swissmedic

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Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report

Galli ad, radionuclide generator

International non-proprietary name:	gallium (68Ga) chloride, germanium (68Ge) chloride
Pharmaceutical form:	radionuclide generator
Dosage strength(s):	Galli Ad 0.74 – 3.70 GBq, radionuclide generator
Route(s) of administration:	parenteral
Marketing authorisation holder:	b.e. imaging.ag
Marketing authorisation no.:	70362
Decision and decision date:	approved on 25.08.2026

Note:

This assessment report is as adopted by Swissmedic with all information of a commercially confidential nature deleted.

SwissPARs are final documents that provide information on submissions at a particular point in time. They are not updated after publication.

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1 Terms, Definitions, Abbreviations

1L	First-line
2L	Second-line
ADA	Anti-drug antibody
ADME	Absorption, distribution, metabolism, elimination
AE	Adverse event
API	Active pharmaceutical ingredient
ATC	Anatomical Therapeutic Chemical Classification System
AUC	Area under the plasma concentration-time curve
$AUC_{0\text{-}24h}$	Area under the plasma concentration-time curve for the 24-hour dosing interval
CI	Confidence interval
C_{max}	Maximum observed plasma/serum concentration of drug
DDI	Drug-drug interaction
DOR	Duration of response
ECOG	Eastern Cooperative Oncology Group
EMA	European Medicines Agency
ERA	Environmental risk assessment
FDA	Food and Drug Administration (USA)
GLP	Good Laboratory Practice
HPLC	High-performance liquid chromatography
IC/EC_{50}	Half-maximal inhibitory/effective concentration
ICH	International Council for Harmonisation
INN	International non-proprietary name
ITT	Intention-to-treat
LoQ	List of Questions
MAH	Marketing Authorisation Holder
Max	Maximum
Min	Minimum
MRHD	Maximum recommended human dose
MTD	Maximum tolerated dose
N/A	Not applicable
NCCN	National Comprehensive Cancer Network
NO(A)EL	No observed (adverse) effect level
ORR	Objective response rate
OS	Overall survival
PBPK	Physiology-based pharmacokinetics
PD	Pharmacodynamics
PET	Positron emission tomography
PFS	Progression-free survival
PIP	Paediatric Investigation Plan (EMA)
PK	Pharmacokinetics
PopPK	Population pharmacokinetics
PSP	Pediatric study plan (US FDA)
RMP	Risk management plan
SAE	Serious adverse event
SwissPAR	Swiss Public Assessment Report
TEAE	Treatment-emergent adverse event
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21)

2 Background information on the procedure

2.1 Applicant's request(s) and information regarding procedure

New active substance status
The applicant requested new active substance status for gallium (68Ga) chloride, germanium (68Ge) chloride, radionuclide generator, in the above-mentioned medicinal product.

Diagnostic or therapeutic radiopharmaceutical
This application for a diagnostic radiopharmaceutical / therapeutic radiopharmaceutical has been reviewed by Swissmedic and the Expert Commission for Radiopharmaceuticals.

2.2 Indication and dosage

2.2.1 Requested indication

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 (ligand) developed and approved for radiolabelling with such solution to be used for positron emission tomography (PET) imaging.

2.2.2 Approved indication

This medicinal product is not intended for direct use on patients.
The eluate from the radionuclide generator (gallium(^{68}Ga) chloride solution) is intended for the in vitro radiolabelling of various kits for the production of radiopharmaceuticals that have been developed and authorised for radiolabelling with this solution and are intended for use in positron emission tomography (PET).

2.2.3 Requested dosage

Summary of the requested standard dosage:
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. This is described in the corresponding SmPC.
Three tables of radiation exposure for the organs are available.

2.2.4 Approved dosage

(see appendix)

2.3 Regulatory history (milestones)

Application	18 July 2025
Formal control completed	15 August 2025
List of Questions (LoQ)	17 December 2025
Response to LoQ	6 February 2026
Preliminary decision	13 May 2026
Response to preliminary decision	2 June 2026
Final decision	25 August 2026
Decision	approval

3 Quality aspects

3.1 Drug substance

Drug substance *intermediate* (^{68}Ge solution intermediate)
INN: Germanium-68 Chloride
Chemical name: Germanium-68 Chloride
Molecular formula: $GeCl_4$
Molecular mass: 214.44 g/mol

Drug substance (^{68}Ge API)
Molecular formula: $[^{68}Ge]GeCl_4/[^{68}Ga]GaCl_3$
Molecular mass: 209.74 g/mol / 174.29 g/mol

Physicochemical properties: The active substance used in the ^{68}Ge/^{68}Ga-generator is germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride in equilibrium. Germanium-68 chloride is a clear, colourless aqueous solution. ^{68}Ge decays into the short-lived isotope ^{68}Ga. The daughter nuclide ^{68}Ga with a half-life of 67.71 min decays into stable ^{68}Zn.

Synthesis: Ge-68 is produced by proton bombardment of a Ga-containing target. The production of the ^{68}Ge API grade solution starts from the ^{68}Ge solution intermediate. The ^{68}Ge API manufacturing process includes a series of purification steps and is able to produce a ^{68}Ge solution appropriate for generator manufacturing. The successive steps of the manufacturing process (^{68}Ge solution intermediate manufacturing, final purification and specific activity adjustment) have been described and validated.

Specification: The final active substance, ^{68}Ge API, is controlled by a specification consisting of identification, radionuclidic purity, chemical purity and specific activity of the solution for the intended generator. The radionuclidic purity and chemical purity specification have been defined in order to ensure compliance of the generator eluate with the specifications of the Ph. Eur. Monograph 2464.The specific activity has been set up to ensure a sufficient generator elution yield while safely ensuring, at the same time, that any non-conforming ^{68}Ge breakthrough can occur. Results of the analysis of several batches of API manufactured confirm the quality of the API and its compliance with specifications.

Stability: Appropriate stability data have been submitted and ^{68}Ge intermediate solution stability data are provided. Five batches stored at room temperature and ambient humidity were tested for stability at 45 days, 90 days and > 180 days post product calibration date. Stability assessments included tests for normality, radiochemical purity, radionuclidic identity, activity concentration, radionuclidic purity and chemical purity. The ^{68}Ge API has to be used within three days after manufacturing. This lead time was tested as part of the manufacturing of development batches. Therefore, no stability studies were performed.

3.2 Drug product

Description and composition: Galli Ad is a radionuclide generator. This final drug product has two components. Data on the HCl eluent solution is provided, as are data on the final drug product, the radionuclide generator. The generator is composed of a chromatographic column made of polyetheretherketone containing a stationary phase of TiO_2 on which a defined radioactivity amount of ^{68}Ge API is loaded. A polyethylene bag containing 0.1M HCl solution (eluent) is connected to the column and used for elution. The eluate (gallium (^{68}Ga) chloride solution) is used for in vitro radiolabelling of

specific carrier molecules that have been specifically developed and authorised for radiolabelling with this radionuclide to be used for diagnostic imaging with positron emission tomography (PET).

Manufacture: The manufacturing process consists of 3 main steps, including preparation of the column of the generator, loading and steam sterilisation of the column, followed by final assembly and packaging.

Specification: The ^{68}Ge/^{68}Ga generator eluted by 0.1 M HCl solution produces an eluate complying with the Ph. Eur. Monograph 2464 *"Gallium (^{68}Ga) Chloride Solution for Radiolabelling"*. The specifications proposed by the applicant allow additional quality attributes essential for radiopharmaceutical preparation to be guaranteed.

Stability: Due to its specificity, a radio-isotope generator is supposed to be used frequently over the shelf-life of the product, not stored on a shelf for a long period of time before use. An in-use stability study in non-ICH conditions has been performed on three generators. According to a well-defined protocol, and on the basis of stability data currently obtained, a shelf-life of 12 months without any special temperature storage conditions is defined.

3.3 Quality conclusions

Satisfactory and consistent quality of the drug substance and drug product has been demonstrated.

4 Nonclinical aspects

4.1 Pharmacology

The large number of studies on primary pharmacodynamics conducted over several decades highlights the interest of the scientific community in ^{68}Ga. This radionuclide has proven to be an effective and user-friendly radiopharmaceutical with significant potential for expanding its use to a broader range of diagnostic applications. Only a few studies on secondary and safety-relevant pharmacodynamic aspects are available, and these did not raise any safety concerns.
The absence of a traditional safety pharmacology and pharmacodynamic interaction package is justified by the fact that the quantities of ^{68}Ga used in diagnostic applications are extremely low, and the proportion of free ^{68}Ga is further reduced, thereby minimising the risk of any potential impact on the patient.

4.2 Pharmacokinetics

The majority of retrieved publications on non-clinical pharmacokinetic studies were not directly relevant to the diagnostic application of ^{68}Ga. Studies on absorption primarily provide information on routes of administration other than intravenous injection, and investigations of distribution, metabolism, and excretion predominantly refer to labelled tracers. Overall, the relevant findings indicate accumulation in the liver, spleen, and urine, as well as a non-negligible placental and fetal transfer. A distribution study on ^{68}Ge shows reassuring results regarding radiation exposure.
The original study, specifically conducted on the eluate of the Galli Ad radionuclide generator, was carried out in accordance with the recommendations of the Danish Medicines Agency (see the protocol of the scientific advice in Module 1.2). The effective doses calculated for humans are comparable to those of other ^{68}Ga-based diagnostic agents.

4.3 Toxicology

The package presented provides some pivotal or relevant data, whereas some studies were only informative. However, as a whole, this package is not in line with the standards pertaining to a full application as per Directive 2001/83/EC Art. 8.3, both in terms of the type of data (gaps in the package) and their quality (GLP status unknown or not adequate, partial information due to the absence of full reports).
The available publications relating to toxicity provide limited information on the diagnostic use of gallium in humans. These studies are outdated, and many relied on the LD_{50} parameter or tested only a single dose, making it difficult to establish a NOAEL. However, the amount of injected gallium is extremely low, 20 pg/kg, which is approximately 10^6-fold lower than the LD_{50}s observed. Per ICH Q3B (R2), the dose of gallium administered is so low that the element would not even need to be qualified if it was an impurity of a new medicinal product. Thus, the chemical toxicology of gallium would not need to be further investigated. Uncertainty remains, however, regarding the toxicity of gallium to the respiratory system.
Gallium-68 is an unstable isotope, with a very short half-life of 68 minutes, that decays into a stable isotope of zinc. So, after a few hours, the initial - very low - dose of gallium will be converted into a limited amount of zinc, an essential element present in our diet.
In summary, the lack of any specific studies is acceptable, as the administration of the eluate alone is not intended, and the potential toxicity of the radiolabel ^{68}Ga will depend on the carrier molecule and furthermore, due to the short half-life of ^{68}Ga, radioactive gallium will decay to inactive zinc, at levels well below the daily acceptable limit of 1300 µg/day Zn per day, according to the EMA guideline on

the specification limits for residues of metal catalysts or metal reagents (EMEA/CHMP/SWP/4446/2000).
Annex I Part III section 2.2 of Directive 2001/83/EC clearly states that results from genotoxicity studies are not necessary for radio-pharmaceutical precursors, and ICH Guideline S1A on the Need for Carcinogenicity Studies of Pharmaceuticals mentions that such information is only expected for products administered for more than 6 months of a patient's lifetime.
The negative embryo-fetal data, the absence of retrieved publications related to peri- and post-natal development, as well as the fact the product as used in humans is radioactive, justify the contraindication in (potentially) pregnant women and the temporary interruption of breast-feeding.

4.4 Nonclinical conclusions

The toxicological profile of $^{68}Ga/^{68}Ge$ eluate is considered to be sufficiently characterised. The submitted nonclinical data support the use for radioactive labelling of specific ligands *in vitro*. The relevant information has been included in the Information for healthcare professionals.

5 Clinical aspects

Swissmedic has not assessed the primary data relating to clinical aspects submitted with this application and relies on the assessment of the reference member state Denmark.
For further information regarding clinical and clinical pharmacology aspects, please refer to the attached Information for healthcare professionals.

6 Risk management plan summary

The RMP summaries contain information on the medicinal products′ safety profiles and explain the measures that are taken to further investigate and monitor the risks, as well as to prevent or minimise them.
The RMP summaries are published separately on the Swissmedic website. It is the responsibility of the marketing authorisation holder to ensure that the content of the published RMP summaries is accurate and correct. As the RMPs are international documents, their summaries might differ from the content in the Information for healthcare professionals / product information approved and published in Switzerland, e.g. by mentioning risks that occur in populations or indications not included in the Swiss authorisations.

7 Appendix

Approved Information for healthcare professionals

Please be aware that the following version of the Information for healthcare professionals for Galli ad, radionuclide generator, was approved with the submission described in the SwissPAR. This Information for healthcare professionals may have been updated since the SwissPAR was published.

Please note that the valid and relevant reference document for the effective and safe use of medicinal products in Switzerland is the Information for healthcare professionals currently authorised by Swissmedic (see www.swissmedicinfo-pro.ch).

Note:
The following Information for healthcare professionals has been translated by the MAH. It is the responsibility of the authorisation holder to ensure the translation is correct. The only binding and legally valid text is the Information for healthcare professionals approved in one of the official Swiss languages.

Galli Ad 0.74 – 3.70 GBq Radionuclide Generator

This medicinal product is subject to additional monitoring, which helps to rapidly identify new findings relating to safety. Healthcare professionals are urged to report any suspected new or serious adverse reactions. For information on reporting side effects, refer to section “Adverse reactions”.

Composition

Active substances

Germanium chloride [^{68}Ge]$GeCl_4$ (parent nuclide), immobilised on a column matrix
Gallium chloride [^{68}Ga]$GaCl_3$ (daughter nuclide), eluted with dilute hydrochloric acid

Excipients

Acidum hydrochloricum, aqua ad injectabilia (0.1 mol/l)
Column matrix: titanium dioxide

Specifications
In accordance with Ph. Eur. 2464, in particular:
Ge-68 and gamma-ray-emitting impurities ≤ 0.001 % of total radioactivity
pH ≤ 2.

Pharmaceutical form and active substance quantity per unit

The radionuclide generator contains germanium (^{68}Ge) as the parent nuclide, which decays into the daughter nuclide gallium (^{68}Ga).
The germanium (^{68}Ge) used in the production of the (^{68}Ge/^{68}Ga) generator is carrier-free.
The Galli Ad 0.74 – 3.70 GBq Radionuclide Generator is a system for the elution of (^{68}Ga) solution for radioactive labelling in accordance with Ph. Eur. 2464. The solution is eluted from a column on which parent nuclide germanium (^{68}Ge), the precursor of gallium (^{68}Ga), has been immobilised.

For example, 1.1 ml of eluate from a 1.85 GBq generator contains a potential maximum of 1850 MBq ^{68}Ga and 18.5 kBq ^{68}Ge (0.001 % breakthrough). This is equivalent to 1.2 ng of gallium ^{68}Ga and 0.07 ng of germanium ^{68}Ge. Table 1 shows the values for each generator activity.

Table 1: Values for each generator activity

Radionuclide generator activity (GBq)	^{68}Ga (MBq)	^{68}Ge (kBq)	^{68}Ga – gallium (ng)	^{68}Ge – germanium (ng)

0.74	740	0.74	0.5	0.03
1.11	1110	11.1	0.7	0.04
1.48	1480	14.8	1.0	0.06
1.85	1850	18.5	1.2	0.07
3.70	3700	37.0	2.4	0.14

The amount of gallium (^{68}Ga) chloride solution that can be eluted from the generator depends on the amount of germanium (^{68}Ge) present and the time that has elapsed since the previous elution. If the parent and daughter nuclides are in equilibrium, more than 55 per cent of the gallium (^{68}Ga) present can be eluted as chloride. A fixed volume of 1.1 ml (^{68}Ga) chloride solution is eluted.

Table 2 summarises the activity of the generator as supplied and that obtained by elution at the start and end of its service life.

Table 2: Activity of the generator as supplied and as obtained by elution

Strength	Generator activity at the beginning of its service life	Generator activity at the end of its service life	Eluted activity at the beginning of the service life*	Eluted activity at the end of the service life*
0.74 GBq	0.74 GBq ± 10 %	0.3 GBq ± 10 %	min. 0.41 GBq	min. 0.16 GBq
1.11 GBq	1.11 GBq ± 10 %	0.4 GBq ± 10 %	min. 0.61 GBq	min. 0.22 GBq
1.48 GBq	1.48 GBq ± 10 %	0.6 GBq ± 10 %	min. 0.81 GBq	min. 0.32 GBq
1.85 GBq	1.85 GBq ± 10 %	0.7 GBq ± 10 %	min. 1.02 GBq	min. 0.40 GBq
3.70 GBq	3.70 GBq ± 10 %	1.4 GBq ± 10 %	min. 2.04 GBq	min. 0.80 GBq

min. = at least

* in radioactive equilibrium

For more detailed explanations and examples of activities that can be carried out at various times, refer to section “other information”.

Radionuclide generator

The generator is sold in a plastic casing and equipped with an outlet port and a button. The elution solution is integrated in the plastic housing. The eluate can be collected at the outlet port or fed directly into a synthesis apparatus.

Indications/Uses

This medicinal product is not intended for direct use on patients.

The eluate from the radionuclide generator (gallium(^{68}Ga) chloride solution) is intended for the in vitro radiolabelling of various kits for the production of radiopharmaceuticals, which have been developed and authorised for radiolabelling with this solution and are intended for use in positron emission tomography (PET).

Dosage/Administration

This medicinal product must only be used in approved nuclear medicine facilities and should only be handled by persons experienced in in vitro radiolabelling.

Dosage

The volume of eluate ((^{68}Ga) gallium chloride solution) required for radiolabelling and the subsequent dose of the ^{68}Ga-labelled medicinal product depend on the specific radiolabelled medicinal product and its intended use. For further details, refer to the summary of product characteristics of the relevant radiopharmaceutical.

Radiation exposure

Following the intravenous administration of a ^{68}Ga-labelled medicinal product, the radiation dose received by the various organs depends on the specific radiolabelled medicinal product. For further information on radiation dosimetry, refer to the summary of product characteristics of the relevant medicinal product.

A distribution study on rats was used to assess the contribution of unconjugated ^{68}Ga to the radiation dose following administration of the ^{68}Ga-labelled medicinal product or following accidental intravenous injection of the gallium (^{68}Ga) chloride solution. The values were calculated using the so-called OLINDA (Organ Level Internal Dose Assessment) code. Measurements for dosimetry were made after 5 minutes, 30 minutes, 60 minutes, 120 minutes, 180 minutes and 360 minutes.

The effective dose resulting from an accidental intravenous injection of 250 MBq is therefore approximately 12.1 mSv for an adult woman weighing 57 kg and 8.45 mSv for an adult man weighing 70 kg.

Children and young people

For information on the use in children and adolescents, refer to the SmPC for the ^{68}Ga-labelled medicinal product.

Method of use

For information on the use of this medicine, refer to the SmPC for the ^{68}Ga-labelled medicinal product.

Contraindications

Gallium (^{68}Ga) chloride solution must not be administered directly to the patient.

The use of ^{68}Ga-labelled medicinal products is contraindicated in the event of hypersensitivity to the active substance or to any of the excipients listed in section “Composition”.

For further information on the contraindications for certain ^{68}Ga-labelled medicinal products, which are produced by radiolabelling with (^{68}Ga)gallium chloride solution, refer to the SmPC for the respective medicinal product to be radiolabelled.

Warnings and precautions

Accidental direct administration of the (^{68}Ga) gallium chloride solution results in unjustified radiation exposure for patients and must be reported to the FOPH as a medical incident. As the eluate contains 0.1 mol/l of hydrochloric acid, local venous irritation and, in the case of paravenous injections, tissue necrosis may also occur. The wound and the contaminated area of skin should therefore be rinsed with isotonic saline solution.

The ^{68}Ge breakthrough in the eluate may exceed 0.001 % if the radionuclide generator has not been eluted for several days. In order to avoid the risk of excessive exposure to ^{68}Ge, all instructions listed in section “*Instructions for the preparation of radioactive medicinal products”* must be followed scrupulously.

Individual benefit/risk assessment

For each patient, the radiation exposure must be justified by the expected benefit. Every administered activity should be as low as is realistically possible whilst still achieving the required effect.

General warnings

For further information on specific warnings and precautions regarding the use of ^{68}Ga-labelled medicinal products, refer to the SmPC for the relevant medicinal product to be radiolabelled.

Interactions

For further information on interactions associated with the use of ^{68}Ga-labelled medicinal products, refer to the SmPC for the medicinal product to be radiolabelled.

Pregnancy, lactation

Women of childbearing age

For information on the use of ^{68}Ga-labelled medicinal products in women of childbearing age, refer to the SmPC for the relevant radiopharmaceutical.

Pregnancy

For information on the use of ^{68}Ga-labelled medicinal products during pregnancy and breastfeeding, refer to the SmPC for the relevant radiopharmaceutical.

Breastfeeding

See the note under “Pregnancy”.

Effects on ability to drive and use machines

The effects on the fitness to drive and the ability to operate machinery following the administration of ^{68}Ga-labelled medicinal products are set out in the SmPC for the medicinal product to be radiolabelled.

Undesirable effects

Possible adverse reactions following the administration of a ^{68}Ga-labelled medicinal product depend on the specific medicinal product used. This information is set out in the SmPC for the medicinal product to be radiolabelled.

Reporting suspected adverse reactions after authorisation of the medicinal product is very important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions online via the ElViS portal (Electronic Vigilance System). You can obtain information about this at www.swissmedic.ch.

Overdose

If the dose of a ^{68}Ga-labelled radiopharmaceutical administered to a patient exceeds the recommended activity, this may result in excessive radiation exposure. For further information, refer to the SmPC for this medicine.

In the event of accidental use of the eluate, no toxic effects are to be expected from the free ^{68}Ga. The administered free ^{68}Ga decays almost completely within a short time to the inactive ^{68}Zn (97 % decay within 6 hours). During this period, ^{68}Ga is mainly concentrated in the blood/plasma (bound to transferrin) and in the urine. The patient should be hydrated to increase ^{68}Ga excretion. In addition, increased urine output and frequent emptying of the bladder are recommended.

The radiation dose to humans can be estimated using the information in section “Dosage / Administration”.

Properties/Effects

ATC code

V09X

Physical properties

Table 3 summarises the physical properties of the parent nuclide germanium (^{68}Ge) and the daughter nuclide gallium (^{68}Ga).

Table 3: Physical properties of germanium (^{68}Ge) and gallium (^{68}Ga)

	^{68}Ge	**^{68}Ga**
Half-life	270.95 days	67.71 minutes
Type of particle decay	Electron capture	Positron emission
X-rays	9–10 keV (44.1 %)	9–10 keV (4.7 %)
Gamma radiation		511 keV (178.3 %) 1077 keV (3.2 %)
Positron radiation		353 keV (1.2 %) 836 keV (87.9 %)

Data taken from NuDat (www.nndc.bnl.gov)

Mechanism of action

Imaging by means of positron emission tomography uses the 511 keV gamma radiation resulting from the positron decay of Ga-68.

Pharmacodynamics

The pharmacodynamic properties of ^{68}Ga-labelled drugs depend on the labelled carrier molecule. For further information, refer to the SmPC for the medicinal product to be radiolabelled.

Clinical efficacy

No data available (see note under “Pharmacodynamics”).

Pharmacokinetics

The gallium (^{68}Ga) chloride solution is not intended for direct use in patients, but for the in vitro radiolabelling of various kits used to prepare a radiopharmaceutical. The pharmacokinetic properties of ^{68}Ga-labelled medicinal products therefore depend on the type of medicinal product to be radiolabelled. The absorption, distribution and elimination of free ^{68}Ga following direct injection of a gallium (^{68}Ga) chloride solution were investigated in rats. However, no summary of the results is provided here; instead, only the resulting estimate of radiation exposure is used in the relevant section of this SmPC.

Absorption

No data available (see note under “Pharmacodynamics”).

Distribution

No data available (see note under “Pharmacodynamics”).

Metabolism

No data available (see note under “Pharmacodynamics”).

Elimination

No data available (see note under “Pharmacodynamics”).

Kinetics in specific patient groups

No data available (see note under “Pharmacodynamics”).

Preclinical data

The toxicological properties of ^{68}Ga-labelled medicinal products, which are radiolabelled with a gallium (^{68}Ga) chloride solution prior to use, depend on the medicinal product being radiolabelled.

Other information

Incompatibilities

No data available (see note under “Pharmacodynamics”).

Shelf life

Radionuclide generator: 12 months from the date of calibration.
The calibration and expiry dates are shown on the label.
Gallium (^{68}Ga) chloride eluate: Use the eluate immediately after elution.

Special precautions for storage

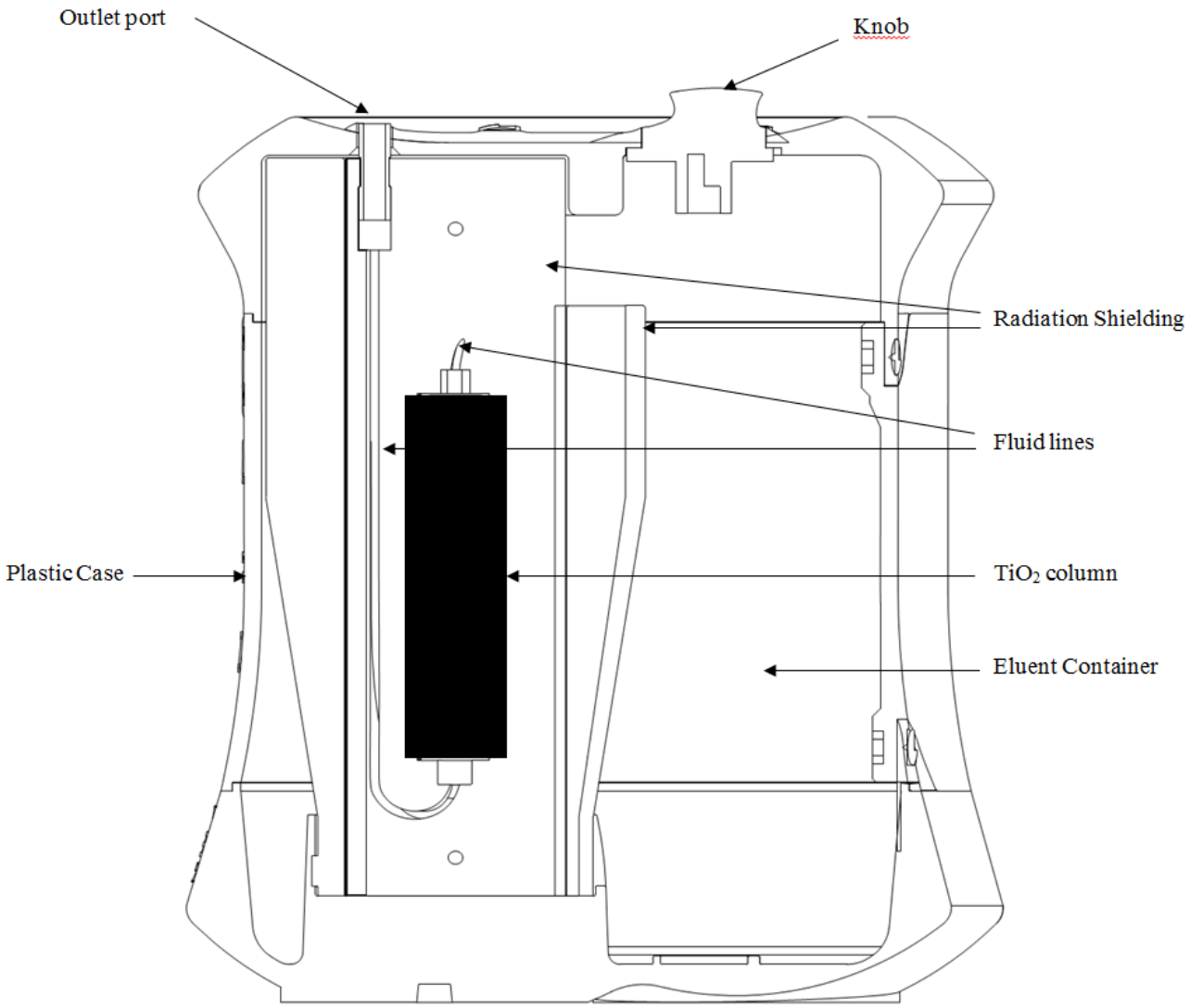
Radionuclide generator: Do not keep above 25 °C.
Radioactive medicinal products must be kept in accordance with national requirements for radioactive material.
The average dose rate at the surface of the (^{68}Ge/^{68}Ga) radionuclide generator is less than 0.054 µSv/h per MBq ^{68}Ge for generators up to 1.85 GBq and less than 0.036 µSv/h per MBq ^{68}Ge for a 3.70 GBq generator. Consequently, a 1.85 or 3.7 GBq generator achieves a maximum average surface dose rate of 100 or 133 µSv/h respectively. It is generally recommended that the generator be housed in a auxiliary shield to minimise the dose to operating staff.

Instructions for handling

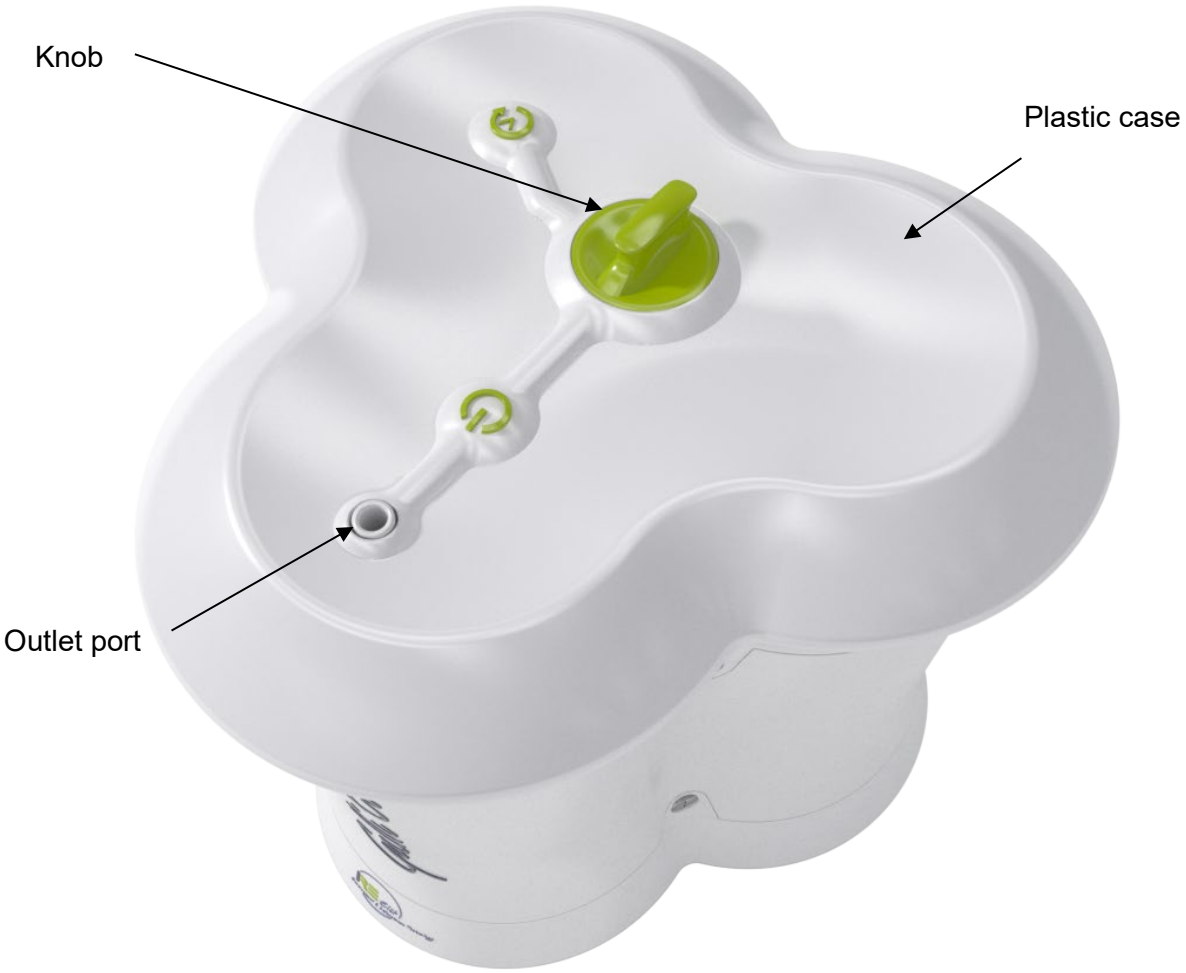
As the radioactive label is sensitive to traces of metal, all materials used must minimise the risk of metallic contamination. Glassware must be cleaned thoroughly to ensure it is free from residues. Furthermore, only acid-resistant needles (e.g. silicone-coated) should be used.

It is recommended that uncoated chlorobutyl stoppers should not be used for the acidic eluate, as these may release zinc. Ideally, the vials supplied with the labelling substance should be used. Alternatively, an identical or equivalent material should be used.

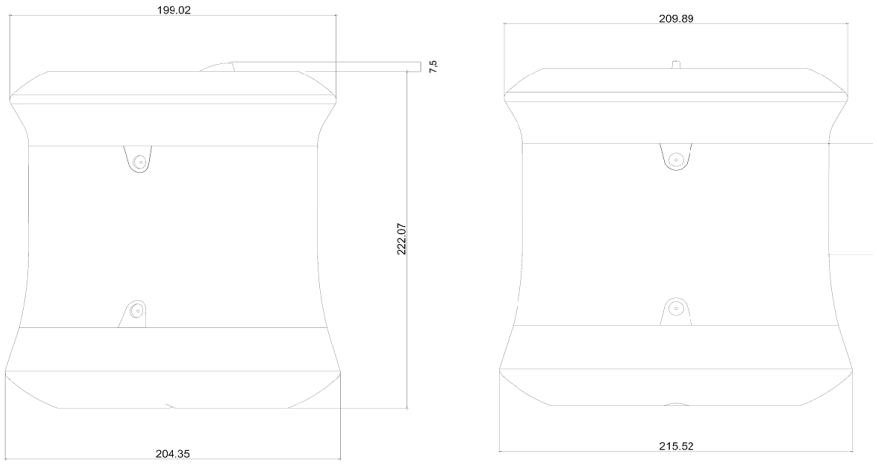
Sectional view of the Galli Ad radionuclide generator



3D view of the Galli Ad radionuclide generator



Size



Weight: approximately 17 kg

Instructions for the preparation of radioactive medicinal products

The generator must be eluted in buildings that comply with national regulations on the safe use of radioactive products.

Elution must be carried out under aseptic conditions.

Unpacking the generator

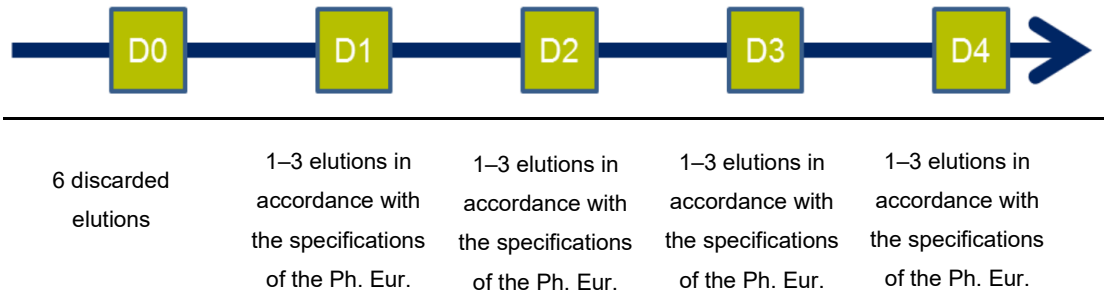
1. Check the outer packaging for any transport damage. If the packaging is damaged, carry out a wipe test for radioactive contamination on the damaged area. Please inform the radiation protection expert if the activity exceeds 40 becquerels per 100 cm².
2. Please note the arrows before opening the packaging to ensure that the transport packaging is positioned correctly. Check that the security seals are not broken. Then cut through the seals and open all the clip fastenings. Remove the top part of the outer packaging by pulling it straight up. Remove the small, detachable foam supports from the base of the outer packaging to allow the generator to be removed.
3. Carefully remove the generator and check that the radiation dose rate at a distance of 1 metre from the sides of the transport packaging corresponds to the specified transport index value.
   NOTE: Avoid any risks: the Galli Ad Generator weighs approximately 17 kg. Handle the device with care to avoid any injury. If the generator has been dropped, or if the transport damage has also affected the inner packaging, check the system for leaks and carry out a wipe test on the generator.
4. Carry out a wipe test on the items supplied and the exterior of the generator. Please inform the radiation protection expert if the wipe test reveals a reading in excess of 40 becquerels per 100 cm².
5. Check the entire generator casing, the outlet port and the seal for damage.
6. Do not remove the outlet port plug either before the generator has been installed or before the generator has been prepared for elution.

Ideal setup:

1. The generator must always be placed upright, i.e. with the green control knob facing upwards.
2. When setting up the Galli Ad radionuclide generator in its final position – i.e. alongside the synthesis unit or for manual elution – it is recommended that the outlet tubing be kept as short as possible (maximum 50 cm), as the length of this tubing can affect the yield recovered in the collection/reaction vial.
3. Local containment is recommended (particularly when performing elution) and personal protective equipment, including eye and hand protection, must be worn.

First use of the generator:

IMPORTANT: Before doing the first radiolabelling, complete a preparation procedure involving the discarding of six consecutive elutions, all of which must be performed within 24 hours. These elutions can also be carried out immediately one after the other. Following this procedure, the eluates are in accordance with the specifications of the Ph.Eur., provided that the final elution was carried out within 24 hours. This procedure applies only to the first eluates intended for radiolabelling during the first four days (i.e. normally only during the first week of generator use).



The eluate must be tested for ^{68}Ge breakthrough after the first six preparative elutions have been discarded, and again after six months use. To this end, compare the activity levels of ^{68}Ga and ^{68}Ge. For further information on the method, refer to monograph 2464, Ph. Eur.

Preparation:

1. Maintain aseptic conditions whilst using the generator, particularly when handling the elution port. This is of crucial importance for maintaining sterility. Carry out all procedures while the generator is in use in a suitably clean environment and in accordance with the applicable national requirements. This applies to procedures which may expose the generator's internal surfaces to the environment.

2. Unscrew the outlet port plug from the Luer-Lock connector by hand (Fig. 1).



Fig.1

3. Connect the sterile tube (extension tube) to the Luer-Lock connector by hand (Fig. 2). Any polyethylene tubing intended for parenteral use is suitable, provided that the dead space volume does not exceed 1 ml.



Fig.2

4. **A.** When using a synthesis unit, connect the other end of the hose to the synthesis unit. Avoid bending or kinking the cable sharply.
   B. In the case of manual elution, connect a sterile needle to the other end of the tubing using a male-to-male Luer-Lock adapter (Fig. 3); (see, for example, section “Packages”, “Accessories supplied with the generator”). Avoid bending or kinking the cable sharply.



Fig.3

5. The Galli Ad Generator is now ready for use.

Elution

1. Prepare the following additional materials:
   Personal protective equipment: Operators should always wear eye and hand protection and suitable laboratory clothing while eluting.

Use a shielded 10 ml vacuum vial to collect the eluate in the event of manual elution (see section “Instructions for handling”).

When using an automated radiosynthesis module, it is recommended that a sterile, single-use non-return valve be fitted between the male-to-male Luer-Lock adaptor and the automated radiosynthesis module.

2. Turn the green knob by 90° to the charging position and wait at least 10 seconds (Fig. 4).



Fig.4

IMPORTANT: Discard the eluate if the button has not returned to its initial position after more than 6 hours in the charging position.

3. Then turn the knob back by 90° to its original position (Fig. 5).



Fig.5

4. The generator is now ready for elution, either by manual elution or by connecting it to a synthesis module. In the latter case, follow the instructions provided by the synthesis module for elution. Once elution and labelling with the synthesis module have been completed, please proceed directly to step 7.

5. Remove the cap from the needle and quickly insert it vertically into the centre of the septum of a shielded, sterile, evacuated vial for elution (Fig. 6). Wait at least 3 minutes for the elution process to complete (a fixed volume of 1.1 ml has been eluted) and for the line to vent. Apply local shielding or radiation protection measures as soon as the activity is transferred from the generator to the vial. Measure the solution using a calibrated radiation counter to determine the yield. Calculate the precisely measured radioactivity at the start of the elution process.



Fig.6

6. Remove the needle from the vial and replace the cap (Figs. 7 and 8).



Fig.7

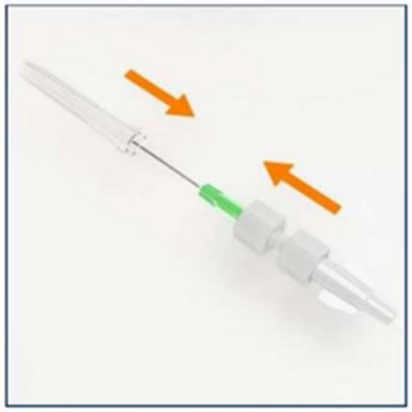


Fig.8

7. Disconnect the tubing from the Luer-Lock connector by hand and fit the cap to seal the generator outlet (Figs. 9 and 10).



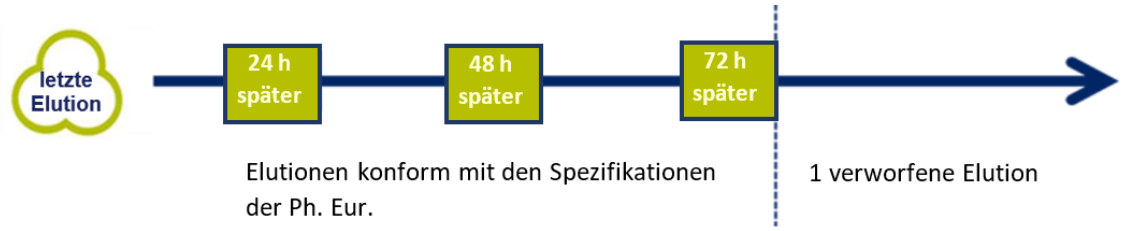
Fig.9



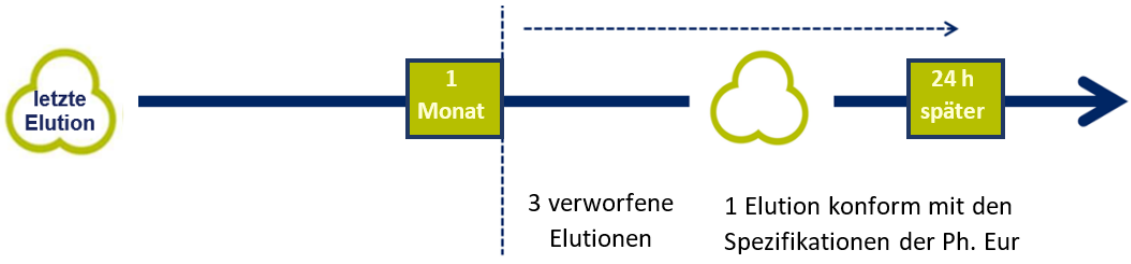
Fig.10

Routine elution during continuous operation:

Throughout the generator's service life, all eluates comply with the specifications of Ph. Eur., provided that a previous elution has been carried out within the last 72 hours. If radiolabelling is to be carried out and the generator has not been eluted within this time, carry out an elution first and discard the eluate. It is also important to check whether the kit manufacturers recommend any additional requirements for the eluate (e.g. the use of eluate from shorter elution intervals).



If the generator has not been eluted for more than one month, three consecutive elutions (which are to be discarded) must be carried out, and the first eluate intended for radiolabelling must be extracted within the next 24 hours.



The eluted solution is a clear, sterile and colourless gallium (^{68}Ga) chloride solution with a pH between 0.5 and 2.0 and a radiochemical purity of more than 95 per cent. Check that the eluate is clear before use and discard it if it is not clear.

IMPORTANT: If the column has not been completely vented (e.g. due to insufficient vacuum in the vial), a new vacuum vial may be connected to the generator outlet (via the tube, connector and needle) for one minute. In this case, the green button on the generator must be set to the elution/standby position. This procedure completes the venting process. If any additional eluate is obtained in the process, this can also be used, provided it is applied immediately after the previous (incomplete) elution. Otherwise, it must be discarded.

Yield in Galli Ad elution

The activity shown on the Galli Ad generator's label is the ^{68}Ge activity measured on the calibration date (12:00 CET). The available ^{68}Ga activity depends on the ^{68}Ge activity at the time of elution and the time elapsed since the previous elution.
A Gallium Ad generator operating in full equilibrium achieves a yield of more than 55 per cent of ^{68}Ga.

Over time, the remaining ^{68}Ga activity decreases as its parent nuclide ^{68}Ge decays. For example, following a decay period of 9 months (39 weeks), the ^{68}Ge activity has dropped by 50 % (see Table 4).

Table 4: Decay table for ^{68}Ge

Time elapsed in weeks	**Decay factor**	**Time elapsed in weeks**	**Decay factor**
1	0.98	**27**	0.62
2	0.96	**28**	0.61
3	0.95	**29**	0.59
4	0.93	**30**	0.58
5	0.91	**31**	0.57
6	0.90	**32**	0.56
7	0.88	**33**	0.55
8	0.87	**34**	0.54
9	0.85	**35**	0.53
10	0.84	**36**	0.52
11	0.82	**37**	0.52
12	0.81	**38**	0.51
13	0.79	**39**	0.50
14	0.78	**40**	0.49
15	0.76	**41**	0.48
16	0.75	**42**	0.47
17	0.74	**43**	0.46

18	0.72	**44**	0.45
19	0.71	**45**	0.45
20	0.70	**46**	0.44
21	0.69	**47**	0.43
22	0.67	**48**	0.42
23	0.66	**49**	0.42
24	0.65	**50**	0.41
25	0.64	**51**	0.40
26	0.63	**52**	0.39

Following elution by the Galli Ad generator, ^{68}Ga is produced through the continuous decay of its precursor, ^{68}Ge. The generator requires at least 7 hours to achieve a nearly complete yield following elution. In practice, however, it is also possible to elute the generator earlier. Recommended time between two elutions:

- At least 3 hours for the 0.74 GBq, 1.11 GBq, 1.48 GBq and 1.85 GBq generators
- At least 1 hour for the 3.70 GBq generator

Table 5 shows the build-up factor of the ^{68}Ga activity as a function of the time (60 to 410 minutes) elapsed since the previous elution:

Table 5: Build-up factors of ^{68}Ga

Time elapsed, in minutes	**Build-up factor**	**Time elapsed, in minutes**	**Build-up factor**
60	0.46	**270**	0.94
70	0.51	**280**	0.94
80	0.56	**290**	0.95
90	0.60	**300**	0.95
100	0.64	**310**	0.96
110	0.68	**320**	0.96
120	0.71	**330**	0.97
130	0.74	**340**	0.97
140	0.76	**350**	0.97
150	0.78	**360**	0.97
160	0.81	**370**	0.98
170	0.82	**380**	0.98
180	0.84	**390**	0.98

190	0.86	**400**	0.98
200	0.87	**410**	0.98

Examples

A 1.85 GBq generator is 12 weeks old. According to Table 4, the ^{68}Ge activity on the column calculates as follows:

1.85 GBq x 0.81 = 1.499 GBq

At complete equilibrium, the ^{68}Ga activity on the column is also 1.499 GBq.

The generator is eluted and the ^{68}Ga activity measured is 1.049 GBq, corresponding to a representative yield of 70 %.

The same generator is eluted 4 hours later. The 7 hours required to reach the ^{68}Ge/^{68}Ga equilibrium have not yet elapsed, and, in accordance with Table 5, the ^{68}Ga activity accumulated on the column calculates as follows:

1.499 GBq x 0.91 = 1.364 GBq

Assuming a representative yield of 70 % ^{68}Ga, the accumulated activity would be:

1.364 GBq x 0.70 = 955 MBq

Note:

The ^{68}Ga activity in the eluate can be measured to verify quality in terms of identity and content. The activity should be measured immediately after elution. To minimise radiation exposure, the measurement may also be carried out at a later stage, but no later than 5 times the half-life period following elution.

Due to the short half-life of ^{68}Ga (67.71 minutes), the time elapsed between elution and the measurement of activity must be corrected for decay using the ^{68}Ga decay table (Table 6) to account for decay.

Examples:

A new 1.85 GBq generator is being eluted. The ^{68}Ga activity measured 10 minutes after elution is 1.169 GBq.

The yield at the time of elution can be calculated by dividing the measured activity by the corresponding factor in Table 6
on the basis of the elapsed time:
1.169 GBq / 0.903 = 1.295 GBq

This corresponds to a ^{68}Ga yield of 70 % at the time of elution: 1.295 GBq / 1.85 GBq x 100 % = 70 %

Table 6: ^{68}Ga decay table

Time elapsed, in minutes	**Decay factor**	**Time elapsed, in minutes**	**Decay factor**
1	0.990	**35**	0.700
2	0.980	**36**	0.693
3	0.970	**37**	0.686
4	0.960	**38**	0.679
5	0.950	**39**	0.672
6	0.941	**40**	0.665
7	0.931	**41**	0.658
8	0.922	**42**	0.652
9	0.912	**43**	0.645
10	0.903	**44**	0.639
11	0.894	**45**	0.632
12	0.885	**46**	0.626
13	0.876	**47**	0.619
14	0.867	**48**	0.613
15	0.858	**49**	0.607
16	0.850	**50**	0.601
17	0.841	**51**	0.595
18	0.832	**52**	0.589
19	0.824	**53**	0.583
20	0.816	**54**	0.577
21	0.807	**55**	0.571
22	0.799	**56**	0.565
23	0.791	**57**	0.559

24	0.783	**58**	0.554
25	0.775	**59**	0.548
26	0.767	**60**	0.543
27	0.759	**61**	0.537
28	0.752	**62**	0.532
29	0.744	**63**	0.526
30	0.737	**64**	0.521
31	0.729	**65**	0.516
32	0.722	**66**	0.510
33	0.714	**67**	0.505
34	0.707	**68**	0.500

Quality control

Before using a new generator for the first time in a clinical setting, it is recommended that an eluate be tested for clarity of the solution and ^{68}Ge breakthrough in order to rule out any transport damage.

Germanium-68 (^{68}Ge) breakthrough

With each elution, a small amount of ^{68}Ge is washed out of the column. The ^{68}Ge breakthrough is expressed as a percentage of the total eluted and decay-corrected ^{68}Ga activity. When used in accordance with the instructions in this document, it does not exceed 0.001 % over the generator's entire service life (12 months).

Gamma-ray spectrometry is carried out to regularly monitor the ^{68}Ge breakthrough, as well as other radionuclide contaminants with a half-life of more than 5 hours. A gamma counter (usually a scintillation counter) or a high-purity germanium spectrometer (HPGe detector) can be used to ensure reliable and precise quantification. The measurement is carried out on sealed sample vials in a shielded detector; the measurement time – depending on the remaining activity and concentration – may vary from a few minutes to several hours.

To ensure a reliable detection of the low ^{68}Ge activity, the eluate sample to be tested must be stored for at least 48 hours prior to measurement. This allows the eluted short-lived ^{68}Ga to decay completely to a level that makes it possible to detect the long-lived impurities within the specific energy windows. For further information, refer to the latest edition of Monograph 2464, Ph. Eur.

General warnings

Radioactive medicinal products may only be received, used and administered by authorised persons at the designated clinical facility. The receipt, storage, use, transport and disposal of goods are subject to the regulations and/or the relevant authorisations issued by the competent official authorities.
The manufacture of radioactive medicinal products must comply with the requirements of both radiation safety and pharmaceutical quality. Appropriate aseptic precautions must be taken.
The generator must not be dismantled under any circumstances, as this may damage the internal components and could lead to the release of radioactive material. It is also forbidden to remove the plastic sleeve, as this exposes the lead sheath.
Use of the product must minimise the risk of contamination to the medicinal product and the risk of radiation exposure to staff. Adequate shielding is absolutely essential.
The administration of radiopharmaceuticals may put other people at risk due to external radiation or contamination from splashes of urine, vomit, etc. It is therefore essential to comply with the relevant national radiation protection regulations.
Expired generators must be returned to IRE-ELiT. Before returning the generator, its remaining activity must be estimated.
Any unused medicinal products or waste material must be disposed of in accordance with national requirements.

Authorisation number

70632

Packs

One radionuclide generator. [A]

The radionuclide generators are supplied with the following ^{68}Ge activity levels as at the calibration date: 0.74 GBq, 1.11 GBq, 1.48 GBq, 1.85 GBq, 3.70 GBq. The integrated elution volume (610 ml) in the 0.74 GBq, 1.11 GBq, 1.48 GBq and 1.85 GBq radionuclide generators is enough for 450 elutions. The total elution volume (740 ml) of the 3.70 GBq generator is enough for 550 elutions.

The column consists of a PEEK (polyether ether ketone) column, which is connected to the PEEK inlet and outlet lines by HPLC-style fittings. The inlet pipe is connected first to a dosing system (PE/EVA/PVC/PC/PTFE) and a flexible C-type pipe and then to the eluate vessel (PE/EVOH), whilst the outlet pipe is connected to an adaptor piece that passes through the outer casing of the Galli Ad generator.
The column is located inside the radiation shielding housing (Pb, W). The shielding housing and the eluate container are secured within a plastic casing.

Accessories supplied with the generator:

5 x 10 ml sterile, vacuum-sealed vials, ref: SVV-10A (Huayi)

5 x sterile tubing, ref: 1155.03 or 1155.05 (Vygon)

5 x sterile needles 0.8 x 16 mm 21G 5/8", ref: AN*2116R1 (Terumo)

5 x male-to-male Luer-Lock connectors, ref: 893.00 (Vygon)

Marketing authorisation holder

b.e.imaging AG, Schwyz

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May 2026