree. The total radioactivity due to germanium (^{68}Ge) and gamma-ray-emitting impurities is not more than 0.001%. The GalliAd 0.74 - 1.85 GBq radionuclide generator is a system for the elution of gallium (^{68}Ga) chloride solution for radiolabelling in accordance with Ph. Eur. 2464. This solution is eluted from a column on which the mother nuclide germanium (^{68}Ge), parent of gallium (^{68}Ga) is fixed. The system is shielded. Physical characteristics of both mother and daughter nuclides are summarized : ^{68}Ge : Half-live : 270.95 days. Type of decay : Electron capture. X-rays : 9.225 (13.1 %), 9.252 (25.7 %), 10.26 (1.64 %), 10.264 (3.2 %), 10.366 (0.03 %). ^{68}Ga : Half-live : 67.71 minutes. Type of decay : Positron emission. X-rays : 8.616 (1.37 %), 8.639 (2.69 %), 9.57 (0.55 %). Gammas : 511 keV (178.28 %), 578.55 keV (0.03 %), 805.83 keV (0.09 %), 1077.34 keV (3.22 %), 1260.97 keV (0.09 %), 1883.16 keV (0.14 %). Beta+ : Energie 352.60 keV / Max energie 821.71 keV (1.20 %); Energie 836.00 keV / Max energie 1899.01 keV (87.94 %). Data derived from nudat (www.nndc.bnl.gov). 1.1 ml of the GalliAd eluate contains a potential maximum of 1850 MBq ^{68}Ga and 18.5 kBq ^{68}Ge (0.001 % breakthrough). This corresponds to 1.2 ng ^{68}Ga -gallium and 0.07 ng ^{68}Ge -germanium. The quantity of gallium (^{68}Ga) chloride solution for radiolabelling Ph. Eur. that may be eluted from the generator is dependent on the quantity of germanium (^{68}Ge) chloride present and the lapsed time since the previous elution. If mother and daughter nuclides are in equilibrium more than 60% of the present gallium (^{68}Ga) chloride can be eluted. A fixed volume of 1.1 mL (^{68}Ga) chloride solution is eluted. Table below summarizes the activity on the generator and obtained by elution at the start of the shelf-life and at the end of the shelf-life.

Activity on the generator and obtained by elution

NLT not less than * in equilibrium

STRENGTH	ACTIVITY INSIDE GENERATOR AT THE START OF SHELF-LIFE	ACTIVITY INSIDE GENERATOR AT THE END OF SHELF-LIFE	ELUTED ACTIVITY AT THE START OF SHELF-LIFE*	ELUTED ACTIVITY AT THE END OF SHELF-LIFE*
0.74 GBq	0.74 GBq \pm 10 %	0.3 GBq \pm 10 %	NLT 0.41 GBq	NLT 0.16 GBq
1.11 GBq	1.11 GBq \pm 10 %	0.4 GBq \pm 10 %	NLT 0.61 GBq	NLT 0.22 GBq
1.48 GBq	1.48 GBq \pm 10 %	0.6 GBq \pm 10 %	NLT 0.81 GBq	NLT 0.32 GBq
1.85 GBq	1.85 GBq \pm 10 %	0.7 GBq \pm 10 %	NLT 1.02 GBq	NLT 0.40 GBq

More detailed explanations and examples for elutable activities at various time points are given in section 12 of the SmPC.

Excipients : Matrix: Titanium dioxide. Integrated eluent: Sterile 0.1 mol/l hydrochloric acid.

Pharmaceutical form Radionuclide generator. The generator is presented as a plastic case with an outlet port and a knob. The solution for elution is integrated inside the plastic case. The eluate can be collected at the outlet port or inserted directly into a synthesis apparatus.

Therapeutic indications This medicinal product is not intended for direct use in patients. The eluate from the radionuclide generator (gallium (^{68}Ga) chloride solution) is indicated for in vitro radiolabelling of various kits for radiopharmaceutical preparation developed and approved for radiolabelling with such solution to be used for positron emission tomography (PET) imaging.

Posology and method of administration This medicinal product is for use in designated nuclear medicine facilities only, and should only be handled by specialists experienced with in vitro radiolabelling. Posology : The quantity of the eluate (gallium (^{68}Ga) chloride solution) required for radiolabelling and the quantity of ^{68}Ga -labelled medicinal product that is subsequently administered will depend on the medicinal product that is radiolabelled and its intended use. Refer to the Summary of Product Characteristics/package leaflet of the particular medicinal product to be radiolabelled. One elution corresponds to a fixed volume of 1.1 mL. Paediatric population : Please refer to the Summary of Product Characteristics/package leaflet of the ^{68}Ga -labelled medicinal product for more information concerning its paediatric use. Method of administration : The gallium (^{68}Ga) chloride solution is not intended for direct use in patients but is used for in vitro radiolabelling of various kits for radiopharmaceutical preparation. The route of administration of the final medicinal product should be adhered to. For instructions on extemporary preparation of the medicinal product before administration, see section 12 of the SmPC.

Contraindications Do not administer gallium (^{68}Ga) chloride solution directly to the patient. The use of ^{68}Ga -labelled medicinal products is contraindicated in case of hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the SmPC. For information on contraindications to particular ^{68}Ga -labelled medicinal products prepared by radiolabelling with gallium (^{68}Ga) chloride solution, refer to the Summary of Product Characteristics/package leaflet of the particular medicinal product to be radiolabelled.

Special warnings and precautions for use Gallium (^{68}Ga) chloride solution is not to be administered directly to the patient but is used for in vitro radiolabelling of various kits for radiopharmaceutical preparation. Individual benefit/risk justification : For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required effect. General warnings : For information concerning special warnings and special precautions for use of ^{68}Ga -labelled medicinal products refer to the Summary of Product Characteristics/package leaflet of the medicinal product to be radiolabelled.

Undesirable effects Possible adverse reactions following the use of a ^{68}Ga -labelled medicinal product, 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. Reporting of suspected adverse reactions : Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Marketing authorisation holder IRE-ELiT, Avenue de l'Espérance, B-6220 Fleurus, Belgium.

Date of first authorisation May 2018 **Date of revision of the text** 06 June 2018

Legal classification Prescription-Only Medicine

Marketing authorisation numbers

COUNTRY	NAME	MARKETING AUTHORIZATION NUMBER
Austria	Galli Ad	438495
Belgium	Galli Ad	BE531991
Bulgaria	Galli Ad	Under national phase process
Croatia	GalliAd	Under national phase process
Cyprus	Galli Ad	Under national phase process
Czechia	GalliAd	Under national phase process
Denmark	Galli Ad	30517
Estonia	GalliAd	1202925
Finland	Galli Ad	407835/2016
France	GalliAd	34009 550 579 0 1
Germany	GalliAd	98990.00.00
Greece	Galli Ad	Under national phase process
Hungary	Galli Ad	Under national phase process
Ireland	GalliAd	Under national phase process
Italy	Germanio cloruro	046512012, 046512024, 046512036, 046512048
Latvia	GalliAd	25-0133
Lithuania	GalliAd	Under national phase process
Luxembourg	Galli Ad	2018110338
Malta	Galli Ad	Under national phase process
Norway	GalliAd	16-11374
Poland	Galli Ad	Under national phase process
Portugal	Galli Ad	5907431, 5907449, 5907456, 5907464
Romania	Galli Ad	Under national phase process
Slovakia	Galli Ad	Under national phase process
Slovenia	Galli Ad	Under national phase process
Spain	Galli Ad	83618
Sweden	GalliAd	55545
The Netherlands	GalliAd	RVG 120151
United Kingdom	GalliAd	PL43883/0001



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