B. PACKAGE LEAFLET FOR RADIOPHARMACEUTICALS

Package leaflet: Information for the patient

GalliaPharm, 0.74 -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

This medicine is a radiopharmaceutical product for diagnostic use only.
This medicine is a radiopharmaceutical product not intended for direct use in patients.

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 and approved 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 to obtain images of the body. 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 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 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 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.

It is not known whether gallium (^{68}Ga) chloride solution 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.

<u>If you are pregnant</u>
The nuclear medicine doctor will only administer this 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 medicine used in combination with GalliaPharm. Please read the package leaflet of that medicine carefully.

3. How gallium (^{68}Ga) chloride solution obtained 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 gallium (^{68}Ga) chloride solution and conduct of the procedure

You will not get the gallium (^{68}Ga) chloride solution, but another product radiolabelled with GalliaPharm. Gallium (^{68}Ga) chloride solution must be used only in combination with another medicine which has been specifically developed and approved 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.

If you have been given more medicine radiolabelled with GalliaPharm than you should

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.

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

4. Possible side effects

Like all medicines, the medicine radiolabelled with GalliaPharm can cause side effects, although not everybody gets them.

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.

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. Do not store above 25°C.

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 is gallium (^{68}Ga) chloride solution.

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 in 12/2019.

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.