Galli Ad®

$^{68}Ge/^{68}Ga$ generator

From 0.74 to 1.85 GBq

Developed for *successful* labellings

01

Galli Ad® is perfectly *suitable for the one-step PSMA cold kit recently approved in Europe* [01]

Knowing that the Galli Ad® generator is the only generator which works by suction (via vacuum) unlike others that need positive pressure, it's simple to create vacuum and elute the generator directly into the cold kit labelling vial ("elute and label"). [01]

+ **Optimal vacuum vials** (30 mL) for the reconstitution of this cold kit with our generator* can be ordered at IRE ELiT.

We offer the possibility to work with minimal infrastructure.

+ No syringe pump or peristaltic pump needed.
+ A double shielding (lead and tungsten) inside the generator allows an optimal protection by itself. [02]
+ Using an approved generator and an approved cold kit **simplifies the quality control** (equipment and timing).

It allows fast and productive process similar to Techne kits.

+ The low elution volume 1.1 mL **speeds up the labelling preparation**. [03]
+ The integration of the eluent bag ensures that the generator is **always ready to use** (without the need of any new supply of HCl bags) and minimal risk of contamination.

[01] Locametz SmPC [see figure 02]

[02] Galli Ad SmPC

[03] *Development of a simple kit-based method for the preparation of pharmaceutical grade ^{68}Ga labelled radiopharmaceuticals*, Scientific Poster presented to the European Association of Nuclear Medicine 2016, M. Asti

* *Please note that 30 mL vacuum vials are only to be used for this reconstitution and not for simple elutions.*

Direct elution with vacuum vials

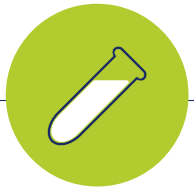
Galli Ad®

Minimal equipment and infrastructure

Fast and productive process

02

Galli Ad® has the *appropriate number of elutions*, all your needs for the year are covered with at least 450[04] elutions for labelling



- Up to **three elutions** per day.

- Allowing an average of 30 patients per week and 1500 patiens per year.

- The number of elutions is **scalable** to high PSMA imaging demand.

[04] Gallli Ad SmPC. The number of elutions is often not the limiting factor, which remains the elutable activity due to Ge-68 decay.

03 Galli Ad® is *always available for an optimal and smooth patient flow*

- IRE ELiT's capacity has been increased to 3 times to meet market needs. So we offer a **minimal lead time** between order and delivery.

- If you need assistance for using IRE ELiT generator, you get a **rapid response** (< 48 h) and solutions are set up to ensure the continuity of your activity.

- The advantage to have your own generator is to be able to perform elutions **on demand all day long** [05] to cope with emergencies and schedule changes.

[05] 91 % of regrowth after 4 hours.

04

Galli Ad® is a *fair and sustainable approach* that respects customers & planet

Fair price that covers:

The eluent **for 1 year**, packaging, starter kit, transportation costs for delivery, pick-up & recycling at IRE ELiT.

Galli Ad is a generator that operates manually **without electricity** or power source.

After expiry, **recycling** and reducing our environmental impact is a priority.

+ We facilitate the return of the generator from the user to IRE ELiT site. We **recycle /reuse** about 70% of the non-radioactive parts of the generator (plastic parts and shielding).

To encourage a **circular economy** and **control costs** for our customers we have invested in the construction of a cyclotron-based facility to produce our own Germanium-68 in the future. It is our long-term commitment to you.

Fair price

Without electricity

Easy return, smart recycling

Germanium-68 in-house production coming soon

Galli Ad®

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}Ge/^{68}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

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 SHELFLIFE*
0.74 GBq	0.74 GBq ± 10 %	0.3 GBq ± 10 %	NLT 0.41 GBq	NLT 0.16 GBq
1.11 GBq	1.11 GBq ± 10 %	0.4 GBq ± 10 %	NLT 0.61 GBq	NLT 0.22 GBq
1.48 GBq	1.48 GBq ± 10 %	0.6 GBq ± 10 %	NLT 0.81 GBq	NLT 0.32 GBq
1.85 GBq	1.85 GBq ± 10 %	0.7 GBq ± 10 %	NLT 1.02 GBq	NLT 0.40 GBq

NLT not less than
* in equilibrium

More detailed explanations and examples for elutable activities at various time points are given in section 12 of the SPC. 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 (68Ga) 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 SPC.

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 SPC. 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}Galabelled 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.

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Legal classification Prescription-Only Medicine

Marketing authorisation numbers

COUNTRY	NAME	MARKETING AUTHORIZATION NUMBER
Austria	Galli Ad	438495
Belgium	Galli Ad	BE531991
Denmark	Galli Ad	30517
Finland	Galli Ad	407835/2016
France	Galliad	34009 550 579 0 1
Germany	GalliAd	98990.00.00
Italy	Germanio cloruro	046512012, 046512024, 046512036, 046512048
Luxembourg	Galli Ad	2018110338
Norway	Galliad	16-11374
Spain	Galli Ad	83618
Sweden	Galliad	55545
The Netherland	Galliad	RVG 120151
United Kingdom	GalliAd	PL43883/0001

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From 0.74 to 1.85 GBq

IRE ELIT, A LABORATORY OF IDEAS AND ACTIONS FOR RADIOPHARMACEUTICAL INNOVATION

IRE ELiT connects ideas and action. Its aim is to create methods of diagnosis and treatment that are increasingly effective and beneficial for public health. It provides adapted, innovative and sustainable solutions that meet the quality requirements for radiopharmaceuticals administered to patients.

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