ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GalliaPharm 1.11 GBq radionuclide generator
GalliaPharm 1.48 GBq radionuclide generator
GalliaPharm 1.85 GBq radionuclide generator
GalliaPharm 2.22 GBq radionuclide generator
GalliaPharm 2.59 GBq radionuclide generator
GalliaPharm 2.96 GBq radionuclide generator
GalliaPharm 3.33 GBq radionuclide generator
GalliaPharm 3.70 GBq radionuclide generator

2. 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 no carrier added. The total radioactivity due to germanium (^{68}Ge) and gamma-ray-emitting impurities in the eluate is not more than 0.001 %.

The GalliaPharm 1.11 - 3.70 GBq radionuclide generator is a system for the elution of sterile 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 summarised in table 1.

Table 1: Physical characteristics of germanium (^{68}Ge) and gallium (^{68}Ga)

	^{68}Ge	**^{68}Ga**
Half-life	270.95 days	67.71 minutes
Type of physical decay	Electron capture	Positron emission
X-rays	9.225 keV (13.1 %) 9.252 keV (25.7 %) 10.26 keV (1.64 %) 10.264 keV (3.2 %) 10.366 keV (0.03 %)	8.616 keV (1.37 %) 8.639 keV (2.69 %) 9.57 keV (0.55 %)
Gamma-rays		511 keV (178.28 %) 578.55 keV (0.03 %) 805.83 keV (0.09 %) 1,077.34 keV (3.22 %) 1,260.97 keV (0.09 %) 1,883.16 keV (0.14 %)
Beta+		Energy max. Energy 352.60 keV 821.71 keV (1.20 %) 836.00 keV 1,899.01 keV (87.94 %)

Data derived from nudat (www.nndc.bnl.gov)

5 ml of the eluate from the radionuclide generator with highest strength (3.70 GBq) contains a potential maximum of 3.70 GBq of ^{68}Ga and 0.000037 GBq (37 kBq) of ^{68}Ge (0.001 % breakthrough in the eluate). This corresponds to 2.4 ng of gallium and 0.14 ng of germanium.

The quantity of gallium (^{68}Ga) chloride solution for radiolabelling Ph.Eur. that may be eluted from the radionuclide generator is dependent on the quantity of germanium (^{68}Ge) present on the date/time of elution, the volume of eluent used (typically 5 ml), 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) activity can be eluted.

Table 2 summarises the activity on the radionuclide generator, the minimum activities obtained by elution at the start of the shelf-life and at the end of the shelf-life as well as the potential maxima of ^{68}Ga and ^{68}Ge in the eluate.

Table 2: Activity on the radionuclide generator and activity obtained by elution

Strength, GBq	**Activity inside the radionuclide generator at the start of shelf-life*, GBq**	**Activity inside the radionuclide generator at the end of shelf-life*, GBq**	**Eluted activity at the start of shelf-life**, GBq**	**Potential maximum amount of ^{68}Ga in 5 ml eluate, GBq / ng**	**Potential maximum amount of ^{68}Ge in 5 ml eluate, kBq / ng**	**Eluted activity at the end of shelf-life**, GBq**
1.11	1.11	0.27	NLT 0.67	1.11 / 0.73	11.1 / 0.04	NLT 0.16
1.48	1.48	0.36	NLT 0.89	1.48 / 0.98	14.8 / 0.06	NLT 0.22
1.85	1.85	0.46	NLT 1.11	1.85 / 1.22	18.5 / 0.07	NLT 0.27
2.22	2.22	0.55	NLT 1.33	2.22 / 1.47	22.2 / 0.08	NLT 0.33
2.59	2.59	0.64	NLT 1.55	2.59 / 1.71	25.9 / 0.10	NLT 0.38
2.96	2.96	0.73	NLT 1.78	2.96 / 1.96	29.6 / 0.11	NLT 0.44
3.33	3.33	0.82	NLT 2.00	3.33 / 2.20	33.3 / 0.13	NLT 0.49
3.70	3.70	0.91	NLT 2.22	3.70 / 2.45	37.0 / 0.14	NLT 0.55

NLT = not less than
** The actual activity inside the radionuclide generator may deviate by ± 10 % from the nominal strength*
*** In equilibrium*

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Radionuclide generator.

The radionuclide generator is presented as an unstained stainless-steel case with two handles and an inlet and an outlet port.

The radionuclide generator provides after elution a sterile gallium (^{68}Ga) chloride solution for radiolabelling. The solution is clear and colourless.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This radionuclide generator is not intended for direct use in patients.

The sterile eluate (gallium (^{68}Ga) chloride solution) from the radionuclide generator GalliaPharm is indicated for *in vitro* radiolabelling of various kits for radiopharmaceutical preparation developed and approved for radiolabelling with such eluate, to be used for positron emission tomography (PET) imaging.

4.2 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 radiopharmaceutical that is subsequently administered will depend on the kit that is to be radiolabelled and its intended use. Refer to the Summary of Product Characteristics/package leaflet of the particular kit for radiopharmaceutical preparation to be radiolabelled.

Paediatric population

Please refer to the Summary of Product Characteristics/package leaflet of the kit for radiopharmaceutical preparation to be radiolabelled with ^{68}Ga 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 ^{68}Ga-labelled radiopharmaceutical is defined in the Summary of Product Characteristics/package leaflet of the respective kit for radiopharmaceutical preparation and should be adhered to.

For instructions on extemporary preparation of the medicinal product before administration, see section 12.

4.3 Contraindications

Gallium (^{68}Ga) chloride solution should not be administered 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.

For information on contraindications to particular ^{68}Ga-labelled radiopharmaceuticals 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.

4.4 Special warnings and precautions for use

Gallium (^{68}Ga) chloride solution for radiolabelling is not to be administered directly to the patient but is used for *in vitro* radiolabelling of various kits for radiopharmaceutical preparation.

Unintended direct administration of gallium (^{68}Ga) chloride solution may lead to increased radiation exposure to patients (see sections 4.9, 5.2, and 11). Accidental administration of gallium (^{68}Ga)

chloride solution for radiolabelling containing 0.1 mol/l hydrochloric acid may also cause local venous irritation and, in case of paravenous injection, tissue necrosis. The catheter or affected area should be irrigated with 9 mg/ml (0.9 %) sodium chloride solution for injection.

Safe handling of GalliaPharm and its eluate in accordance with the instructions in this document should be permanently ensured to protect patients and healthcare professionals from unintentional excess radiation exposure (see sections 6 and 12).

^{68}Ge breakthrough can increase in the eluate above 0.001 % if the radionuclide generator is not eluted for several days (see section 12). All instructions provided in section 12 should be strictly followed to avoid the risk of excess exposure to ^{68}Ge.

Individual benefit/risk justification

For each patient, the radiation exposure must be justifiable by the likely benefit.
The radioactivity administered should in every case be as low as reasonably achievable to obtain the required information.

General warnings

For information concerning special warnings and special precautions for use of ^{68}Ga-labelled radiopharmaceuticals refer to the Summary of Product Characteristics/package leaflet of the kit for radiopharmaceutical preparation to be radiolabelled.

Precautions with respect to environmental hazard are included in section 6.6.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies of the gallium (^{68}Ga) chloride solution for radiolabelling with other medicinal products have been performed, because it is used for *in vitro* radiolabelling of medicinal products.

For information concerning interactions associated with the use of ^{68}Ga-labelled radiopharmaceuticals, refer to the Summary of Product Characteristics/package leaflet of the kit for radiopharmaceutical preparation to be radiolabelled.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential

When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. If in doubt about her potential pregnancy (if the woman has missed a period, if the period is very irregular etc.), alternative techniques not using ionising radiation (if there are any) should be offered to the patient.

Pregnancy

Radionuclide procedures carried out on pregnant women also involve radiation dose to the foetus. Only essential investigations should therefore be carried out during pregnancy, when the likely benefit far exceeds the risk incurred by the mother and the foetus.

Breast-feeding

Before administering a radiopharmaceutical to a mother who is breast-feeding, consideration should be given to whether the investigation could be reasonably delayed until the mother has ceased breast-feeding. If the administration is considered necessary, breast-feeding should be interrupted, and the expressed feeds discarded.

Further information concerning the use of a ^{68}Ga-labelled radiopharmaceutical in pregnancy and breast-feeding is specified in the Summary of Product Characteristics/package leaflet of the kit for radiopharmaceutical preparation to be radiolabelled.

Fertility

Further information concerning the use of a ^{68}Ga-labelled radiopharmaceutical concerning fertility is specified in the Summary of Product Characteristics/package leaflet of the kit for radiopharmaceutical preparation to be radiolabelled.

4.7 Effects on ability to drive and use machines

Effects on ability to drive and use machines following administration of ^{68}Ga-labelled radiopharmaceutical will be specified in the Summary of Product Characteristics/package leaflet of the kit for radiopharmaceutical preparation to be radiolabelled.

4.8 Undesirable effects

Possible adverse reactions following the use of a ^{68}Ga-labelled radiopharmaceutical will be dependent on the specific kit for radiopharmaceutical preparation being used. Such information will be supplied in the Summary of Product Characteristics/package leaflet of the kit for radiopharmaceutical preparation to be radiolabelled.

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects.

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 the national reporting system listed in Appendix V.

4.9 Overdose

Excess radiation exposure may occur if higher than recommended activity of a ^{68}Ga-labelled radiopharmaceutical is administered to a patient. For further information refer to the Summary of Product Characteristics/package leaflet of the kit for radiopharmaceutical preparation to be radiolabelled.

No toxic effects are to be expected from the free ^{68}Ga after an inadvertent administration of the eluate. The administered free ^{68}Ga decays almost completely to stable ^{68}Zn within a short time (97 % are decayed in 6 hours). During this time, ^{68}Ga is mainly concentrated in the blood/plasma (bound to transferrin) and in the urine. The patient should be hydrated to increase the excretion of the ^{68}Ga. Forced diuresis as well as frequent bladder voiding are recommended.

Human radiation dose in case of an inadvertent administration of the eluate should be estimated using the information given in section 11.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diagnostic radiopharmaceuticals; other diagnostic radiopharmaceuticals, ATC code: V09X.

The pharmacodynamic properties of ^{68}Ga-labelled radiopharmaceutical prepared by radiolabelling with the radionuclide generator eluate prior to administration will be dependent on the nature of the carrier molecule to be labelled. Refer to the Summary of Product Characteristics/package leaflet of the kit for radiopharmaceutical preparation to be radiolabelled.

Paediatric population

The European Medicines Agency has waived the obligation to submit the results of studies with GalliaPharm 1.11 – 3.70 GBq radionuclide generator in all subsets of the paediatric population as it is a radiolabelling agent. See section 4.2 for information on paediatric use.

5.2 Pharmacokinetic properties

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. Therefore, the pharmacokinetic properties of ^{68}Ga-labelled radiopharmaceuticals will depend on the nature of carrier molecules to be radiolabelled.

The absorption, distribution, and excretion of free ^{68}Ga following direct injection of gallium (^{68}Ga) chloride solution were investigated in rats. The rat study has shown that following direct intravenous administration of gallium (^{68}Ga) chloride, ^{68}Ga is slowly cleared from the blood with a biological half-life of 188 h in male and 254 h in female rats. This is because free Ga^{3+} likely behaves in a similar way as Fe^{3+}. However, as the biological half-life of ^{68}Ga is much longer than its physical half-life (67.71 min), at 188 h or 254 h almost all ^{68}Ga anyway decays to inactive ^{68}Zn. Already in 6 h approx. 97 % of the initial ^{68}Ga disappear via decay to ^{68}Zn.

In rats, ^{68}Ga was excreted predominantly into the urine, with some retention in the liver and kidneys. The organs with the highest ^{68}Ga activity, other than blood, plasma, and urine, were liver, lungs, spleen, and bones. In female rats, the ^{68}Ga activity in female genital organs, i.e., uterus and ovaries, was comparable to that seen in the lungs. ^{68}Ga activity in the testes was very low.

Extrapolating from the rat data, the estimated sex-averaged effective dose resulting from an inadvertently intravenously injected gallium (^{68}Ga) chloride would be 0.0216 mSv/MBq for an adult (see section 11 for more details).

The activity resulting from ^{68}Ge breakthrough in the rat study was extremely low and is not of clinical importance.

5.3 Preclinical safety data

The toxicological properties of ^{68}Ga-labelled radiopharmaceuticals prepared by *in vitro* radiolabelling with gallium (^{68}Ga) chloride solution will depend on the nature of the kit for radiopharmaceutical preparation to be radiolabelled.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Column matrix

Titanium dioxide

Solution for elution

Sterile ultrapure 0.1 mol/l hydrochloric acid

6.2 Incompatibilities

Radiolabelling of carrier molecules with gallium (^{68}Ga) chloride is very sensitive to the presence of trace metal impurities.

It is important that all glassware, syringe needles etc., used for the preparation of the radiolabelled medicinal product are thoroughly cleaned to ensure freedom from such trace metal impurities. Only syringe needles (for example, non-metallic) with proven resistance to dilute acids should be used to minimise trace metal impurity levels.

It is recommended not to use uncoated stoppers for the elution vial as they may contain considerable amounts of zinc that is extracted by the acidic eluate.

6.3 Shelf life

Radionuclide generator

18 months from calibration date.
The calibration date and the expiry date are stated on the label.

Gallium (^{68}Ga) chloride solution for radiolabelling

After elution, immediately use the eluate.

Sterile ultrapure hydrochloric acid solution for elution

2 years.

6.4 Special precautions for storage

Warm temperatures substantially exceeding 25 °C can reversibly reduce the yield of ^{68}Ga in the eluate to below 60 %. Therefore, to obtain optimal elution yield (> 60 %), the radionuclide generator should be operated at temperatures not exceeding 25 °C. If the radionuclide generator is routinely stored at higher temperatures, make sure to equilibrate it at < 25 °C for several hours before elution. Elutions at temperatures above 25 °C are nevertheless possible and will not harm the radionuclide generator or have an impact on the quality of the eluate except for the possibly reduced yield of ^{68}Ga.

Storage of radiopharmaceuticals should be in accordance with national regulations on radioactive materials.

6.5 Nature and contents of container and special equipment for use

The glass column consists of a borosilicate glass tube (type I) and Polyetheretherketone (PEEK) end plugs which are attached to PEEK inlet and outlet lines via HPLC-style fingertight fittings. These lines are connected to two ports that pass through the outer case of the radionuclide generator.

The column is contained within the lead shield assembly. The shield assembly is secured in a stainless-steel outer case with two handles.

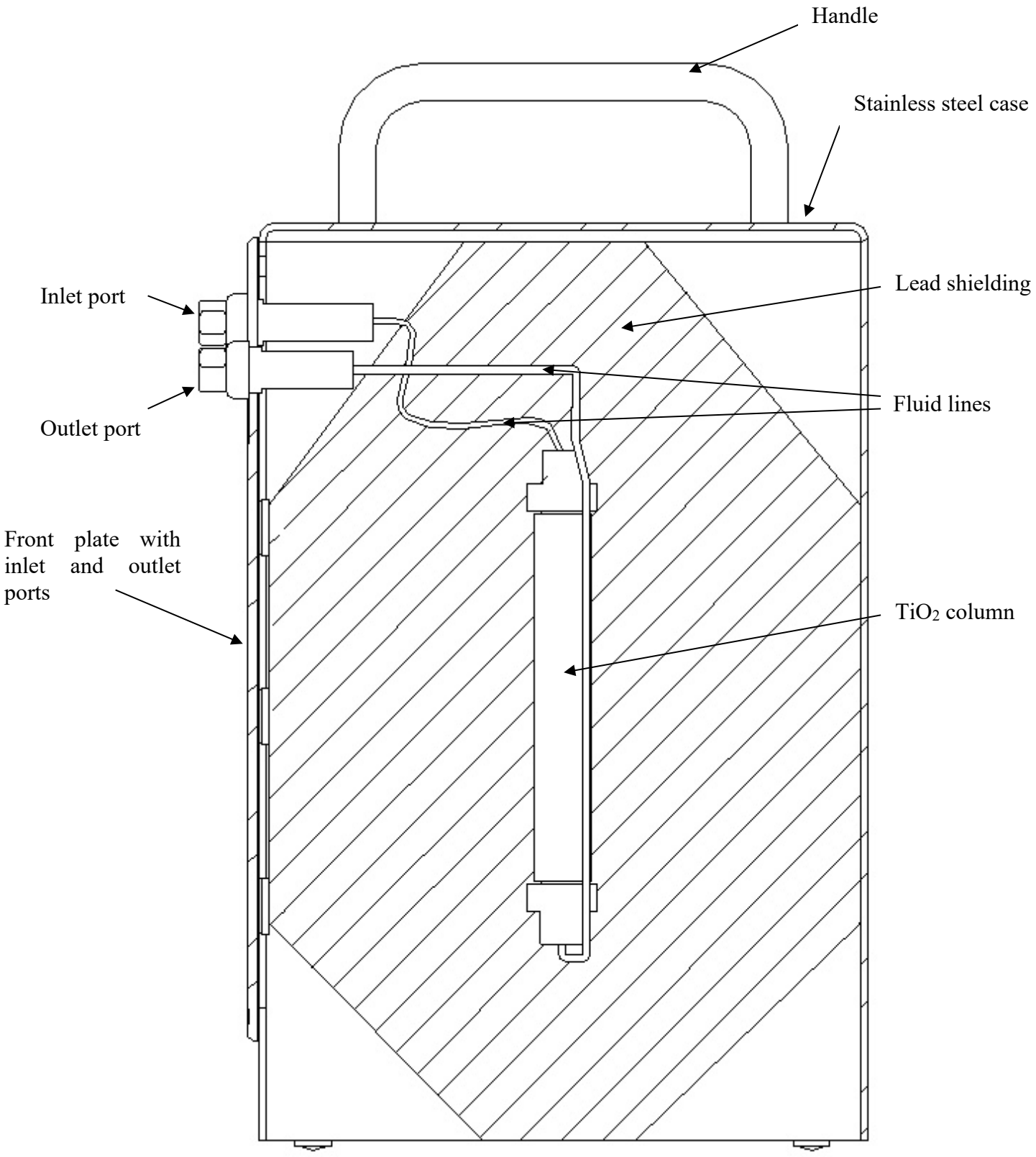
Accessories supplied with the radionuclide generator (minimum amounts):

1. 1 x PP – container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid (including a separate hanger for PP-bottles; PP = Polypropylene)
2. 1 x Vented spike (ABS = Acrylonitrile Butadiene Styrene/PE = Polyethylene)
3. 2 x Adapter 1/16" to male LUER (PEEK)
4. 2 x Tubing 60 cm (PEEK)
5. 1 x Tubing 40 cm (PEEK)
6. 1 x Tubing 20 cm (PEEK)
7. 3 x Fingertight fitting 1/16" 10-32 (PEEK)
8. 1 x Fingertight fitting 1/16" M6 (PEEK)
9. 1 x Stopcock manifold (TPX = Polymethylpentene/HDPE = High Density Polyethylene)
10. 1 x Male LUER union (PP)

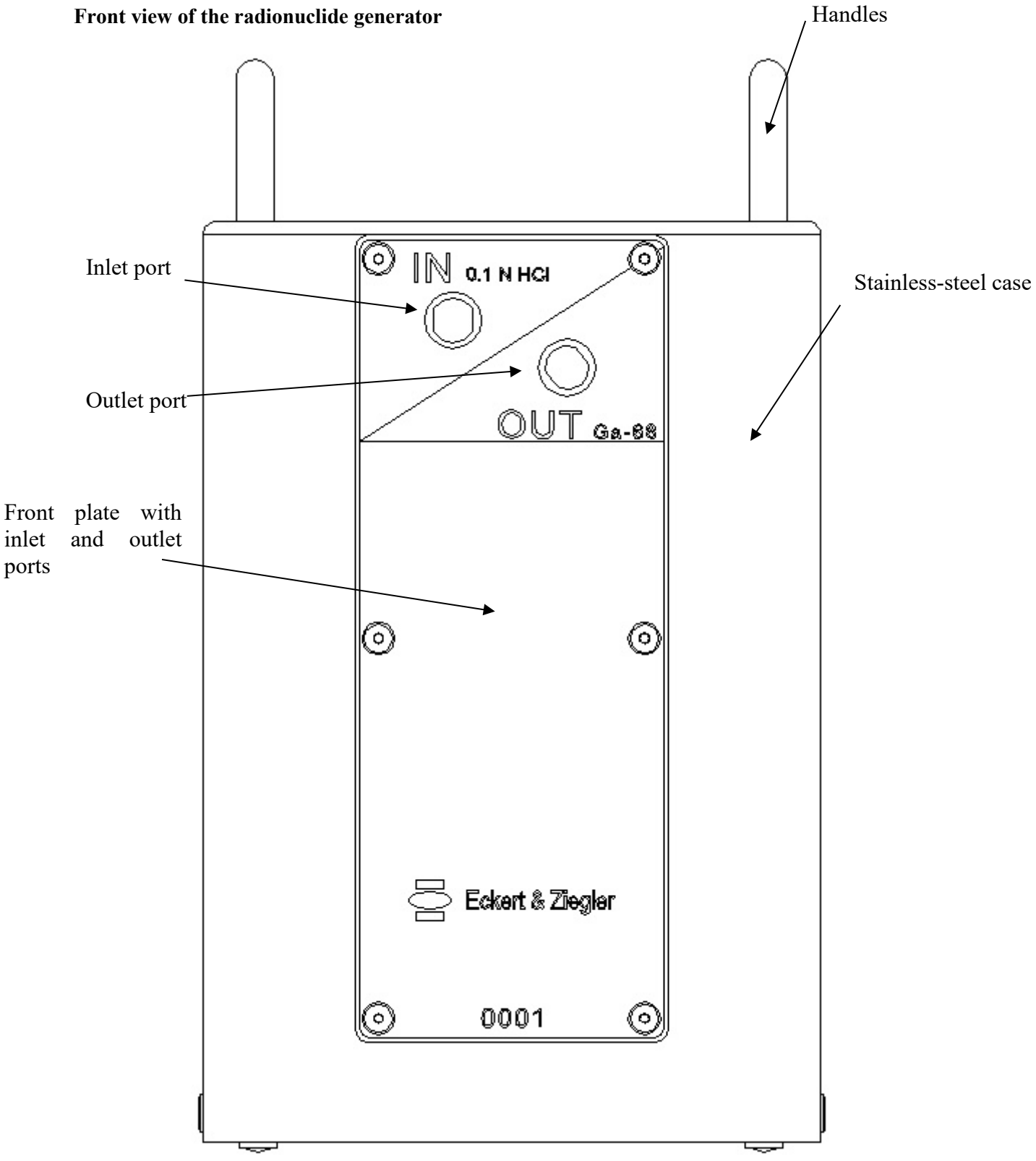
Pack sizes:

The radionuclide generators are supplied with the following ^{68}Ge activity amounts at calibration date: 1.11 GBq, 1.48 GBq, 1.85 GBq, 2.22 GBq, 2.59 GBq, 2.96 GBq, 3.33 GBq, and 3.70 GBq.

Sectional view of the radionuclide generator



Front view of the radionuclide generator



Size: 230 mm x 132 mm x 133 mm (H x W x D)

Weight: approx. 14 kg

6.6 Special precautions for disposal and other handling

General warnings

Radiopharmaceuticals should be received, used, and administered only by authorised persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licenses of the competent official organisation.

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

The radionuclide generator must not be disassembled for any reason as this may damage the internal components and possibly lead to a leak of radioactive material. Also, disassembly of the stainless-steel case will expose the lead shielding to the operator.

Administration procedures should be carried out in a way to minimise risk of contamination of the medicinal product and irradiation of the operators. Adequate shielding is mandatory.

The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spill of urine, vomiting, etc. Radiation protection precautions in accordance with national regulations must therefore be taken.

The residual activity of the radionuclide generator must be estimated before disposal.

Any unused gallium (^{68}Ga) chloride solution for radiolabelling or radiolabelled medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1836/001 - GalliaPharm 1.11 GBq radionuclide generator
EU/1/24/1836/002 - GalliaPharm 1.48 GBq radionuclide generator
EU/1/24/1836/003 - GalliaPharm 1.85 GBq radionuclide generator
EU/1/24/1836/004 - GalliaPharm 2.22 GBq radionuclide generator
EU/1/24/1836/005 - GalliaPharm 2.59 GBq radionuclide generator
EU/1/24/1836/006 - GalliaPharm 2.96 GBq radionuclide generator
EU/1/24/1836/007 - GalliaPharm 3.33 GBq radionuclide generator
EU/1/24/1836/008 - GalliaPharm 3.70 GBq radionuclide generator

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10. DATE OF REVISION OF THE TEXT

11. DOSIMETRY

The radiation dose received by the various organs following intravenous administration of a ^{68}Ga-radiolabelled medicinal product is dependent on the specific kit for radiopharmaceutical preparation being radiolabelled. Information on radiation dosimetry of each different ^{68}Ga-labelled radiopharmaceutical following its administration will be available in the Summary of Product Characteristics of the particular kit for radiopharmaceutical preparation.

The dosimetry tables 3 and 4 below are presented in order to support the assessment of the contribution by unbound ^{68}Ga to the radiation dose following the administration of ^{68}Ga-labelled radiopharmaceutical or of the radiation dose resulting from an inadvertent intravenous injection of gallium (^{68}Ga) chloride solution.

The dosimetry estimates were based on a rat distribution study. Time points for measurements were 5 minutes, 30 minutes, 60 minutes, 120 minutes, and 180 minutes.

The effective radiation dose of ^{68}Ga for an adult is 0.0216 mSv/MBq, resulting in an approximate effective radiation dose of 5.6 mSv from an accidental intravenously injected activity of 259 MBq.

Table 3: Absorbed dose per unit activity administered - inadvertent administration of the eluate - gallium (^{68}Ga) chloride - in women

Absorbed dose per administered unit of activity (mGy/MBq)						
Organ	**Adult[1] (60 kg)**	**15 years[2] (50 kg)**	**10 years[2] (30 kg)**	**5 years[2] (17 kg)**	**1 year[2] (10 kg)**	**Newborn[2] (5 kg)**
Adipose/residual tissue	0.0121	0.0199	0.0327	0.0531	0.1050	0.2680
Adrenals	0.0398	0.0304	0.0440	0.0618	0.0959	0.1020
Bone marrow	0.0299	0.0202	0.0331	0.0606	0.1540	0.6050
Bone surface	0.0169	ND	ND	ND	ND	ND
Brain	0.0081	0.0048	0.0061	0.0081	0.0126	0.0282
Colon wall	0.0210	0.0224	0.0373	0.0609	0.1170	0.2930
Heart wall	0.0838	0.0263	0.0407	0.0639	0.1150	0.2280
Kidneys	0.0424	0.0333	0.0474	0.0712	0.1280	0.3250
Liver	0.0640	0.0598	0.0906	0.1360	0.2630	0.6080
Lungs	0.0552	0.0497	0.0708	0.1090	0.2160	0.5840
Muscle	0.0131	0.0131	0.0248	0.0698	0.1370	0.1950
Osteogenic cells	0.0567[2]	0.0558	0.0869	0.1420	0.3310	1.0100
Ovaries	0.0372	0.0332	0.0944	0.1650	0.3720	0.7550
Pancreas	0.0309	0.0276	0.0533	0.0704	0.1490	0.4730
Salivary glands	0.0194	ND	ND	ND	ND	ND
Skin	0.0115	0.0115	0.0189	0.0311	0.0612	0.1570
Small intestine wall	0.0256	0.0273	0.0459	0.0749	0.1460	0.3630
Spleen	0.0407	0.0263	0.0403	0.0642	0.1180	0.3030
Stomach wall	0.0284	0.0188	0.0293	0.0482	0.0939	0.2540
Thymus	0.0129	0.0094	0.0115	0.0157	0.0261	0.0518
Thyroid	0.0265	0.0282	0.0434	0.0923	0.1730	0.2490
Urinary bladder wall[4]	0.0174	0.0155	0.0251	0.0419	0.0770	0.2000
Uterus/cervix	0.0291	0.0325	0.4560	0.6900	1.2500	0.5360
Effective dose (mSv/MBq)	0.0216[3]					

ND = not determined as organ/tissue not available in OLINDA/EXM v1.0.

[1] calculations made in IDAC-Dose 2.1 v1.01 software.

[2] calculations made in OLINDA v1.0 software.

[3] sex-averaged dose derived according to ICRP Publication 103.

[4] Due to the methodological limitations of the underlying distribution study in rats, it was not feasible to consider urinary bladder content as an explicit source region for the dosimetry. Since gallium (^{68}Ga) chloride is excreted predominantly into the urine according to the rat data, the reported effective dose is thus possibly underestimated.

Table 4: Absorbed dose per unit activity administered – inadvertent administration of the eluate - gallium (^{68}Ga) chloride - in men

Absorbed dose per administered unit of activity (mGy/MBq)						
Organ	**Adult[1] (73 kg)**	**15 years[2] (50 kg)**	**10 years[2] (30 kg)**	**5 years[2] (17 kg)**	**1 year[2] (10 kg)**	**Newborn[2] (5 kg)**
Adipose/residual tissue	0.0065	0.0128	0.0210	0.0341	0.0672	0.1720
Adrenals	0.0189	0.0200	0.0289	0.0405	0.0628	0.0669
Bone marrow	0.0124	0.0149	0.0244	0.0454	0.1120	0.4180
Bone surface	0.0079	ND	ND	ND	ND	ND
Brain	0.0046	0.0034	0.0043	0.0056	0.0088	0.0196
Colon wall	0.0121	0.0162	0.0274	0.0449	0.0865	0.2150
Heart wall	0.0335	0.0195	0.0303	0.0478	0.0858	0.1710
Kidneys	0.0221	0.0239	0.0340	0.0510	0.0915	0.2340
Liver	0.0307	0.0388	0.0588	0.0881	0.1700	0.3940
Lungs	0.0262	0.0327	0.0466	0.0718	0.1420	0.3850
Muscle	0.0072	0.0111	0.0219	0.0658	0.1300	0.1800
Osteogenic cells	0.0308[2]	0.0402	0.0633	0.1050	0.2440	0.7550
Pancreas	0.0167	0.0211	0.0412	0.0540	0.1150	0.3720
Salivary glands	0.0132	ND	ND	ND	ND	ND
Skin	0.0073	0.0063	0.0102	0.0166	0.0326	0.0828
Small intestine wall	0.0126	0.0167	0.0282	0.0460	0.0892	0.2220
Spleen	0.0238	0.0259	0.0400	0.0634	0.1170	0.3060
Stomach wall	0.0145	0.0116	0.0179	0.0295	0.0573	0.1570
Testes	0.0098	0.0182	0.1210	0.1410	0.1910	0.2770
Thymus	0.0092	0.0082	0.0093	0.0122	0.0193	0.0384
Thyroid	0.0163	0.0248	0.0383	0.0825	0.1550	0.2200
Urinary bladder wall[4]	0.0116	0.0095	0.0151	0.0252	0.0458	0.1190
Small intestine wall	0.0126	0.0167	0.0282	0.0460	0.0892	0.2220
Effective dose (mSv/MBq)	0.0216[3]					

ND = not determined as organ/tissue not available in OLINDA/EXM v1.0.

[1] calculations made in IDAC-Dose 2.1 v1.01 software.

[2] calculations made in OLINDA v1.0 software.

[3] sex-averaged dose derived according to ICRP Publication 103.

[4] Due to the methodological limitations of the underlying distribution study in rats, it was not feasible to consider urinary bladder content as an explicit source region for the dosimetry. Since gallium (^{68}Ga) chloride is excreted predominantly into the urine according to the rat data, the reported effective dose is thus possibly underestimated.

External radiation exposure

The average surface or contact radiation for the radionuclide generator is less than 0.14 µSv/h per MBq of ^{68}Ge, but local hot spots of higher radiation can occur. Nevertheless, a 3.70 GBq radionuclide generator will reach an overall average surface dose rate of approx. 518 µSv/h. It is generally recommended that the radionuclide generator is stored within auxiliary shielding to minimise dose to operating personnel.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Elution of the radionuclide generator must be performed in premises complying with the national regulations concerning the safety of use of radioactive products.

The general handling, the attachment of tubing, the exchange of the sterile ultrapure 0.1 mol/l hydrochloric acid container, the elution of the generator and other activities potentially exposing the generator to the environment should be undertaken using aseptic techniques in an appropriate clean environment according to current national legislation.

Preparation

Unpacking of the radionuclide generator:

1. Check outer shipping package for shipping damage. If damaged, perform radiation wipe survey of the damaged area. If counts exceed 40 counts per second per 100 cm^2, notify your Radiation Safety Officer.

2. Cut security seal on top of shipping package. Remove the inner foam support from the shipping package. Separate the foam elements carefully.

3. Carefully remove radionuclide generator.

   CAUTION: Drop hazard: The radionuclide generator weighs approx. 14 kg. Handle with care to avoid potential injuries. If radionuclide generator is dropped or if shipping damage extends into the shipping package, check for leaks and perform a wipe survey of the radionuclide generator. Also check for internal damage by slowly tilting the radionuclide generator 90°. Listen for broken/loose parts.

4. Perform wipe survey of shipping package inserts and radionuclide generator outer surface. If wipes exceed 40 counts per second per 100 cm^2, notify your Radiation Safety Officer.

5. Check sealed inlet and outlet ports for damage. Do not remove the port plugs before the elution lines are prepared and ready for installation.

Optimal positioning:

1. When installing the radionuclide generator in its final position, i.e., with a synthesis device or for manual elutions, it is recommended to keep the outlet line as short as possible as the length of this tubing may influence the yield in the receiving/reaction vial. For this reason, the radionuclide generator is supplied with three different lengths of tubing to choose the appropriate length.

2. Local auxiliary shielding is recommended when positioning the radionuclide generator.

Please note: Moving the radionuclide generator after installation in its final position should be avoided.

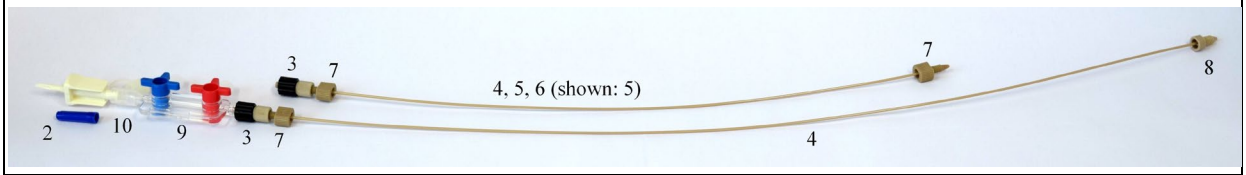
Assembly of the radionuclide generator:

Accessories supplied with the radionuclide generator (minimum amounts):

1. 1 x PP – container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid (including a separate hanger for PP-bottles; PP = Polypropylene)
2. 1 x Vented spike (ABS = Acrylonitrile Butadiene Styrene/PE = Polyethylene).
3. 2 x Adapter 1/16" to male LUER (PEEK)
4. 2 x Tubing 60 cm (PEEK)
5. 1 x Tubing 40 cm (PEEK)
6. 1 x Tubing 20 cm (PEEK)
7. 3 x Fingertight fitting 1/16" 10-32 (PEEK)
8. 1 x Fingertight fitting 1/16" M6 (PEEK)
9. 1 x Stopcock manifold (TPX = Polymethylpentene/HDPE = High Density Polyethylene)
10. 1 x Male LUER union (PP)

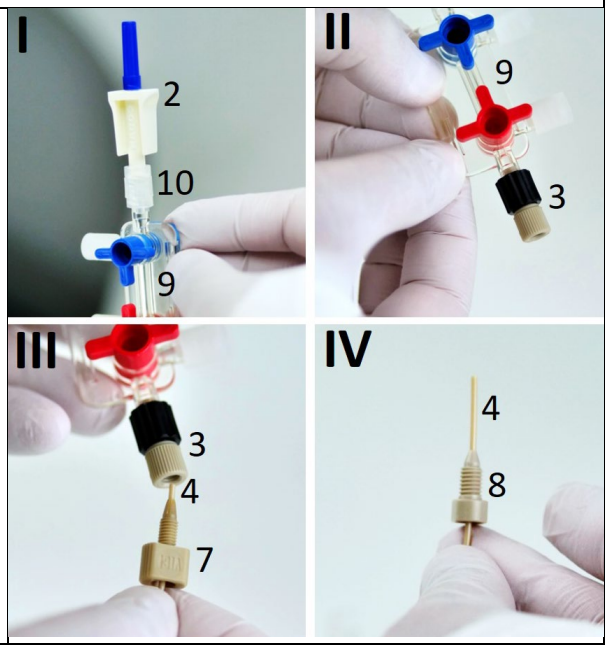
Assemble the radionuclide generator in an appropriately clean environment. Aseptic working technique must be maintained during the whole assembly process. Wear gloves during preparation and connecting of the lines to the radionuclide generator and to the eluent container. This is critical for the maintenance of sterility.

Picture of assembled elution accessories before connection to the radionuclide generator (The indicated identification numbers of accessories are as presented in the list above. They are also used accordingly in the pictures and assembly instructions following below.):



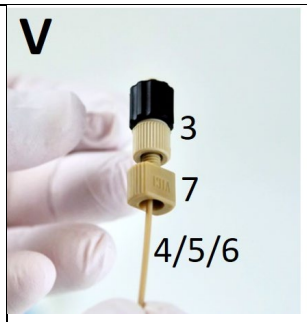
1. Assembling the inlet line:

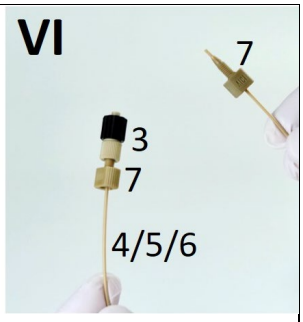
Please note: the inlet port has a customised thread to avoid misconnection. Only the special fingertight fitting 1/16" M6 will fit into this port. For assembling the inlet line, connect the vented spike (2) to one end of the stopcock manifold (9) using the male LUER union (10) **[I]**. On the other end of the stopcock manifold (9) connect the adapter 1/16" to male LUER (3) **[II]**. Attach one of the 60 cm long PEEK tubing (4) with a 1/16" 10-32 fingertight fitting (7) **[III]**. Put the special 1/16" M6 fingertight fitting (8) on the other end of the line, <u>but do not connect yet</u> **[IV]**.



2. Assembling the outlet line:

For the outlet line, choose the appropriate length of tubing (20 cm, 40 cm, or 60 cm) based on your local setting. Use the shortest line possible. Attach the chosen PEEK line (4,5 or 6) to the second adapter 1/16" to male LUER (3) using a 1/16" 10-32 fingertight fitting (7) **[V]**. Put the third 1/16" 10-32 fingertight fitting (7) on the other end of the prepared outlet line, but do not connect yet **[VI]**.



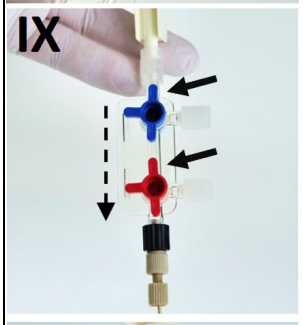


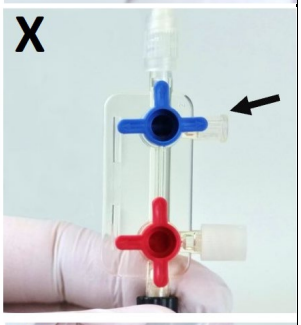
3. Connecting the hydrochloric acid container to the inlet line:

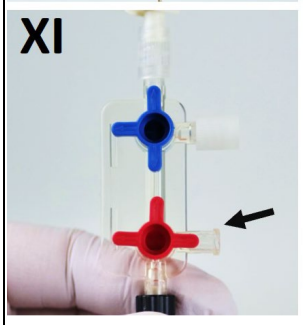
Hang the PP - container with the 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid solution close to the inlet port above the radionuclide generator.
The valves of the stopcock manifold have a T-type flow pattern with three openings inside - one in each direction of the external prongs. Turn the valves at the stopcock manifold in the appropriate direction (3-6-9 clock position ⊤) so that no liquid can enter through the spike **[VII].** Remove the lid of the vented spike and push the vented spike into the PP - container connection **[VIII]**.

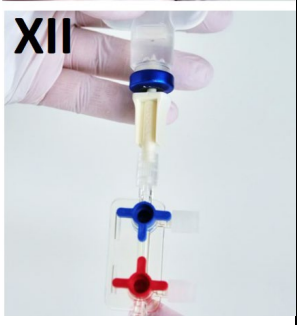
Now the air must be removed from the stopcock manifold and the attached inlet line. Be aware, that hydrochloric acid will thereby flow through and may drip out of the line and the side ports. Be prepared to remove the drops immediately.

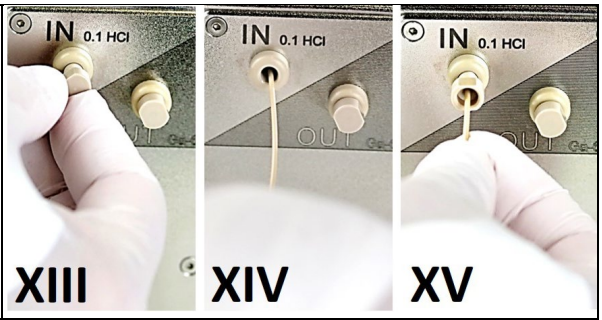
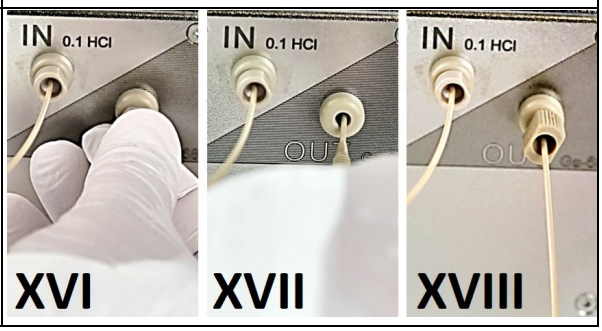
To remove the air, start by turning both valves of the stopcock manifold as shown in the picture **[IX]** (the prongs of both valves should be in the 6-9-12 clock position ┤). This will fill the inlet line with liquid and push the air out of it. Then turn the upper valve into the 9-12-3 clock position ⊥ and remove the cap of the upper side port to remove the air **[X]**. Afterwards, close the upper side port again with the cap. Now turn the upper valve back into the 6-9-12 clock position ┤ . Turn the lower valve into the 9-12-3 clock position ⊥ and remove the cap of the lower side port to remove the air **[XI]**. Close the lower side port again with the cap. Finally, place the upper valve into the 3-6-9 clock position ⊤ to stop flow of the liquid from the hydrochloric acid container **[XII]**.









4. Connecting the inlet line to the port of the radionuclide generator: Remove the plug from the inlet port of the radionuclide generator **[XIII].** To connect prepared and filled inlet line using the 1/16" M6 fingertight fitting, push the line into the inlet port **[XIV]** and screw in the fingertight fitting **[XV]**. Avoid hard bending or pinching of the line.	
5. Connecting the outlet line to the port of the radionuclide generator: Remove plug from the outlet port of the radionuclide generator **[XVI]**. To connect prepared outlet line using the 1/16" 10-32 fingertight fitting, push the line into the outlet port **[XVII]** and screw in the fingertight fitting **[XVIII]**. Avoid hard bending or pinching of the line.	

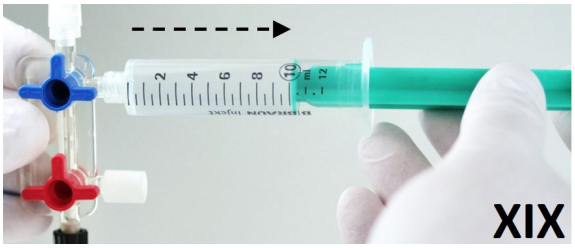
The radionuclide generator is now ready for the first elution:

Please note: The radionuclide generator is designed not to drain itself, when no lines are connected to the inlet and outlet ports, but it is not recommended to leave the ports open at any time.
When the container with the sterile ultrapure 0.1 mol/l hydrochloric acid is connected and the fluid path is open, the radionuclide generator will be eluted by gravity. Therefore, it is necessary to keep the inlet and outlet lines as well as the positions of the stopcock valves under control.

First manual elution:

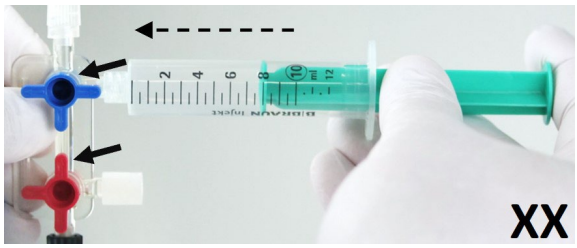
1. Prepare additional necessary materials:
   - Personal protective equipment: elutions should be performed while wearing eye and hand protection, and appropriate laboratory cloth.
   - Sterile syringe with 10 ml volume (avoid syringes with rubber plunger, preferably use two-piece syringes).
   - Shielded receiving vial or vessel with 10 ml or larger volume. Avoid uncoated stoppers as they may contain considerable amounts of zinc that is extracted by the acidic eluate.

2. Attach the syringe to the upper side port of the stopcock manifold and fill with 10 ml of sterile ultrapure 0.1 mol/l hydrochloric acid from the PP - container by turning the valve into the shown position, then moving the plunger of the syringe in the indicated direction while avoiding any air inside the syringe **[XIX]**.



3. Connect the shielded receiving vessel to the outlet line using the appropriate connector. The vessel must have sufficient capacity to accept the eluate volume. Avoid using metal syringe needles for connection.

4. Turn both valves of stopcock manifold towards the inlet port of the radionuclide generator. Push the 10 ml sterile ultrapure 0.1 mol/l hydrochloric acid at a flow rate not greater than 2 ml/minute **[XX]**. Eluting at a faster flow rate may reduce the shelf-life of the radionuclide generator. Five millilitres of eluent will fully elute the radionuclide generator, but for the first elution it is recommended to use 10 ml. If high resistance is encountered, do not force solution into radionuclide generator. If a peristaltic pump is used for elution, it should be set to a flow rate of not more than 2 ml/minute. The user should also verify that eluent is flowing without unusual resistance. If high resistance is noticed, discontinue elution.



CAUTION:
Be sure to introduce eluent through the inlet port; do not elute the radionuclide generator in reverse direction.
Elution efficiency (^{68}Ga yield) may be reduced if air is introduced into the radionuclide generator column.

5. Collect eluate in shielded receiving vessel and measure solution with a calibrated dose calibrator to determine the yield. If less than 5 ml of eluate have been collected, measurement may not represent the total potential yield of radionuclide generator. Please decay correct the measured activity to the starting time of the elution. For optimal yield of the radionuclide generator in its final position it is recommended to determine the elution peak by collecting small fractions of 0.5 ml.

6. The first eluate should be discarded due to the potential ^{68}Ge breakthrough in this eluate.

It is recommended to test the eluate for ^{68}Ge breakthrough after the first elutions by comparing the activity level of the ^{68}Ga and the ^{68}Ge. For further details please refer to Ph. Eur. monograph 2464.

Routine elution:

CAUTION:
Free ^{68}Ge ions can accumulate in the column over time. If the radionuclide generator has not been used for a period of 96 hours or more, the column should be pre-eluted once, at least 7 hours prior to eluting for radiolabelling. If the radiolabelling procedure does not require maximum achievable eluate activity, the time between the pre-elution and the elution for radiolabelling can be reduced (see also table 6 and calculation example below it). The pre-elution should be done using 10 ml of sterile ultrapure 0.1 mol/l hydrochloric acid.

1. Repeat the steps of the first elution but use only 5 ml eluent for the routine elution. The radionuclide generator is designed to elute all of the available ^{68}Ga activity in a volume of 5 ml.

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

3. It is recommended to test the eluate for ^{68}Ge breakthrough during routine elutions by comparing the activity level of the ^{68}Ga and the ^{68}Ge. For further details please refer to Ph. Eur. monograph 2464.

CAUTION:
If fluid leaks are observed at any time, immediately stop eluting and attempt to contain the leaking fluid.

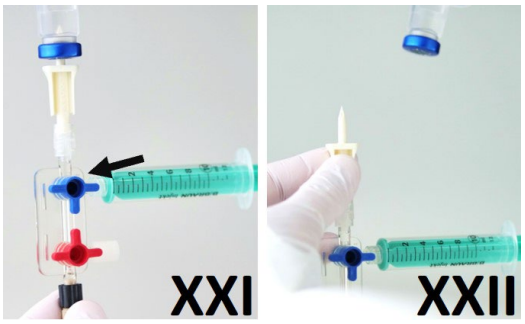
The radionuclide generator is supplied with 250 ml of sterile ultrapure 0.1 mol/l hydrochloric acid. This amount is usually sufficient for at least 40 elutions. The radionuclide generator should only be eluted with sterile ultrapure 0.1 mol/l hydrochloric acid supplied by the marketing authorisation holder. Additional containers may be purchased as consumables from the marketing authorisation holder only.

Exchange of sterile ultrapure 0.1 mol/l hydrochloric acid container:

CAUTION:
Aseptic technique is critical for maintenance of sterility and must be used during the exchange procedure.

1. When the sterile ultrapure 0.1 mol/l hydrochloric acid is almost consumed, the empty container can be replaced by a new sterile ultrapure 0.1 mol/l hydrochloric acid container.

   CAUTION:
   No air should enter the radionuclide generator. Before disconnecting the empty container, close all valves at the stopcock manifold and cap the side ports so that no air can enter into the manifold and spike **[XXI]**. Disconnect the container from the vented spike **[XXII]**. It is recommended to replace the vented spike with the new sterile vented spike supplied with each new sterile ultrapure 0.1 mol/l hydrochloric acid container.



2. Hang the new container with the 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid close to the inlet port above the radionuclide generator.

3. Push the connected vented spike into the container stopper; carefully check for air bubbles and slowly remove all air from the stopcock manifold using the valves. It is not necessary to detach the attached inlet line from the radionuclide generator or from the stopcock manifold. Entering of air into the radionuclide generator should be avoided.

4. When stopcock manifold is filled, close valves to stop flow. The radionuclide generator is now ready for elution again.

Radionuclide generator elution yield:

The activity stated on the label of the radionuclide generator is expressed in ^{68}Ge available at the calibration date (12:00 CET). The available ^{68}Ga activity depends on the ^{68}Ge activity at the time of elution and the elapsed time since the previous elution.

A radionuclide generator in full equilibrium yields more than 60 % of ^{68}Ga using an elution volume of 5 ml sterile ultrapure 0.1 mol/l hydrochloric acid.

The output will decrease with decay of the parent nuclide ^{68}Ge over time. For example, after 9 months' decay (39 weeks), the ^{68}Ge will be reduced by 50 % (see table 5). To calculate the current ^{68}Ge activity, multiply the ^{68}Ge activity at calibration date with the respective decay factor of the corresponding elapsed time in weeks.

Table 5: Decay Chart for ^{68}Ge

Elapsed Time in weeks	**Decay Factor**	**Elapsed Time 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

After elution, the ^{68}Ga will be built up by the continuous decay of the parent ^{68}Ge. The radionuclide generator requires at least 7 hours to achieve almost full yield after being eluted, but in practice it is also possible to elute the radionuclide generator earlier, depending on its strength and the activity required for radiolabelling. Table 6 shows the build-up factor of ^{68}Ga activity over time, up to 410 minutes after an elution.

Table 6: Build-up factors of ^{68}Ga

Elapsed Time in minutes	Build-Up Factor	Elapsed Time in minutes	Build-Up Factor
0	0.00	**210**	0.88
10	0.10	**220**	0.89
20	0.19	**230**	0.91
30	0.26	**240**	0.91
40	0.34	**250**	0.92
50	0.40	**260**	0.93
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

Calculation examples
A 1.85 GBq radionuclide generator is 12 weeks old. According to table 5, the activity of ^{68}Ge on the column can be calculated as follows:

1.85 GBq × 0.81 = 1.50 GBq

In full equilibrium, the activity of ^{68}Ga on the column is also 1.50 GBq.

The radionuclide generator is eluted and the collected ^{68}Ga activity is 1.05 GBq which corresponds to a yield of 70 %.

The same radionuclide generator is eluted 4 hours later. The 7 hours needed to reach the ^{68}Ge/^{68}Ga-equilibrium have not elapsed yet. The ^{68}Ga activity built up on the column in 4 hours (240 minutes) post-elution can be calculated according to table 6 as follows:

1.50 GBq × 0.91 = 1.37 GBq

With a typical yield of 70 % ^{68}Ga, the collected activity would then be:

1.37 GBq × 0.70 = 1.00 GBq

Note:
The activity of ^{68}Ga in the eluate can be measured to check the quality with regard to identity and content. The activity should be measured immediately after elution but may also be measured up to 5 half-life periods after elution.

Due to the short half-time of ^{68}Ga (67.71 minutes), the elapsed time between the elution and the measurement of the activity has to be decay-corrected to determine the actual yield at the elution time with the decay chart of ^{68}Ga, table 7.

Calculation Example
A new 1.85 GBq radionuclide generator is eluted. The activity of ^{68}Ga measured 10 minutes after the elution was 1.17 GBq.

The yield at the time of the elution can be obtained by dividing the measured activity by the corresponding decay factor of the elapsed time stated in table 7:
1.17 GBq / 0.90 = 1.30 GBq

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

Table 7: Decay chart of ^{68}Ga

Elapsed Time in minutes	Decay Factor	Elapsed Time in minutes	Decay Factor
1	0.99	**35**	0.70
2	0.98	**36**	0.69
3	0.97	**37**	0.69
4	0.96	**38**	0.68
5	0.95	**39**	0.67
6	0.94	**40**	0.67
7	0.93	**41**	0.66
8	0.92	**42**	0.65
9	0.91	**43**	0.65
10	0.90	**44**	0.64
11	0.89	**45**	0.63
12	0.89	**46**	0.63
13	0.88	**47**	0.62
14	0.87	**48**	0.61
15	0.87	**49**	0.61
16	0.85	**50**	0.60
17	0.84	**51**	0.60
18	0.83	**52**	0.59
19	0.82	**53**	0.58
20	0.82	**54**	0.58
21	0.82	**55**	0.57
22	0.80	**56**	0.57
23	0.79	**57**	0.56
24	0.78	**58**	0.55
25	0.78	**59**	0.55
26	0.77	**60**	0.54
27	0.76	**61**	0.54
28	0.75	**62**	0.53
29	0.74	**63**	0.53
30	0.74	**64**	0.52
31	0.73	**65**	0.52
32	0.72	**66**	0.51
33	0.71	**67**	0.51
34	0.71	**68**	0.50

Quality control

If possible, clarity of the solution, pH and the radioactivity should be checked before radiolabelling.

^{68}Ge breakthrough

A small amount of ^{68}Ge is washed from the radionuclide generator column with each elution. ^{68}Ge breakthrough is expressed as a percentage of total ^{68}Ga activity eluted from the column, corrected for decay, and does not exceed 0.001 % of the eluted ^{68}Ga activity. ^{68}Ge breakthrough can, however, increase above 0.001 % if the radionuclide generator is not eluted for several days. Therefore, if the radionuclide generator has not been eluted for 96 hours or more, it should be pre-eluted with 10 ml of sterile ultrapure 0.1 mol/l hydrochloric acid at least 7 hours prior to the intended use (the time between the pre-elution and the elution for radiolabelling can be reduced if the intended radiolabelling procedure does not require maximum achievable eluate activity). When this instruction is followed, the ^{68}Ge breakthrough should constantly stay below 0.001 % in eluates obtained for radiolabelling. For testing the ^{68}Ge breakthrough, the activity levels of ^{68}Ga and ^{68}Ge in the eluate should be compared. For further details please refer to Ph. Eur. monograph 2464.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Detailed information on this medicinal product available on the website of the European Medicines Agency http://www.ema.europa.eu.

ANNEX II

A. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) responsible for batch release

Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

RADIONUCLIDE GENERATOR

1. NAME OF THE MEDICINAL PRODUCT

GalliaPharm 1.11 GBq radionuclide generator

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride 1.11 GBq

3. LIST OF EXCIPIENTS

Column matrix: Titanium dioxide

Solution for elution: Sterile ultrapure 0.1 mol/l hydrochloric acid

4. PHARMACEUTICAL FORM AND CONTENTS

Radionuclide generator.

Germanium (^{68}Ge) activity at calibration date: {X.XX}

Elutable gallium (^{68}Ga) activity: > 60 % at equilibrium

Calibration date: {DD/MM/YYYY} (12:00 CET)

1. 1 x Container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid
2. 1 x Vented spike
3. 2 x Adapter 1/16" to male LUER
4. 2 x Tubing 60 cm
5. 1 x Tubing 40 cm
6. 1 x Tubing 20 cm
7. 3 x Fingertight fitting 1/16" 10-32
8. 1 x Fingertight fitting 1/16" M6
9. 1 x Stopcock manifold
10. 1 x Male LUER union

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For *in vitro* radiolabelling.

Not intended for direct use in patients.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Radiopharmaceutical

8. EXPIRY DATE

EXP {DD/MM/YYYY}

After elution, use eluate immediately.

9. SPECIAL STORAGE CONDITIONS

Do not dismantle the stainless-steel case.

Storage should be in accordance with national regulations for radioactive materials.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Read the package leaflet for instructions for use, handling, and disposal.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1836/001

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

RADIONUCLIDE GENERATOR

1. NAME OF THE MEDICINAL PRODUCT

GalliaPharm 1.48 GBq radionuclide generator

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride 1.48 GBq

3. LIST OF EXCIPIENTS

Column matrix: Titanium dioxide

Solution for elution: Sterile ultrapure 0.1 mol/l hydrochloric acid

4. PHARMACEUTICAL FORM AND CONTENTS

Radionuclide generator.

Germanium (^{68}Ge) activity at calibration date: {X.XX}

Elutable gallium (^{68}Ga) activity: > 60 % at equilibrium

Calibration date: {DD/MM/YYYY} (12:00 CET)

1. 1 x Container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid
2. 1 x Vented spike
3. 2 x Adapter 1/16" to male LUER
4. 2 x Tubing 60 cm
5. 1 x Tubing 40 cm
6. 1 x Tubing 20 cm
7. 3 x Fingertight fitting 1/16" 10-32
8. 1 x Fingertight fitting 1/16" M6
9. 1 x Stopcock manifold
10. 1 x Male LUER union

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For *in vitro* radiolabelling.

Not intended for direct use in patients.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Radiopharmaceutical

8. EXPIRY DATE

EXP {DD/MM/YYYY}

After elution, use eluate immediately.

9. SPECIAL STORAGE CONDITIONS

Do not dismantle the stainless-steel case.

Storage should be in accordance with national regulations for radioactive materials.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Read the package leaflet for instructions for use, handling, and disposal.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1836/002

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

RADIONUCLIDE GENERATOR

1. NAME OF THE MEDICINAL PRODUCT

GalliaPharm 1.85 GBq radionuclide generator

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride 1.85 GBq

3. LIST OF EXCIPIENTS

Column matrix: Titanium dioxide

Solution for elution: Sterile ultrapure 0.1 mol/l hydrochloric acid

4. PHARMACEUTICAL FORM AND CONTENTS

Radionuclide generator.

Germanium (^{68}Ge) activity at calibration date: {X.XX}

Elutable gallium (^{68}Ga) activity: > 60 % at equilibrium

Calibration date: {DD/MM/YYYY} (12:00 CET)

1. 1 x Container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid
2. 1 x Vented spike
3. 2 x Adapter 1/16" to male LUER
4. 2 x Tubing 60 cm
5. 1 x Tubing 40 cm
6. 1 x Tubing 20 cm
7. 3 x Fingertight fitting 1/16" 10-32
8. 1 x Fingertight fitting 1/16" M6
9. 1 x Stopcock manifold
10. 1 x Male LUER union

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For *in vitro* radiolabelling.

Not intended for direct use in patients.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Radiopharmaceutical

8. EXPIRY DATE

EXP {DD/MM/YYYY}

After elution, use eluate immediately.

9. SPECIAL STORAGE CONDITIONS

Do not dismantle the stainless-steel case.

Storage should be in accordance with national regulations for radioactive materials.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Read the package leaflet for instructions for use, handling, and disposal.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1836/003

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

RADIONUCLIDE GENERATOR

1. NAME OF THE MEDICINAL PRODUCT

GalliaPharm 2.22 GBq radionuclide generator

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride 2.22 GBq

3. LIST OF EXCIPIENTS

Column matrix: Titanium dioxide

Solution for elution: Sterile ultrapure 0.1 mol/l hydrochloric acid

4. PHARMACEUTICAL FORM AND CONTENTS

Radionuclide generator.

Germanium (^{68}Ge) activity at calibration date: {X.XX}

Elutable gallium (^{68}Ga) activity: > 60 % at equilibrium

Calibration date: {DD/MM/YYYY} (12:00 CET)

1. 1 x Container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid
2. 1 x Vented spike
3. 2 x Adapter 1/16" to male LUER
4. 2 x Tubing 60 cm
5. 1 x Tubing 40 cm
6. 1 x Tubing 20 cm
7. 3 x Fingertight fitting 1/16" 10-32
8. 1 x Fingertight fitting 1/16" M6
9. 1 x Stopcock manifold
10. 1 x Male LUER union

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For *in vitro* radiolabelling.

Not intended for direct use in patients.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Radiopharmaceutical

8. EXPIRY DATE

EXP {DD/MM/YYYY}

After elution, use eluate immediately.

9. SPECIAL STORAGE CONDITIONS

Do not dismantle the stainless-steel case.

Storage should be in accordance with national regulations for radioactive materials.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Read the package leaflet for instructions for use, handling, and disposal.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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Robert-Rössle-Str. 10
13125 Berlin
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1836/004

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

RADIONUCLIDE GENERATOR

1. NAME OF THE MEDICINAL PRODUCT

GalliaPharm 2.59 GBq radionuclide generator

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride 2.59 GBq

3. LIST OF EXCIPIENTS

Column matrix: Titanium dioxide

Solution for elution: Sterile ultrapure 0.1 mol/l hydrochloric acid

4. PHARMACEUTICAL FORM AND CONTENTS

Radionuclide generator.

Germanium (^{68}Ge) activity at calibration date: {X.XX}

Elutable gallium (^{68}Ga) activity: > 60 % at equilibrium

Calibration date: {DD/MM/YYYY} (12:00 CET)

1. 1 x Container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid
2. 1 x Vented spike
3. 2 x Adapter 1/16" to male LUER
4. 2 x Tubing 60 cm
5. 1 x Tubing 40 cm
6. 1 x Tubing 20 cm
7. 3 x Fingertight fitting 1/16" 10-32
8. 1 x Fingertight fitting 1/16" M6
9. 1 x Stopcock manifold
10. 1 x Male LUER union

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For *in vitro* radiolabelling.

Not intended for direct use in patients.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Radiopharmaceutical

8. EXPIRY DATE

EXP {DD/MM/YYYY}

After elution, use eluate immediately.

9. SPECIAL STORAGE CONDITIONS

Do not dismantle the stainless-steel case.

Storage should be in accordance with national regulations for radioactive materials.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Read the package leaflet for instructions for use, handling, and disposal.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1836/005

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

RADIONUCLIDE GENERATOR

1. NAME OF THE MEDICINAL PRODUCT

GalliaPharm 2.96 GBq radionuclide generator

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride 2.96 GBq

3. LIST OF EXCIPIENTS

Column matrix: Titanium dioxide

Solution for elution: Sterile ultrapure 0.1 mol/l hydrochloric acid

4. PHARMACEUTICAL FORM AND CONTENTS

Radionuclide generator.

Germanium (^{68}Ge) activity at calibration date: {X.XX}

Elutable gallium (^{68}Ga) activity: > 60 % at equilibrium

Calibration date: {DD/MM/YYYY} (12:00 CET)

1. 1 x Container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid
2. 1 x Vented spike
3. 2 x Adapter 1/16" to male LUER
4. 2 x Tubing 60 cm
5. 1 x Tubing 40 cm
6. 1 x Tubing 20 cm
7. 3 x Fingertight fitting 1/16" 10-32
8. 1 x Fingertight fitting 1/16" M6
9. 1 x Stopcock manifold
10. 1 x Male LUER union

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For *in vitro* radiolabelling.

Not intended for direct use in patients.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Radiopharmaceutical

8. EXPIRY DATE

EXP {DD/MM/YYYY}

After elution, use eluate immediately.

9. SPECIAL STORAGE CONDITIONS

Do not dismantle the stainless-steel case.

Storage should be in accordance with national regulations for radioactive materials.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Read the package leaflet for instructions for use, handling, and disposal.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1836/006

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

RADIONUCLIDE GENERATOR

1. NAME OF THE MEDICINAL PRODUCT

GalliaPharm 3.33 GBq radionuclide generator

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride 3.33 GBq

3. LIST OF EXCIPIENTS

Column matrix: Titanium dioxide

Solution for elution: Sterile ultrapure 0.1 mol/l hydrochloric acid

4. PHARMACEUTICAL FORM AND CONTENTS

Radionuclide generator.

Germanium (^{68}Ge) activity at calibration date: {X.XX}

Elutable gallium (^{68}Ga) activity: > 60 % at equilibrium

Calibration date: {DD/MM/YYYY} (12:00 CET)

1. 1 x Container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid
2. 1 x Vented spike
3. 2 x Adapter 1/16" to male LUER
4. 2 x Tubing 60 cm
5. 1 x Tubing 40 cm
6. 1 x Tubing 20 cm
7. 3 x Fingertight fitting 1/16" 10-32
8. 1 x Fingertight fitting 1/16" M6
9. 1 x Stopcock manifold
10. 1 x Male LUER union

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For *in vitro* radiolabelling.

Not intended for direct use in patients.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Radiopharmaceutical

8. EXPIRY DATE

EXP {DD/MM/YYYY}

After elution, use eluate immediately.

9. SPECIAL STORAGE CONDITIONS

Do not dismantle the stainless-steel case.

Storage should be in accordance with national regulations for radioactive materials.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Read the package leaflet for instructions for use, handling, and disposal.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1836/007

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

RADIONUCLIDE GENERATOR

1. NAME OF THE MEDICINAL PRODUCT

GalliaPharm 3.70 GBq radionuclide generator

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride 3.70 GBq

3. LIST OF EXCIPIENTS

Column matrix: Titanium dioxide

Solution for elution: Sterile ultrapure 0.1 mol/l hydrochloric acid

4. PHARMACEUTICAL FORM AND CONTENTS

Radionuclide generator.

Germanium (^{68}Ge) activity at calibration date: {X.XX}

Elutable gallium (^{68}Ga) activity: > 60 % at equilibrium

Calibration date: {DD/MM/YYYY} (12:00 CET)

1. 1 x Container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid
2. 1 x Vented spike
3. 2 x Adapter 1/16" to male LUER
4. 2 x Tubing 60 cm
5. 1 x Tubing 40 cm
6. 1 x Tubing 20 cm
7. 3 x Fingertight fitting 1/16" 10-32
8. 1 x Fingertight fitting 1/16" M6
9. 1 x Stopcock manifold
10. 1 x Male LUER union

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For *in vitro* radiolabelling.

Not intended for direct use in patients.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Radiopharmaceutical

8. EXPIRY DATE

EXP {DD/MM/YYYY}

After elution, use eluate immediately.

9. SPECIAL STORAGE CONDITIONS

Do not dismantle the stainless-steel case.

Storage should be in accordance with national regulations for radioactive materials.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Read the package leaflet for instructions for use, handling, and disposal.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1836/008

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

COLUMN INSIDE THE RADIONUCLIDE GENERATOR

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

4. BATCH NUMBER

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

6. OTHER

Ge-68/Ga-68

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

STERILE ULTRAPURE 0.1 MOL/L HYDROCHLORIC ACID – OUTER AND INNER PACKAGING

1. NAME OF THE MEDICINAL PRODUCT

Solvent for GalliaPharm

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Hydrochloric acid (0.1 mol/l)

3. LIST OF EXCIPIENTS

Water

4. PHARMACEUTICAL FORM AND CONTENTS

Solvent for GalliaPharm

250 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For elution of the radionuclide generator.

Not intended for direct use in patients.

Read package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Read the package leaflet for instructions for use, handling, and disposal.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin, Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1836/001-008

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

Read the package leaflet for instructions for use, handling, and disposal.

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable.

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

GalliaPharm 1.11 GBq radionuclide generator

Gallium (^{68}Ga) chloride solution

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What GalliaPharm is and what it is used for
2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
3. How gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
4. Possible side effects
5. How GalliaPharm is stored
6. Contents of the pack and other information

1. What GalliaPharm is and what it is used for

GalliaPharm is a germanium (^{68}Ge)/gallium (^{68}Ga) radionuclide generator, a device used to obtain a solution of gallium (^{68}Ga) chloride. Gallium (^{68}Ga) chloride is a radioactive substance that is handled by specialised doctors (nuclear medicine doctors) and pharmacists trained to work with radioactive materials. Gallium (^{68}Ga) chloride is not intended for direct use in patients, but is used for radiolabelling, a technique in which a substance is tagged (radiolabelled) with a radioactive compound, here ^{68}Ga.

Only medicines that have been specifically developed and approved for radiolabelling with ^{68}Ga undergo the radiolabelling procedure with gallium (^{68}Ga) chloride. These radiolabelled medicines can recognise and attach to particular types of cells in the body and take the radioactive ^{68}Ga to these cells in your body. The low amount of radioactivity present in the ^{68}Ga-labelled medicine can be detected from outside of the body by special cameras. This may help your doctor with the diagnosis. Please refer to the Package Leaflet of the medicine that is to be radiolabelled with gallium (^{68}Ga) chloride for more information.

The nuclear medicine doctor will explain to you in more detail what type of examination will be performed.

The use of a ^{68}Ga-labelled medicine does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the ^{68}Ga-labelled medicine overcomes the risk due to radiation.

2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must not be used

- if you are allergic to gallium (^{68}Ga) chloride or any of the other ingredients of this medicine (listed in section 6).

If you are using a ^{68}Ga-labelled medicine, you should read information on contraindications in the Package Leaflet of the medicine to be radiolabelled.

Warnings and precautions
For information concerning special warnings and special precautions for use of ^{68}Ga-labelled medicines please refer to the Package Leaflet of the medicine to be radiolabelled.

Children and adolescents
Please speak to your nuclear medicine doctor if you or your child are under 18 years old.

Other medicines and gallium (^{68}Ga) chloride solution
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines since they may interfere with the interpretation of the images by your doctor.

It is not known whether gallium (^{68}Ga) chloride solution may interact with other medicines as specified studies have not been carried out. You will not receive an injection of gallium (^{68}Ga) chloride, but a medicine radiolabelled with ^{68}Ga.

For information concerning other medicines in combination with the use of ^{68}Ga-labelled medicines, please read the Package Leaflet of the radiolabelled medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given ^{68}Ga-labelled medicines.

You must inform the nuclear medicine doctor before the administration of ^{68}Ga-labelled medicines if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.

When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

<u>If you are pregnant</u>
The nuclear medicine doctor will only administer a ^{68}Ga-labelled medicine during pregnancy if a benefit is expected which would outweigh the risks.

<u>If you are breast-feeding</u>
You will be asked to stop breast-feeding. Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines
There could be effects on your ability to drive and to use machines due to the use of ^{68}Ga-labelled medicines. Please read the Package Leaflets of these medicines carefully.

3. How gallium (^{68}Ga) chloride solution produced with GalliaPharm is used

There are strict laws on the use, handling, and disposal of radiopharmaceutical products. GalliaPharm will only be used in special controlled areas. The production of gallium (^{68}Ga) chloride solution, radiolabelling of a specific carrier medicine, as well as administration of ^{68}Ga-labelled medicine to you, will only be handled by people who are trained and qualified to use it safely. They will take special care for the safe use of this medicine and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the amount of medicine radiolabelled with ^{68}Ga to be used in your case. It will be the smallest quantity necessary to achieve the appropriate outcome.

Administration of gallium (^{68}Ga) chloride solution and conduct of the procedure
You will not be given the gallium (^{68}Ga) chloride solution, but another medicine which has been combined (radiolabelled) with gallium (^{68}Ga) chloride solution.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure with a ^{68}Ga-labelled medicine. For more information, please read the Package Leaflet of the radiolabelled medicine.

After the medicine radiolabelled with gallium (^{68}Ga) chloride solution has been given
The nuclear medicine doctor will inform you if you need to take any special precautions after receiving the ^{68}Ga-labelled medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more medicine radiolabelled with gallium (^{68}Ga) chloride solution than you should, or have received direct injection of gallium (^{68}Ga) chloride solution inadvertently
An overdose, or inadvertent direct injection of gallium (^{68}Ga) chloride solution is unlikely, because you will only receive the ^{68}Ga-labelled medicine precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, or inadvertent direct injection you will receive the appropriate care.

Should you have any further questions on the use of this medicine, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, the ^{68}Ga-labelled medicine can cause side effects, although not everybody gets them.

After the ^{68}Ga-labelled medicine is administered, it will deliver low amounts of ionising radiation with the least risk of cancer and hereditary abnormalities.

For more information about possible side effects, please read the Package Leaflet of the radiolabelled medicine.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How GalliaPharm is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.

The radionuclide generator must not be used after the expiry date stated on the container after "EXP".

Do not dismantle the case.

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must be used immediately.

6. Contents of the pack and other information

What GalliaPharm contains

- The active substance consists of germanium (^{68}Ge) chloride and gallium (^{68}Ga) chloride dissolved in sterile ultrapure 0.1 mol/l hydrochloric acid. Germanium (^{68}Ge) is irreversibly trapped inside the radionuclide generator decaying to its daughter nuclide (^{68}Ga), which is obtained from the generator as gallium (^{68}Ga) chloride.
- The other ingredients are: Titanium dioxide (matrix)
  Sterile ultrapure 0.1 mol/l hydrochloric acid (solution for elution)

One radionuclide generator is supplied with:

1. 1 x PP – container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid (including a separate hanger for PP-bottles; PP = Polypropylene)
2. 1 x Vented spike (ABS = Acrylonitrile Butadiene Styrene/PE = Polyethylene)
3. 2 x Adapter 1/16" to male LUER (PEEK)
4. 2 x Tubing 60 cm (PEEK)
5. 1 x Tubing 40 cm (PEEK)
6. 1 x Tubing 20 cm (PEEK)
7. 3 x Fingertight fitting 1/16" 10-32 (PEEK)
8. 1 x Fingertight fitting 1/16" M6 (PEEK)
9. 1 x Stopcock manifold (TPX = Polymethylpentene/HDPE = High Density Polyethylene)
10. 1 x Male LUER union (PP)

What GalliaPharm looks like and contents of the pack
You will not need to obtain or handle this medicine.

Marketing Authorisation Holder and Manufacturer
Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

This leaflet was last revised in.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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The following information is intended for healthcare professionals only:

The complete SmPC of GalliaPharm is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.

Package leaflet: Information for the patient

GalliaPharm 1.48 GBq radionuclide generator

Gallium (^{68}Ga) chloride solution

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What GalliaPharm is and what it is used for
2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
3. How gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
4. Possible side effects
5. How GalliaPharm is stored
6. Contents of the pack and other information

1. What GalliaPharm is and what it is used for

GalliaPharm is a germanium (^{68}Ge)/gallium (^{68}Ga) radionuclide generator, a device used to obtain a solution of gallium (^{68}Ga) chloride. Gallium (^{68}Ga) chloride is a radioactive substance that is handled by specialised doctors (nuclear medicine doctors) and pharmacists trained to work with radioactive materials. Gallium (^{68}Ga) chloride is not intended for direct use in patients, but is used for radiolabelling, a technique in which a substance is tagged (radiolabelled) with a radioactive compound, here ^{68}Ga.

Only medicines that have been specifically developed and approved for radiolabelling with ^{68}Ga undergo the radiolabelling procedure with gallium (^{68}Ga) chloride. These radiolabelled medicines can recognise and attach to particular types of cells in the body and take the radioactive ^{68}Ga to these cells in your body. The low amount of radioactivity present in the ^{68}Ga-labelled medicine can be detected from outside of the body by special cameras. This may help your doctor with the diagnosis. Please refer to the Package Leaflet of the medicine that is to be radiolabelled with gallium (^{68}Ga) chloride for more information.

The nuclear medicine doctor will explain to you in more detail what type of examination will be performed.

The use of a ^{68}Ga-labelled medicine does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the ^{68}Ga-labelled medicine overcomes the risk due to radiation.

2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must not be used

- if you are allergic to gallium (^{68}Ga) chloride or any of the other ingredients of this medicine (listed in section 6).

If you are using a ^{68}Ga-labelled medicine, you should read information on contraindications in the Package Leaflet of the medicine to be radiolabelled.

Warnings and precautions
For information concerning special warnings and special precautions for use of ^{68}Ga-labelled medicines please refer to the Package Leaflet of the medicine to be radiolabelled.

Children and adolescents
Please speak to your nuclear medicine doctor if you or your child are under 18 years old.

Other medicines and gallium (^{68}Ga) chloride solution
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines since they may interfere with the interpretation of the images by your doctor.

It is not known whether gallium (^{68}Ga) chloride solution may interact with other medicines as specified studies have not been carried out. You will not receive an injection of gallium (^{68}Ga) chloride, but a medicine radiolabelled with ^{68}Ga.

For information concerning other medicines in combination with the use of ^{68}Ga-labelled medicines, please read the Package Leaflet of the radiolabelled medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given ^{68}Ga-labelled medicines.

You must inform the nuclear medicine doctor before the administration of ^{68}Ga-labelled medicines if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.

When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

<u>If you are pregnant</u>
The nuclear medicine doctor will only administer a ^{68}Ga-labelled medicine during pregnancy if a benefit is expected which would outweigh the risks.

<u>If you are breast-feeding</u>
You will be asked to stop breast-feeding. Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines
There could be effects on your ability to drive and to use machines due to the use of ^{68}Ga-labelled medicines. Please read the Package Leaflets of these medicines carefully.

3. How gallium (^{68}Ga) chloride solution produced with GalliaPharm is used

There are strict laws on the use, handling, and disposal of radiopharmaceutical products. GalliaPharm will only be used in special controlled areas. The production of gallium (^{68}Ga) chloride solution, radiolabelling of a specific carrier medicine, as well as administration of ^{68}Ga-labelled medicine to you, will only be handled by people who are trained and qualified to use it safely. They will take special care for the safe use of this medicine and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the amount of medicine radiolabelled with ^{68}Ga to be used in your case. It will be the smallest quantity necessary to achieve the appropriate outcome.

Administration of gallium (^{68}Ga) chloride solution and conduct of the procedure
You will not be given the gallium (^{68}Ga) chloride solution, but another medicine which has been combined (radiolabelled) with gallium (^{68}Ga) chloride solution.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure with a ^{68}Ga-labelled medicine. For more information, please read the Package Leaflet of the radiolabelled medicine.

After the medicine radiolabelled with gallium (^{68}Ga) chloride solution has been given
The nuclear medicine doctor will inform you if you need to take any special precautions after receiving the ^{68}Ga-labelled medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more medicine radiolabelled with gallium (^{68}Ga) chloride solution than you should, or have received direct injection of gallium (^{68}Ga) chloride solution inadvertently
An overdose, or inadvertent direct injection of gallium (^{68}Ga) chloride solution is unlikely, because you will only receive the ^{68}Ga-labelled medicine precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, or inadvertent direct injection you will receive the appropriate care.

Should you have any further questions on the use of this medicine, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, the ^{68}Ga-labelled medicine can cause side effects, although not everybody gets them.

After the ^{68}Ga-labelled medicine is administered, it will deliver low amounts of ionising radiation with the least risk of cancer and hereditary abnormalities.

For more information about possible side effects, please read the Package Leaflet of the radiolabelled medicine.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How GalliaPharm is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.

The radionuclide generator must not be used after the expiry date stated on the container after "EXP".

Do not dismantle the case.

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must be used immediately.

6. Contents of the pack and other information

What GalliaPharm contains

- The active substance consists of germanium (^{68}Ge) chloride and gallium (^{68}Ga) chloride dissolved in sterile ultrapure 0.1 mol/l hydrochloric acid. Germanium (^{68}Ge) is irreversibly trapped inside the radionuclide generator decaying to its daughter nuclide (^{68}Ga), which is obtained from the generator as gallium (^{68}Ga) chloride.
- The other ingredients are: Titanium dioxide (matrix)
  Sterile ultrapure 0.1 mol/l hydrochloric acid (solution for elution)

One radionuclide generator is supplied with:

1. 1 x PP – container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid (including a separate hanger for PP-bottles; PP = Polypropylene)
2. 1 x Vented spike (ABS = Acrylonitrile Butadiene Styrene/PE = Polyethylene)
3. 2 x Adapter 1/16" to male LUER (PEEK)
4. 2 x Tubing 60 cm (PEEK)
5. 1 x Tubing 40 cm (PEEK)
6. 1 x Tubing 20 cm (PEEK)
7. 3 x Fingertight fitting 1/16" 10-32 (PEEK)
8. 1 x Fingertight fitting 1/16" M6 (PEEK)
9. 1 x Stopcock manifold (TPX = Polymethylpentene/HDPE = High Density Polyethylene)
10. 1 x Male LUER union (PP)

What GalliaPharm looks like and contents of the pack
You will not need to obtain or handle this medicine.

Marketing Authorisation Holder and Manufacturer
Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

This leaflet was last revised in.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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The following information is intended for healthcare professionals only:

The complete SmPC of GalliaPharm is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.

Package leaflet: Information for the patient

GalliaPharm 1.85 GBq radionuclide generator

Gallium (^{68}Ga) chloride solution

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What GalliaPharm is and what it is used for
2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
3. How gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
4. Possible side effects
5. How GalliaPharm is stored
6. Contents of the pack and other information

1. What GalliaPharm is and what it is used for

GalliaPharm is a germanium (^{68}Ge)/gallium (^{68}Ga) radionuclide generator, a device used to obtain a solution of gallium (^{68}Ga) chloride. Gallium (^{68}Ga) chloride is a radioactive substance that is handled by specialised doctors (nuclear medicine doctors) and pharmacists trained to work with radioactive materials. Gallium (^{68}Ga) chloride is not intended for direct use in patients, but is used for radiolabelling, a technique in which a substance is tagged (radiolabelled) with a radioactive compound, here ^{68}Ga.

Only medicines that have been specifically developed and approved for radiolabelling with ^{68}Ga undergo the radiolabelling procedure with gallium (^{68}Ga) chloride. These radiolabelled medicines can recognise and attach to particular types of cells in the body and take the radioactive ^{68}Ga to these cells in your body. The low amount of radioactivity present in the ^{68}Ga-labelled medicine can be detected from outside of the body by special cameras. This may help your doctor with the diagnosis. Please refer to the Package Leaflet of the medicine that is to be radiolabelled with gallium (^{68}Ga) chloride for more information.

The nuclear medicine doctor will explain to you in more detail what type of examination will be performed.

The use of a ^{68}Ga-labelled medicine does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the ^{68}Ga-labelled medicine overcomes the risk due to radiation.

2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must not be used

- if you are allergic to gallium (^{68}Ga) chloride or any of the other ingredients of this medicine (listed in section 6).

If you are using a ^{68}Ga-labelled medicine, you should read information on contraindications in the Package Leaflet of the medicine to be radiolabelled.

Warnings and precautions
For information concerning special warnings and special precautions for use of ^{68}Ga-labelled medicines please refer to the Package Leaflet of the medicine to be radiolabelled.

Children and adolescents
Please speak to your nuclear medicine doctor if you or your child are under 18 years old.

Other medicines and gallium (^{68}Ga) chloride solution
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines since they may interfere with the interpretation of the images by your doctor.

It is not known whether gallium (^{68}Ga) chloride solution may interact with other medicines as specified studies have not been carried out. You will not receive an injection of gallium (^{68}Ga) chloride, but a medicine radiolabelled with ^{68}Ga.

For information concerning other medicines in combination with the use of ^{68}Ga-labelled medicines, please read the Package Leaflet of the radiolabelled medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given ^{68}Ga-labelled medicines.

You must inform the nuclear medicine doctor before the administration of ^{68}Ga-labelled medicines if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.

When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

<u>If you are pregnant</u>
The nuclear medicine doctor will only administer a ^{68}Ga-labelled medicine during pregnancy if a benefit is expected which would outweigh the risks.

<u>If you are breast-feeding</u>
You will be asked to stop breast-feeding. Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines
There could be effects on your ability to drive and to use machines due to the use of ^{68}Ga-labelled medicines. Please read the Package Leaflets of these medicines carefully.

3. How gallium (^{68}Ga) chloride solution produced with GalliaPharm is used

There are strict laws on the use, handling, and disposal of radiopharmaceutical products. GalliaPharm will only be used in special controlled areas. The production of gallium (^{68}Ga) chloride solution, radiolabelling of a specific carrier medicine, as well as administration of ^{68}Ga-labelled medicine to you, will only be handled by people who are trained and qualified to use it safely. They will take special care for the safe use of this medicine and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the amount of medicine radiolabelled with ^{68}Ga to be used in your case. It will be the smallest quantity necessary to achieve the appropriate outcome.

Administration of gallium (^{68}Ga) chloride solution and conduct of the procedure
You will not be given the gallium (^{68}Ga) chloride solution, but another medicine which has been combined (radiolabelled) with gallium (^{68}Ga) chloride solution.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure with a ^{68}Ga-labelled medicine. For more information, please read the Package Leaflet of the radiolabelled medicine.

After the medicine radiolabelled with gallium (^{68}Ga) chloride solution has been given
The nuclear medicine doctor will inform you if you need to take any special precautions after receiving the ^{68}Ga-labelled medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more medicine radiolabelled with gallium (^{68}Ga) chloride solution than you should, or have received direct injection of gallium (^{68}Ga) chloride solution inadvertently
An overdose, or inadvertent direct injection of gallium (^{68}Ga) chloride solution is unlikely, because you will only receive the ^{68}Ga-labelled medicine precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, or inadvertent direct injection you will receive the appropriate care.

Should you have any further questions on the use of this medicine, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, the ^{68}Ga-labelled medicine can cause side effects, although not everybody gets them.

After the ^{68}Ga-labelled medicine is administered, it will deliver low amounts of ionising radiation with the least risk of cancer and hereditary abnormalities.

For more information about possible side effects, please read the Package Leaflet of the radiolabelled medicine.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How GalliaPharm is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.

The radionuclide generator must not be used after the expiry date stated on the container after "EXP".

Do not dismantle the case.

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must be used immediately.

6. Contents of the pack and other information

What GalliaPharm contains

- The active substance consists of germanium (^{68}Ge) chloride and gallium (^{68}Ga) chloride dissolved in sterile ultrapure 0.1 mol/l hydrochloric acid. Germanium (^{68}Ge) is irreversibly trapped inside the radionuclide generator decaying to its daughter nuclide (^{68}Ga), which is obtained from the generator as gallium (^{68}Ga) chloride.
- The other ingredients are: Titanium dioxide (matrix)
  Sterile ultrapure 0.1 mol/l hydrochloric acid (solution for elution)

One radionuclide generator is supplied with:

1. 1 x PP – container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid (including a separate hanger for PP-bottles; PP = Polypropylene)
2. 1 x Vented spike (ABS = Acrylonitrile Butadiene Styrene/PE = Polyethylene)
3. 2 x Adapter 1/16" to male LUER (PEEK)
4. 2 x Tubing 60 cm (PEEK)
5. 1 x Tubing 40 cm (PEEK)
6. 1 x Tubing 20 cm (PEEK)
7. 3 x Fingertight fitting 1/16" 10-32 (PEEK)
8. 1 x Fingertight fitting 1/16" M6 (PEEK)
9. 1 x Stopcock manifold (TPX = Polymethylpentene/HDPE = High Density Polyethylene)
10. 1 x Male LUER union (PP)

What GalliaPharm looks like and contents of the pack
You will not need to obtain or handle this medicine.

Marketing Authorisation Holder and Manufacturer
Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

This leaflet was last revised in.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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The following information is intended for healthcare professionals only:

The complete SmPC of GalliaPharm is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.

Package leaflet: Information for the patient

GalliaPharm 2.22 GBq radionuclide generator

Gallium (^{68}Ga) chloride solution

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What GalliaPharm is and what it is used for
2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
3. How gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
4. Possible side effects
5. How GalliaPharm is stored
6. Contents of the pack and other information

1. What GalliaPharm is and what it is used for

GalliaPharm is a germanium (^{68}Ge)/gallium (^{68}Ga) radionuclide generator, a device used to obtain a solution of gallium (^{68}Ga) chloride. Gallium (^{68}Ga) chloride is a radioactive substance that is handled by specialised doctors (nuclear medicine doctors) and pharmacists trained to work with radioactive materials. Gallium (^{68}Ga) chloride is not intended for direct use in patients, but is used for radiolabelling, a technique in which a substance is tagged (radiolabelled) with a radioactive compound, here ^{68}Ga.

Only medicines that have been specifically developed and approved for radiolabelling with ^{68}Ga undergo the radiolabelling procedure with gallium (^{68}Ga) chloride. These radiolabelled medicines can recognise and attach to particular types of cells in the body and take the radioactive ^{68}Ga to these cells in your body. The low amount of radioactivity present in the ^{68}Ga-labelled medicine can be detected from outside of the body by special cameras. This may help your doctor with the diagnosis. Please refer to the Package Leaflet of the medicine that is to be radiolabelled with gallium (^{68}Ga) chloride for more information.

The nuclear medicine doctor will explain to you in more detail what type of examination will be performed.

The use of a ^{68}Ga-labelled medicine does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the ^{68}Ga-labelled medicine overcomes the risk due to radiation.

2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must not be used

- if you are allergic to gallium (^{68}Ga) chloride or any of the other ingredients of this medicine (listed in section 6).

If you are using a ^{68}Ga-labelled medicine, you should read information on contraindications in the Package Leaflet of the medicine to be radiolabelled.

Warnings and precautions
For information concerning special warnings and special precautions for use of ^{68}Ga-labelled medicines please refer to the Package Leaflet of the medicine to be radiolabelled.

Children and adolescents
Please speak to your nuclear medicine doctor if you or your child are under 18 years old.

Other medicines and gallium (^{68}Ga) chloride solution
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines since they may interfere with the interpretation of the images by your doctor.

It is not known whether gallium (^{68}Ga) chloride solution may interact with other medicines as specified studies have not been carried out. You will not receive an injection of gallium (^{68}Ga) chloride, but a medicine radiolabelled with ^{68}Ga.

For information concerning other medicines in combination with the use of ^{68}Ga-labelled medicines, please read the Package Leaflet of the radiolabelled medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given ^{68}Ga-labelled medicines.

You must inform the nuclear medicine doctor before the administration of ^{68}Ga-labelled medicines if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.

When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

<u>If you are pregnant</u>
The nuclear medicine doctor will only administer a ^{68}Ga-labelled medicine during pregnancy if a benefit is expected which would outweigh the risks.

<u>If you are breast-feeding</u>
You will be asked to stop breast-feeding. Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines
There could be effects on your ability to drive and to use machines due to the use of ^{68}Ga-labelled medicines. Please read the Package Leaflets of these medicines carefully.

3. How gallium (^{68}Ga) chloride solution produced with GalliaPharm is used

There are strict laws on the use, handling, and disposal of radiopharmaceutical products. GalliaPharm will only be used in special controlled areas. The production of gallium (^{68}Ga) chloride solution, radiolabelling of a specific carrier medicine, as well as administration of ^{68}Ga-labelled medicine to you, will only be handled by people who are trained and qualified to use it safely. They will take special care for the safe use of this medicine and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the amount of medicine radiolabelled with ^{68}Ga to be used in your case. It will be the smallest quantity necessary to achieve the appropriate outcome.

Administration of gallium (^{68}Ga) chloride solution and conduct of the procedure
You will not be given the gallium (^{68}Ga) chloride solution, but another medicine which has been combined (radiolabelled) with gallium (^{68}Ga) chloride solution.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure with a ^{68}Ga-labelled medicine. For more information, please read the Package Leaflet of the radiolabelled medicine.

After the medicine radiolabelled with gallium (^{68}Ga) chloride solution has been given
The nuclear medicine doctor will inform you if you need to take any special precautions after receiving the ^{68}Ga-labelled medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more medicine radiolabelled with gallium (^{68}Ga) chloride solution than you should, or have received direct injection of gallium (^{68}Ga) chloride solution inadvertently
An overdose, or inadvertent direct injection of gallium (^{68}Ga) chloride solution is unlikely, because you will only receive the ^{68}Ga-labelled medicine precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, or inadvertent direct injection you will receive the appropriate care.

Should you have any further questions on the use of this medicine, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, the ^{68}Ga-labelled medicine can cause side effects, although not everybody gets them.

After the ^{68}Ga-labelled medicine is administered, it will deliver low amounts of ionising radiation with the least risk of cancer and hereditary abnormalities.

For more information about possible side effects, please read the Package Leaflet of the radiolabelled medicine.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How GalliaPharm is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.

The radionuclide generator must not be used after the expiry date stated on the container after "EXP".

Do not dismantle the case.

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must be used immediately.

6. Contents of the pack and other information

What GalliaPharm contains

- The active substance consists of germanium (^{68}Ge) chloride and gallium (^{68}Ga) chloride dissolved in sterile ultrapure 0.1 mol/l hydrochloric acid. Germanium (^{68}Ge) is irreversibly trapped inside the radionuclide generator decaying to its daughter nuclide (^{68}Ga), which is obtained from the generator as gallium (^{68}Ga) chloride.
- The other ingredients are: Titanium dioxide (matrix)
  Sterile ultrapure 0.1 mol/l hydrochloric acid (solution for elution)

One radionuclide generator is supplied with:

1. 1 x PP – container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid (including a separate hanger for PP-bottles; PP = Polypropylene)
2. 1 x Vented spike (ABS = Acrylonitrile Butadiene Styrene/PE = Polyethylene)
3. 2 x Adapter 1/16" to male LUER (PEEK)
4. 2 x Tubing 60 cm (PEEK)
5. 1 x Tubing 40 cm (PEEK)
6. 1 x Tubing 20 cm (PEEK)
7. 3 x Fingertight fitting 1/16" 10-32 (PEEK)
8. 1 x Fingertight fitting 1/16" M6 (PEEK)
9. 1 x Stopcock manifold (TPX = Polymethylpentene/HDPE = High Density Polyethylene)
10. 1 x Male LUER union (PP)

What GalliaPharm looks like and contents of the pack
You will not need to obtain or handle this medicine.

Marketing Authorisation Holder and Manufacturer
Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

This leaflet was last revised in.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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The following information is intended for healthcare professionals only:

The complete SmPC of GalliaPharm is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.

Package leaflet: Information for the patient

GalliaPharm 2.59 GBq radionuclide generator

Gallium (^{68}Ga) chloride solution

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What GalliaPharm is and what it is used for
2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
3. How gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
4. Possible side effects
5. How GalliaPharm is stored
6. Contents of the pack and other information

1. What GalliaPharm is and what it is used for

GalliaPharm is a germanium (^{68}Ge)/gallium (^{68}Ga) radionuclide generator, a device used to obtain a solution of gallium (^{68}Ga) chloride. Gallium (^{68}Ga) chloride is a radioactive substance that is handled by specialised doctors (nuclear medicine doctors) and pharmacists trained to work with radioactive materials. Gallium (^{68}Ga) chloride is not intended for direct use in patients, but is used for radiolabelling, a technique in which a substance is tagged (radiolabelled) with a radioactive compound, here ^{68}Ga.

Only medicines that have been specifically developed and approved for radiolabelling with ^{68}Ga undergo the radiolabelling procedure with gallium (^{68}Ga) chloride. These radiolabelled medicines can recognise and attach to particular types of cells in the body and take the radioactive ^{68}Ga to these cells in your body. The low amount of radioactivity present in the ^{68}Ga-labelled medicine can be detected from outside of the body by special cameras. This may help your doctor with the diagnosis. Please refer to the Package Leaflet of the medicine that is to be radiolabelled with gallium (^{68}Ga) chloride for more information.

The nuclear medicine doctor will explain to you in more detail what type of examination will be performed.

The use of a ^{68}Ga-labelled medicine does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the ^{68}Ga-labelled medicine overcomes the risk due to radiation.

2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must not be used

- if you are allergic to gallium (^{68}Ga) chloride or any of the other ingredients of this medicine (listed in section 6).

If you are using a ^{68}Ga-labelled medicine, you should read information on contraindications in the Package Leaflet of the medicine to be radiolabelled.

Warnings and precautions
For information concerning special warnings and special precautions for use of ^{68}Ga-labelled medicines please refer to the Package Leaflet of the medicine to be radiolabelled.

Children and adolescents
Please speak to your nuclear medicine doctor if you or your child are under 18 years old.

Other medicines and gallium (^{68}Ga) chloride solution
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines since they may interfere with the interpretation of the images by your doctor.

It is not known whether gallium (^{68}Ga) chloride solution may interact with other medicines as specified studies have not been carried out. You will not receive an injection of gallium (^{68}Ga) chloride, but a medicine radiolabelled with ^{68}Ga.

For information concerning other medicines in combination with the use of ^{68}Ga-labelled medicines, please read the Package Leaflet of the radiolabelled medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given ^{68}Ga-labelled medicines.

You must inform the nuclear medicine doctor before the administration of ^{68}Ga-labelled medicines if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.

When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

<u>If you are pregnant</u>
The nuclear medicine doctor will only administer a ^{68}Ga-labelled medicine during pregnancy if a benefit is expected which would outweigh the risks.

<u>If you are breast-feeding</u>
You will be asked to stop breast-feeding. Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines
There could be effects on your ability to drive and to use machines due to the use of ^{68}Ga-labelled medicines. Please read the Package Leaflets of these medicines carefully.

3. How gallium (^{68}Ga) chloride solution produced with GalliaPharm is used

There are strict laws on the use, handling, and disposal of radiopharmaceutical products. GalliaPharm will only be used in special controlled areas. The production of gallium (^{68}Ga) chloride solution, radiolabelling of a specific carrier medicine, as well as administration of ^{68}Ga-labelled medicine to you, will only be handled by people who are trained and qualified to use it safely. They will take special care for the safe use of this medicine and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the amount of medicine radiolabelled with ^{68}Ga to be used in your case. It will be the smallest quantity necessary to achieve the appropriate outcome.

Administration of gallium (^{68}Ga) chloride solution and conduct of the procedure
You will not be given the gallium (^{68}Ga) chloride solution, but another medicine which has been combined (radiolabelled) with gallium (^{68}Ga) chloride solution.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure with a ^{68}Ga-labelled medicine. For more information, please read the Package Leaflet of the radiolabelled medicine.

After the medicine radiolabelled with gallium (^{68}Ga) chloride solution has been given
The nuclear medicine doctor will inform you if you need to take any special precautions after receiving the ^{68}Ga-labelled medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more medicine radiolabelled with gallium (^{68}Ga) chloride solution than you should, or have received direct injection of gallium (^{68}Ga) chloride solution inadvertently
An overdose, or inadvertent direct injection of gallium (^{68}Ga) chloride solution is unlikely, because you will only receive the ^{68}Ga-labelled medicine precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, or inadvertent direct injection you will receive the appropriate care.

Should you have any further questions on the use of this medicine, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, the ^{68}Ga-labelled medicine can cause side effects, although not everybody gets them.

After the ^{68}Ga-labelled medicine is administered, it will deliver low amounts of ionising radiation with the least risk of cancer and hereditary abnormalities.

For more information about possible side effects, please read the Package Leaflet of the radiolabelled medicine.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How GalliaPharm is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.

The radionuclide generator must not be used after the expiry date stated on the container after "EXP".

Do not dismantle the case.

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must be used immediately.

6. Contents of the pack and other information

What GalliaPharm contains

- The active substance consists of germanium (^{68}Ge) chloride and gallium (^{68}Ga) chloride dissolved in sterile ultrapure 0.1 mol/l hydrochloric acid. Germanium (^{68}Ge) is irreversibly trapped inside the radionuclide generator decaying to its daughter nuclide (^{68}Ga), which is obtained from the generator as gallium (^{68}Ga) chloride.
- The other ingredients are: Titanium dioxide (matrix)
  Sterile ultrapure 0.1 mol/l hydrochloric acid (solution for elution)

One radionuclide generator is supplied with:

1. 1 x PP – container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid (including a separate hanger for PP-bottles; PP = Polypropylene)
2. 1 x Vented spike (ABS = Acrylonitrile Butadiene Styrene/PE = Polyethylene)
3. 2 x Adapter 1/16" to male LUER (PEEK)
4. 2 x Tubing 60 cm (PEEK)
5. 1 x Tubing 40 cm (PEEK)
6. 1 x Tubing 20 cm (PEEK)
7. 3 x Fingertight fitting 1/16" 10-32 (PEEK)
8. 1 x Fingertight fitting 1/16" M6 (PEEK)
9. 1 x Stopcock manifold (TPX = Polymethylpentene/HDPE = High Density Polyethylene)
10. 1 x Male LUER union (PP)

What GalliaPharm looks like and contents of the pack
You will not need to obtain or handle this medicine.

Marketing Authorisation Holder and Manufacturer
Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

This leaflet was last revised in.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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The following information is intended for healthcare professionals only:

The complete SmPC of GalliaPharm is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.

Package leaflet: Information for the patient

GalliaPharm 2.96 GBq radionuclide generator

Gallium (^{68}Ga) chloride solution

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What GalliaPharm is and what it is used for
2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
3. How gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
4. Possible side effects
5. How GalliaPharm is stored
6. Contents of the pack and other information

1. What GalliaPharm is and what it is used for

GalliaPharm is a germanium (^{68}Ge)/gallium (^{68}Ga) radionuclide generator, a device used to obtain a solution of gallium (^{68}Ga) chloride. Gallium (^{68}Ga) chloride is a radioactive substance that is handled by specialised doctors (nuclear medicine doctors) and pharmacists trained to work with radioactive materials. Gallium (^{68}Ga) chloride is not intended for direct use in patients, but is used for radiolabelling, a technique in which a substance is tagged (radiolabelled) with a radioactive compound, here ^{68}Ga.

Only medicines that have been specifically developed and approved for radiolabelling with ^{68}Ga undergo the radiolabelling procedure with gallium (^{68}Ga) chloride. These radiolabelled medicines can recognise and attach to particular types of cells in the body and take the radioactive ^{68}Ga to these cells in your body. The low amount of radioactivity present in the ^{68}Ga-labelled medicine can be detected from outside of the body by special cameras. This may help your doctor with the diagnosis. Please refer to the Package Leaflet of the medicine that is to be radiolabelled with gallium (^{68}Ga) chloride for more information.

The nuclear medicine doctor will explain to you in more detail what type of examination will be performed.

The use of a ^{68}Ga-labelled medicine does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the ^{68}Ga-labelled medicine overcomes the risk due to radiation.

2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must not be used

- if you are allergic to gallium (^{68}Ga) chloride or any of the other ingredients of this medicine (listed in section 6).

If you are using a ^{68}Ga-labelled medicine, you should read information on contraindications in the Package Leaflet of the medicine to be radiolabelled.

Warnings and precautions
For information concerning special warnings and special precautions for use of ^{68}Ga-labelled medicines please refer to the Package Leaflet of the medicine to be radiolabelled.

Children and adolescents
Please speak to your nuclear medicine doctor if you or your child are under 18 years old.

Other medicines and gallium (^{68}Ga) chloride solution
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines since they may interfere with the interpretation of the images by your doctor.

It is not known whether gallium (^{68}Ga) chloride solution may interact with other medicines as specified studies have not been carried out. You will not receive an injection of gallium (^{68}Ga) chloride, but a medicine radiolabelled with ^{68}Ga.

For information concerning other medicines in combination with the use of ^{68}Ga-labelled medicines, please read the Package Leaflet of the radiolabelled medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given ^{68}Ga-labelled medicines.

You must inform the nuclear medicine doctor before the administration of ^{68}Ga-labelled medicines if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.

When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

<u>If you are pregnant</u>
The nuclear medicine doctor will only administer a ^{68}Ga-labelled medicine during pregnancy if a benefit is expected which would outweigh the risks.

<u>If you are breast-feeding</u>
You will be asked to stop breast-feeding. Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines
There could be effects on your ability to drive and to use machines due to the use of ^{68}Ga-labelled medicines. Please read the Package Leaflets of these medicines carefully.

3. How gallium (^{68}Ga) chloride solution produced with GalliaPharm is used

There are strict laws on the use, handling, and disposal of radiopharmaceutical products. GalliaPharm will only be used in special controlled areas. The production of gallium (^{68}Ga) chloride solution, radiolabelling of a specific carrier medicine, as well as administration of ^{68}Ga-labelled medicine to you, will only be handled by people who are trained and qualified to use it safely. They will take special care for the safe use of this medicine and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the amount of medicine radiolabelled with ^{68}Ga to be used in your case. It will be the smallest quantity necessary to achieve the appropriate outcome.

Administration of gallium (^{68}Ga) chloride solution and conduct of the procedure
You will not be given the gallium (^{68}Ga) chloride solution, but another medicine which has been combined (radiolabelled) with gallium (^{68}Ga) chloride solution.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure with a ^{68}Ga-labelled medicine. For more information, please read the Package Leaflet of the radiolabelled medicine.

After the medicine radiolabelled with gallium (^{68}Ga) chloride solution has been given
The nuclear medicine doctor will inform you if you need to take any special precautions after receiving the ^{68}Ga-labelled medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more medicine radiolabelled with gallium (^{68}Ga) chloride solution than you should, or have received direct injection of gallium (^{68}Ga) chloride solution inadvertently
An overdose, or inadvertent direct injection of gallium (^{68}Ga) chloride solution is unlikely, because you will only receive the ^{68}Ga-labelled medicine precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, or inadvertent direct injection you will receive the appropriate care.

Should you have any further questions on the use of this medicine, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, the ^{68}Ga-labelled medicine can cause side effects, although not everybody gets them.

After the ^{68}Ga-labelled medicine is administered, it will deliver low amounts of ionising radiation with the least risk of cancer and hereditary abnormalities.

For more information about possible side effects, please read the Package Leaflet of the radiolabelled medicine.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How GalliaPharm is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.

The radionuclide generator must not be used after the expiry date stated on the container after "EXP".

Do not dismantle the case.

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must be used immediately.

6. Contents of the pack and other information

What GalliaPharm contains

- The active substance consists of germanium (^{68}Ge) chloride and gallium (^{68}Ga) chloride dissolved in sterile ultrapure 0.1 mol/l hydrochloric acid. Germanium (^{68}Ge) is irreversibly trapped inside the radionuclide generator decaying to its daughter nuclide (^{68}Ga), which is obtained from the generator as gallium (^{68}Ga) chloride.
- The other ingredients are: Titanium dioxide (matrix)
  Sterile ultrapure 0.1 mol/l hydrochloric acid (solution for elution)

One radionuclide generator is supplied with:

1. 1 x PP – container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid (including a separate hanger for PP-bottles; PP = Polypropylene)
2. 1 x Vented spike (ABS = Acrylonitrile Butadiene Styrene/PE = Polyethylene)
3. 2 x Adapter 1/16" to male LUER (PEEK)
4. 2 x Tubing 60 cm (PEEK)
5. 1 x Tubing 40 cm (PEEK)
6. 1 x Tubing 20 cm (PEEK)
7. 3 x Fingertight fitting 1/16" 10-32 (PEEK)
8. 1 x Fingertight fitting 1/16" M6 (PEEK)
9. 1 x Stopcock manifold (TPX = Polymethylpentene/HDPE = High Density Polyethylene)
10. 1 x Male LUER union (PP)

What GalliaPharm looks like and contents of the pack
You will not need to obtain or handle this medicine.

Marketing Authorisation Holder and Manufacturer
Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

This leaflet was last revised in.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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The following information is intended for healthcare professionals only:

The complete SmPC of GalliaPharm is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.

Package leaflet: Information for the patient

GalliaPharm 3.33 GBq radionuclide generator

Gallium (^{68}Ga) chloride solution

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What GalliaPharm is and what it is used for
2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
3. How gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
4. Possible side effects
5. How GalliaPharm is stored
6. Contents of the pack and other information

1. What GalliaPharm is and what it is used for

GalliaPharm is a germanium (^{68}Ge)/gallium (^{68}Ga) radionuclide generator, a device used to obtain a solution of gallium (^{68}Ga) chloride. Gallium (^{68}Ga) chloride is a radioactive substance that is handled by specialised doctors (nuclear medicine doctors) and pharmacists trained to work with radioactive materials. Gallium (^{68}Ga) chloride is not intended for direct use in patients, but is used for radiolabelling, a technique in which a substance is tagged (radiolabelled) with a radioactive compound, here ^{68}Ga.

Only medicines that have been specifically developed and approved for radiolabelling with ^{68}Ga undergo the radiolabelling procedure with gallium (^{68}Ga) chloride. These radiolabelled medicines can recognise and attach to particular types of cells in the body and take the radioactive ^{68}Ga to these cells in your body. The low amount of radioactivity present in the ^{68}Ga-labelled medicine can be detected from outside of the body by special cameras. This may help your doctor with the diagnosis. Please refer to the Package Leaflet of the medicine that is to be radiolabelled with gallium (^{68}Ga) chloride for more information.

The nuclear medicine doctor will explain to you in more detail what type of examination will be performed.

The use of a ^{68}Ga-labelled medicine does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the ^{68}Ga-labelled medicine overcomes the risk due to radiation.

2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must not be used

- if you are allergic to gallium (^{68}Ga) chloride or any of the other ingredients of this medicine (listed in section 6).

If you are using a ^{68}Ga-labelled medicine, you should read information on contraindications in the Package Leaflet of the medicine to be radiolabelled.

Warnings and precautions
For information concerning special warnings and special precautions for use of ^{68}Ga-labelled medicines please refer to the Package Leaflet of the medicine to be radiolabelled.

Children and adolescents
Please speak to your nuclear medicine doctor if you or your child are under 18 years old.

Other medicines and gallium (^{68}Ga) chloride solution
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines since they may interfere with the interpretation of the images by your doctor.

It is not known whether gallium (^{68}Ga) chloride solution may interact with other medicines as specified studies have not been carried out. You will not receive an injection of gallium (^{68}Ga) chloride, but a medicine radiolabelled with ^{68}Ga.

For information concerning other medicines in combination with the use of ^{68}Ga-labelled medicines, please read the Package Leaflet of the radiolabelled medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given ^{68}Ga-labelled medicines.

You must inform the nuclear medicine doctor before the administration of ^{68}Ga-labelled medicines if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.

When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

<u>If you are pregnant</u>
The nuclear medicine doctor will only administer a ^{68}Ga-labelled medicine during pregnancy if a benefit is expected which would outweigh the risks.

<u>If you are breast-feeding</u>
You will be asked to stop breast-feeding. Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines
There could be effects on your ability to drive and to use machines due to the use of ^{68}Ga-labelled medicines. Please read the Package Leaflets of these medicines carefully.

3. How gallium (^{68}Ga) chloride solution produced with GalliaPharm is used

There are strict laws on the use, handling, and disposal of radiopharmaceutical products. GalliaPharm will only be used in special controlled areas. The production of gallium (^{68}Ga) chloride solution, radiolabelling of a specific carrier medicine, as well as administration of ^{68}Ga-labelled medicine to you, will only be handled by people who are trained and qualified to use it safely. They will take special care for the safe use of this medicine and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the amount of medicine radiolabelled with ^{68}Ga to be used in your case. It will be the smallest quantity necessary to achieve the appropriate outcome.

Administration of gallium (^{68}Ga) chloride solution and conduct of the procedure
You will not be given the gallium (^{68}Ga) chloride solution, but another medicine which has been combined (radiolabelled) with gallium (^{68}Ga) chloride solution.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure with a ^{68}Ga-labelled medicine. For more information, please read the Package Leaflet of the radiolabelled medicine.

After the medicine radiolabelled with gallium (^{68}Ga) chloride solution has been given
The nuclear medicine doctor will inform you if you need to take any special precautions after receiving the ^{68}Ga-labelled medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more medicine radiolabelled with gallium (^{68}Ga) chloride solution than you should, or have received direct injection of gallium (^{68}Ga) chloride solution inadvertently
An overdose, or inadvertent direct injection of gallium (^{68}Ga) chloride solution is unlikely, because you will only receive the ^{68}Ga-labelled medicine precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, or inadvertent direct injection you will receive the appropriate care.

Should you have any further questions on the use of this medicine, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, the ^{68}Ga-labelled medicine can cause side effects, although not everybody gets them.

After the ^{68}Ga-labelled medicine is administered, it will deliver low amounts of ionising radiation with the least risk of cancer and hereditary abnormalities.

For more information about possible side effects, please read the Package Leaflet of the radiolabelled medicine.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How GalliaPharm is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.

The radionuclide generator must not be used after the expiry date stated on the container after "EXP".

Do not dismantle the case.

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must be used immediately.

6. Contents of the pack and other information

What GalliaPharm contains

- The active substance consists of germanium (^{68}Ge) chloride and gallium (^{68}Ga) chloride dissolved in sterile ultrapure 0.1 mol/l hydrochloric acid. Germanium (^{68}Ge) is irreversibly trapped inside the radionuclide generator decaying to its daughter nuclide (^{68}Ga), which is obtained from the generator as gallium (^{68}Ga) chloride.
- The other ingredients are: Titanium dioxide (matrix)
  Sterile ultrapure 0.1 mol/l hydrochloric acid (solution for elution)

One radionuclide generator is supplied with:

1. 1 x PP – container with the eluent, 250 ml sterile ultrapure 0.1 mol/l hydrochloric acid (including a separate hanger for PP-bottles; PP = Polypropylene)
2. 1 x Vented spike (ABS = Acrylonitrile Butadiene Styrene/PE = Polyethylene)
3. 2 x Adapter 1/16" to male LUER (PEEK)
4. 2 x Tubing 60 cm (PEEK)
5. 1 x Tubing 40 cm (PEEK)
6. 1 x Tubing 20 cm (PEEK)
7. 3 x Fingertight fitting 1/16" 10-32 (PEEK)
8. 1 x Fingertight fitting 1/16" M6 (PEEK)
9. 1 x Stopcock manifold (TPX = Polymethylpentene/HDPE = High Density Polyethylene)
10. 1 x Male LUER union (PP)

What GalliaPharm looks like and contents of the pack
You will not need to obtain or handle this medicine.

Marketing Authorisation Holder and Manufacturer
Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
13125 Berlin
Germany

This leaflet was last revised in.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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The following information is intended for healthcare professionals only:

The complete SmPC of GalliaPharm is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.

Package leaflet: Information for the patient

GalliaPharm 3.70 GBq radionuclide generator

Gallium (^{68}Ga) chloride solution

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What GalliaPharm is and what it is used for
2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
3. How gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used
4. Possible side effects
5. How GalliaPharm is stored
6. Contents of the pack and other information

1. What GalliaPharm is and what it is used for

GalliaPharm is a germanium (^{68}Ge)/gallium (^{68}Ga) radionuclide generator, a device used to obtain a solution of gallium (^{68}Ga) chloride. Gallium (^{68}Ga) chloride is a radioactive substance that is handled by specialised doctors (nuclear medicine doctors) and pharmacists trained to work with radioactive materials. Gallium (^{68}Ga) chloride is not intended for direct use in patients, but is used for radiolabelling, a technique in which a substance is tagged (radiolabelled) with a radioactive compound, here ^{68}Ga.

Only medicines that have been specifically developed and approved for radiolabelling with ^{68}Ga undergo the radiolabelling procedure with gallium (^{68}Ga) chloride. These radiolabelled medicines can recognise and attach to particular types of cells in the body and take the radioactive ^{68}Ga to these cells in your body. The low amount of radioactivity present in the ^{68}Ga-labelled medicine can be detected from outside of the body by special cameras. This may help your doctor with the diagnosis. Please refer to the Package Leaflet of the medicine that is to be radiolabelled with gallium (^{68}Ga) chloride for more information.

The nuclear medicine doctor will explain to you in more detail what type of examination will be performed.

The use of a ^{68}Ga-labelled medicine does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the ^{68}Ga-labelled medicine overcomes the risk due to radiation.

2. What you need to know before the gallium (^{68}Ga) chloride solution obtained with GalliaPharm is used

The gallium (^{68}Ga) chloride solution obtained with GalliaPharm must not be used

- if you are allergic to gallium (^{68}Ga) chloride or any of the other ingredients of this medicine (listed in section 6).

If you are using a ^{68}Ga-labelled medicine, you should read information on contraindications in the Package Leaflet of the medicine to be radiolabelled.

Warnings and precautions
For information concerning special warnings and special precautions for use of ^{68}Ga-labelled medicines please refer to the Package Leaflet of the medicine to be radiolabelled.

Children and adolescents
Please speak to your nuclear medicine doctor if you or your child are under 18 years old.

Other medicines and gallium (^{68}Ga) chloride solution
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines since they may interfere with the interpretation of the images by your doctor.

It is not known whether gallium (^{68}Ga) chloride solution may interact with other medicines as specified studies have not been carried out. You will not receive an injection of gallium (^{68}Ga) chloride, but a medicine radiolabelled with ^{68}Ga.

For information concerning other medicines in combination with the use of ^{68}Ga-labelled medicines, please read the Package Leaflet of the radiolabelled medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given ^{68}Ga-labelled medicines.

You must inform the nuclear medicine doctor before the administration of ^{68}Ga-labelled medicines if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.

When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

<u>If you are pregnant</u>
The nuclear medicine doctor will only administer a ^{68}Ga-labelled medicine during pregnancy if a benefit is expected which would outweigh the risks.

<u>If you are breast-feeding</u>
You will be asked to stop breast-feeding. Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines
There could be effects on your ability to drive and to use machines due to the use of ^{68}Ga-labelled medicines. Please read the Package Leaflets of these medicines carefully.

3. How gallium (^{68}Ga) chloride solution produced with GalliaPharm is used

There are strict laws on the use, handling, and disposal of radiopharmaceutical products. GalliaPharm will only be used in special controlled areas. The production of gallium (^{68}Ga) chloride solution, radiolabelling of a specific carrier medicine, as well as administration of ^{68}Ga-labelled medicine to you, will only be handled by people who are trained and qualified to use it safely. They will take special care for the safe use of this medicine and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the amount of medicine radiolabelled with ^{68}Ga to be used in your case. It will be the smallest quantity necessary to achieve the appropriate outcome.

Administration of gallium (^{68}Ga) chloride solution and conduct of the procedure
You will not be given the gallium (^{68}Ga) chloride solution, but another medicine which has been combined (radiolabelled) with gallium (^{68}Ga) chloride solution.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure with a ^{68}Ga-labelled medicine. For more information, please read the Package Leaflet of the radiolabelled medicine.

After the medicine radiolabelled with gallium (^{68}Ga) chloride solution has been given
The nuclear medicine doctor will inform you if you need to take any special precautions after receiving the ^{68}Ga-labelled medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more medicine radiolabelled with gallium (^{68}Ga) chloride solution than you should, or have received direct injection of gallium (^{68}Ga) chloride solution inadvertently
An overdose, or inadvertent direct injection of gallium (^{68}Ga) chloride solution is unlikely, because you will only receive the ^{68}Ga-labelled medicine precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, or inadvertent direct injection you will receive the appropriate care.

Should you have any further questions on the use of this medicine, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, the ^{68}Ga-labelled medicine can cause side effects, although not everybody gets them.

After the ^{68}Ga-labelled medicine is administered, it will deliver low amounts of ionising radiation with the least risk of cancer and hereditary abnormalities.

For more information about possible side effects, please read the Package Leaflet of the radiolabelled medicine.

Reporting of side effects
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