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Locametz *(gozetotide)*

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

What is Locametz and what is it used for?

Locametz is a diagnostic medicine used in adults with prostate cancer to detect prostate cancer cells with a protein called prostate-specific membrane antigen (PSMA) using the body scan known as positron-emission tomography (PET).

It is used:

- to find out whether prostate cancer has spread to lymph nodes and other tissues outside the prostate before curative treatment is started;
- to find out whether prostate cancer has returned in patients whose blood levels of prostate specific antigen (PSA) are increasing after previous curative treatment;
- to find out whether patients have PSMA-positive progressive metastatic castration-resistant prostate cancer, which may be suitable for a specific therapy called PSMA-targeted therapy. Metastatic castration-resistant prostate cancer is cancer that has spread to other parts of the body despite treatment to lower testosterone levels, including surgical removal of the testes.

Before use, the medicine is coupled (radiolabelled) with a radioactive substance called gallium (^{68}Ga) so that it can carry radioactivity to the site of the cancer cells and allow detection of these cells using PET.

Locametz contains the active substance gozetotide.

How is Locametz used?

The medicine can only be given in a designated nuclear medicine facility by trained healthcare professionals with technical expertise in using and handling nuclear medicine imaging agents.

Locametz is never given to a patient on its own. Before it is given it must be radiolabelled with gallium (^{68}Ga). The radiolabelled Locametz is then given as a slow injection into a vein at a dose depending on the patient's weight, and a PET scan is done after the injection.

For more information about using Locametz, see the package leaflet or contact your doctor or pharmacist.

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How does Locametz work?

The active substance of Locametz, gozetotide, binds to PSMA, which is found in large numbers on the surface of most prostate cancer cells. When Locametz is radiolabelled with gallium (^{68}Ga) and given to a patient, it binds to PSMA and is taken up by the cells and gives off radiation, which can be detected with a PET scan. This allows the doctors to see where in the body the cancer cells are.

What benefits of Locametz have been shown in studies?

Several published studies have supported the usefulness of gozetotide that has been radiolabelled with gallium (^{68}Ga) as a sensitive and accurate diagnostic medicine to detect if prostate cancer has returned or spread or if cancer cells contain PSMA.

What are the risks associated with Locametz?

The most common side effects with gallium (^{68}Ga)-radiolabelled Locametz are tiredness (which may affect up to 1 in 10 people), nausea (feeling sick), constipation and vomiting (which may affect up to 1 in 100 people).

For the full list of side effects and restrictions with Locametz, see the package leaflet.

Why is Locametz authorised in the EU?

The European Medicines Agency considered that the use of gallium (^{68}Ga)-radiolabelled Locametz was well documented in the scientific literature, with data suggesting that gallium (^{68}Ga)-radiolabelled Locametz may offer improvements over existing methods for detecting prostate cancer that has not yet been treated or has returned, or for screening patients who may benefit from PSMA-targeted treatment. Locametz's side effects were usually mild and its safety profile was considered acceptable. The Agency therefore decided that Locametz'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 Locametz?

The company that markets Locametz will provide medical practitioners who are expected to use gallium (^{68}Ga)-radiolabelled Locametz with educational materials to support interpretation of PET scans.

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

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

Other information about Locametz

Locametz received a marketing authorisation valid throughout the EU on 09 December 2022.

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

This overview was last updated in 12-2022.