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

An overview of GalliaPharm and why it is authorised in the EU

What is GalliaPharm and what is it used for?

GalliaPharm is a so-called 'radionuclide generator', a medicine used to obtain a solution containing gallium (^{68}Ga) chloride, a radioactive substance. GalliaPharm and the obtained gallium (^{68}Ga) chloride solution are not intended for direct use in patients.

The gallium (^{68}Ga) chloride solution is used for radiolabelling other medicines, which are used during the body scan known as positron-emission tomography (PET). Radiolabelling is a technique that tags molecules with a radioactive substance.

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

How is GalliaPharm used?

GalliaPharm and the obtained gallium (^{68}Ga) chloride solution should only be handled by specialists with appropriate training and expertise and can only be used in a designated authorised facility. Detailed instructions for use are included in the Summary of Product Characteristics (information for healthcare professionals).

How does GalliaPharm work?

GalliaPharm provides a gallium (^{68}Ga) chloride solution, which is used for radiolabelling other medicines. These radiolabelled medicines can recognise and attach to certain cells in the body. The low amount of radioactivity present in the ^{68}Ga-labelled medicine can be detected during PET body scans, helping doctors with the diagnosis and monitoring of various diseases, including cancer.

What benefits of GalliaPharm have been shown in studies?

Since ^{68}Ga-containing solutions obtained from ^{68}Ge / ^{68}Ga-generators have been used for radiolabelling for several years, the company that markets GalliaPharm provided data from the medical literature showing its utility in clinical practice. The company also provided data on the quality of the medicine, and data from an animal model (rats) showing that, due to the extremely low amount of ^{68}Ga, no

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effects are expected even after accidental injection of the radioactive solution obtained from GalliaPharm.

What are the risks associated with GalliaPharm?

Exposure to radiation may contribute to a risk of cancer or hereditary defects.

Side effects following the use of a medicine radiolabelled using the gallium (^{68}Ga) chloride solution obtained from GalliaPharm will depend on the specific medicine being used. For more information about possible side effects, read the package leaflet of the respective radiolabelled medicine.

Why is GalliaPharm authorised in the EU?

^{68}Ga has a short half-life, meaning that it quickly loses the radioactivity necessary for radiolabelling. The use of a ^{68}Ge/^{68}Ga generator such as GalliaPharm is a suitable way to make gallium (^{68}Ga) chloride solution readily available for radiolabelling. GalliaPharm is expected to facilitate the process of radiolabelling in authorised facilities and to improve access to cancer diagnostics, which is considered a clinically relevant benefit. Potential risks to patients are considered low, as these can be minimised through quality control procedures and adequate instructions and training of the medical personnel handling GalliaPharm.

The European Medicines Agency therefore decided that GalliaPharm's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of GalliaPharm?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of GalliaPharm have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of GalliaPharm are continuously monitored and any necessary action will be taken to protect patients.

Other information about GalliaPharm

GalliaPharm received a marketing authorisation valid throughout the EU on 01 August 2024.

Further information on GalliaPharm can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/galliapharm.

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