

Package leaflet: Information for the patient

GalliaPharm, 0.74 -1.85 GBq, radionuclide generator

Germanium (^{68}Ge) chloride / Gallium (^{68}Ga) chloride

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 medicine radiolabelled with GalliaPharm is used.
3. How the medicine radiolabelled 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

This medicine is a radiopharmaceutical product for diagnostic use only.

GalliaPharm is not intended to be used on its own.

GalliaPharm is a germanium (^{68}Ge) / gallium (^{68}Ga) radionuclide generator, a device used to obtain a solution of gallium (^{68}Ga) chloride.

The obtained gallium (^{68}Ga) chloride solution is used for radiolabelling, a technique in which a substance is tagged (radiolabelled) with a radioactive compound, here ^{68}Ga .

GalliaPharm is used to label certain medicines that have been specially developed for the use with the active substance gallium (^{68}Ga) chloride. These medicines act as carriers to take the radioactive ^{68}Ga to where it is needed. These may be substances that have been designed to recognise a particular type of cell in the body, including tumour cells (cancer). The low amount of radioactivity administered can be detected outside of the body by special cameras.

Please refer to the package leaflet of the medicine that is to be radiolabelled with gallium (^{68}Ga) chloride. The nuclear medicine doctor will explain to you what type of examination will be performed with this product.

The use of a ^{68}Ga -labelled medicinal product 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 radiopharmaceutical overcomes the risk due to radiation.

2. What you need to know before the medicine radiolabelled with GalliaPharm is used

The medicine radiolabelled 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 medicinal product, you should read information on contraindications in the package leaflet of the product to be radiolabelled.

Warnings and precautions

For information concerning special warnings and special precautions for use of ^{68}Ga labelled medicinal products please refer to the Package Leaflet of the medicinal product to be radiolabelled.

Children and adolescents

Please speak to your nuclear medicine doctor if you are under 18 years old.

Other medicines and medicines radiolabelled with GalliaPharm

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.

It is not known whether gallium (^{68}Ga) chloride may interact with other medicines as specified studies have not been carried out.

For information concerning interactions associated with the use of ^{68}Ga labelled medicinal products refer to the Package Leaflet of the medicinal product to be radiolabelled.

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 medicines radiolabelled with GalliaPharm.

You must inform the nuclear medicine doctor before the administration of medicines radiolabelled with GalliaPharm 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.

If you are pregnant

The nuclear medicine doctor will only administer this product during pregnancy if a benefit is expected which would outweigh the risks.

If you are breast-feeding

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 medicine used in combination with GalliaPharm. Please read the package leaflet of that medicine carefully.

3. How the medicine radiolabelled 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. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of medicine radiolabelled with GalliaPharm to be used in your case. It will be the smallest quantity necessary to achieve the appropriate outcome, depending on the final product and its intended use. Please read the package leaflet of the medicine that is to be radiolabelled for more information.

Administration of the medicine radiolabelled with GalliaPharm and conduct of the procedure

You will not get the pure GalliaPharm, but another product radiolabelled with GalliaPharm. GalliaPharm must be used only in combination with another medicine which has been specifically developed for being combined (radiolabelled) with GalliaPharm. You will only be given the final radiolabelled product.

Duration of the procedure

Your nuclear medicine doctor will inform you about the usual duration of the procedure after the administration of the medicine radiolabelled with GalliaPharm.

After administration of the medicine radiolabelled with GalliaPharm has been performed

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving the medicine radiolabelled with GalliaPharm. Contact your nuclear medicine doctor if you have any questions.

An overdose is unlikely, because you will only receive the medicine radiolabelled with GalliaPharm precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment.

4. Possible side effects

After the medicine radiolabelled with GalliaPharm is administered, it will deliver low amounts of ionising radiation with the least risk of cancer and hereditary abnormalities.

5. How GalliaPharm is stored

The following information is intended for the specialist only.

Do not dismantle the stainless steel case. Do not store above 25°C.

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

What GalliaPharm contains

The active substances are: Germanium (^{68}Ge) chloride (mother nuclide)
Gallium (^{68}Ga) chloride (daughter nuclide)

The radionuclide generator contains at calibration date:
Germanium (^{68}Ge) chloride / Gallium (^{68}Ga) chloride 0.74 – 1.85 GBq

The other ingredients are: Titanium dioxide (matrix)

Sterile ultrapure 0.1 mol/l hydrochloric acid (solution for elution)

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 medicinal product is authorised in the Member States of the EEA under the following names:

Country	Product name
Austria	GalliaPharm 0,74 - 1,85 GBq Radionuklidgenerator
Belgium	GalliaPharm, 0.74 – 1.85 GBq, radionuclidegenerator GalliaPharm, 0,74 à 1,85 GBq, générateur radiopharmaceutique GalliaPharm, 0,74 - 1,85 GBq, Radionuklidgenerator
Czech Republic	GalliaPharm
Denmark	GalliaPharm
Finland	GalliaPharm
France	GalliaPharm
Germany	GalliaPharm
Ireland	GalliaPharm
Italy	Germanio cloruro (⁶⁸ Ge)/Gallio cloruro (⁶⁸ Ga) GalliaPharm
Latvia	GalliaPharm
Netherlands	GalliaPharm, 0,74 - 1,85 GBq, radionuclidegenerator
Norway	GalliaPharm
Poland	GalliaPharm
Slovak Republic	GalliaPharm
Spain	GalliaPharm 0,74 – 1,85 GBq generador de radionúclido
Sweden	Germanium(Ge-68)tetraklorid/Gallium(Ga-68)triklorid Eckert & Ziegler
United Kingdom	GalliaPharm

This leaflet was last revised on 07/2017.

The following information is intended for medical or 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.