



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 November 2025
EMA/354268/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

GalenVita

germanium (⁶⁸Ge) chloride / gallium (⁶⁸Ga) chloride

On 13 November 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product GalenVita, a radionuclide generator. GalenVita is used to produce gallium (⁶⁸Ga) chloride solution, that is applied for *in vitro* radiolabelling of various kits for radiopharmaceutical preparation. Gallium (⁶⁸Ga) chloride solution is not intended for direct use in patients.

The applicant for this medicinal product is Curium Romania SRL.

GalenVita will be available as a 0.74 GBq, 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 radionuclide generator. GalenVita uses germanium (⁶⁸Ge) to generate a gallium (⁶⁸Ga) chloride solution for radiolabelling. This solution contains gallium (⁶⁸Ga), a positron-emitting radioisotope (ATC code: V09X), that is used to label a carrier medicinal product. Gallium (⁶⁸Ga)-labelled carrier molecules are applied in positron emission tomography (PET) imaging.

As shown in the medical literature, gallium (⁶⁸Ga) labelled carrier medicinal products are effective in the diagnosis of neuroendocrine tumours (NETs, primarily in gastroenteropancreatic NETs, i.e., GEP-NETs) meningiomas and prostate cancer (primary staging and diagnosis of recurrence). The safety of the radionuclide generator GalenVita depends on its technical features and functioning. Increased exposure to germanium (⁶⁸Ge) resulting from germanium (⁶⁸Ge) 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 (⁶⁸Ga) depend on the carrier medicinal product labelled with the radionuclide. Gallium (⁶⁸Ga) 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



The sterile eluate (gallium (^{68}Ga) chloride solution) from the radionuclide generator GalenVita 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.

GalenVita 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 on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.