30 May 2024
EMA/CHMP/149530/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

GalliaPharm

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

On 30 May 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product GalliaPharm, a radionuclide generator. GalliaPharm is not intended for direct use in patients and must be used only for *in vitro* radiolabelling of various kits for radiopharmaceutical preparation. The applicant for this medicinal product is Eckert & Ziegler Radiopharma GmbH.

GalliaPharm will be available as a 1.11, 1.48, 1.85, 2.22, 2.59, 2.96, 3.33 and 3.70 GBq radionuclide generator. Galliapharm uses germanium (^{68}Ge) to generate a gallium (^{68}Ga) chloride solution for radiolabelling. This solution contains gallium (^{68}Ga), a positron-emitting radioisotope (ATC code: V09X), that is used to label a carrier medicinal product. Gallium (^{68}Ga)-labelled carrier molecules are applied in positron emission tomography (PET) imaging.

As shown in the medical literature, gallium (^{G8}Ga) labelled carrier medicinal products are effective in the diagnosis of neuroendocrine tumours (NETs, primarily in gastroenteropancreatic NETs, i.e., GEP-NETs) and prostate cancer (primary imaging, recurrence diagnostics). The safety of the radionuclide generator GalliaPharm depends on its technical features and functioning. Increased exposure to germanium (^{68}Ge) resulting from germanium (^{68}Ge) breakthrough may occur if the radionuclide generator is not used and maintained adequately. This may lead to increased and prolonged radiation exposure. Unfavourable effects relating to the use of gallium (^{68}Ga) depend on the carrier medicinal product labelled with the radionuclide. Gallium (^{68}Ga) emits radiation that contributes to a risk of cancer or hereditary abnormalities. Information on the radiation exposure and unfavourable effects will be supplied in the summary of product characteristics (SmPC) of the kit for radiopharmaceutical preparation of these carrier medicinal products.

The full indication is:

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

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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The sterile eluate (gallium (^{68}Ga) chloride solution for radiolabelling) 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.

GalliaPharm should only be used in designated nuclear medicine facilities and only be handled by specialists experienced with *in vitro* radiolabelling.

Detailed recommendations for the use of this product will be described in the SmPC, which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.