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

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

What is GalenVita and what is it used for?

GalenVita is a radionuclide generator, a device used to obtain a solution containing gallium (^{68}Ga) chloride, a radioactive substance. GalenVita and the gallium (^{68}Ga) chloride solution it produces are not intended for direct use in patients.

The gallium (^{68}Ga) chloride solution is used for radiolabelling 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.

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

How is GalenVita used?

GalenVita and the gallium (^{68}Ga) chloride solution it produces 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 GalenVita work?

GalenVita provides a gallium (^{68}Ga) chloride solution, which is used for radiolabelling 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 GalenVita 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 GalenVita provided data from the medical literature showing its utility in clinical practice, mainly in the diagnosis of neuroendocrine tumours (cancers that form from cells that release hormones), meningiomas (a tumour that grows from the membranes that surround the brain and spinal cord, called the meninges) and prostate cancer.

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What are the risks associated with GalenVita?

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 GalenVita 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 GalenVita 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 GalenVita is a suitable way to make gallium (^{68}Ga) chloride solution readily available for radiolabelling. GalenVita 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 GalenVita.

The European Medicines Agency therefore decided that GalenVita'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 GalenVita?

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

As for all medicines, data on the use of GalenVita are continuously monitored. Suspected side effects reported with GalenVita are carefully evaluated and any necessary action taken to protect patients.

Other information about GalenVita

GalenVita received a marketing authorisation valid throughout the EU on 8 January 2026.

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

This overview was last updated in 01-2026.