swissmedic

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Locametz® (active substance: gozetotide)

First authorisation in Switzerland: 3 March 2023

Medicinal product (multiple-dose kit) for diagnostic use in adults with prostate cancer

About the medicinal product

The medicinal product Locametz, containing the active substance gozetotide, is intended for diagnostic purposes.

The medicinal product is coupled (radiolabelled) with a radioactive substance called gallium-68. This enables PSMA[1]-positive lesions (tissue damage) to be identified in adults with prostate cancer by means of positron emission tomography (PET)[2].

Prostate cancer is the second most frequent type of cancer in men: in 2020, there were 1.4 million diagnoses worldwide.

Locametz was authorised in connection with "Project Orbis". Project Orbis is a programme for promising cancer treatments coordinated by the FDA, the US regulatory authority. It provides a framework for the concurrent submission and review of cancer medicines by several international partner authorities in various countries. The ultimate aim is to give patients faster access to innovative cancer treatments. Currently, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Israel (MOH), Canada (HC), Singapore (HSA), Switzerland (Swissmedic), and the United Kingdom (MHRA) are represented in Project Orbis.

Mode of action

The active substance of Locametz which is radiolabelled with gallium-68 (68+Ga gozetotide) binds to cells, including prostate cancer cells, that have a particular structure (known as PSMA). PSMA is found in large amounts on the surface of most prostate cancer cells. As the medicinal product binds to the target structure (PSMA), the radioactivity is carried (via the coupled gallium-68 component) to the site of the cancer cells. These cells are then visibile in a PET-CT scan (a PET scan combined with a computed tomography scan).

[1] PSMA: prostate-specific membrane antigen

[2] PET: Positron emission tomography (PET) is a body scan used to show metabolic activity in the tissue.

Indication

Locametz, containing the active substance gozetotide, is a prescription-only medicine. It is used exclusively in institutions that are allowed to use radioactive substances.

Locametz is a multiple-dose kit to prepare a solution that is injected into the veins.

The recommended dose of Locametz is 1.8-2.2 MBq[3]/kg body weight.

It is administered by appropriately qualified professional medical staff.

Efficacy

Efficacy is assessed mainly on the basis of already existing research data.

Two studies have provided sufficient evidence that Locametz is effective in diagnosing prostate cancer. One study (Study 1) investigated the use of Locametz in patients with high-risk[4] prostate cancer before a curative operation or radiotherapy. This method was more accurate than traditional imaging, such as computed tomography or bone scintigraphy[5].

The second study (Study 2) showed the efficacy of Locametz in men with previously treated prostate cancer and in whom a relapse was suspected. Cancer cells were found in 92% of the patients.

Two further meta-analyses[6] confirmed the results in initial diagnosis and diagnosis of disease relapse.

A third study (VISION Study) investigated the use of Locametz in 1003 patients with metastatic prostate cancer, in order to identify them for subsequent PSMA-targeted radioligand therapy[7]. 831 patients were thereby identified.

Precautions, undesirable effects, & risks

Locametz must not be used in those who are hypersensitive to the active substance or any of the excipients.

Locametz contributes to patients' total long-term cumulative radiation exposure. This is associated with an increased risk of cancer.

The most frequent undesirable effect of Locametz was fatigue, which was observed in 1.2% of patients.

No serious adverse drug reactions occurred.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

[3] MBq: a mega-Becquerel is the unit of activity of a determined quantity of a radioactive substance. M stands for "mega", i.e. one million

[4] High-risk cancer: Very aggressive form of tumour

[5] Bone scintigraphy: Imaging procedure to show areas in the bone with increased bone metabolism such as occurs in metastasis (the spread of cancer to other tissues).

[6] Meta-analyses: Research method that evaluates previous research into a particular research topic.

[7] Radioligand therapy: Nuclear medical treatment of PSMA-positive prostate cancer

Why the medicinal product has been authorised

Prostate cancer is the second most frequent cancer diagnosis in men and in the event of metastasis is frequently fatal. Despite progress in imaging procedures, there continue to be difficulties in the diagnosis and staging of prostate tumours. Locametz binds to PSMA and allows PSMA-positive tumours to be detected by PET. This improves treatment and shows if the PSMA therapy is suitable.

Taking all the risks and precautions into account, and based on the available data, the benefits of Locametz outweigh the risks for the described area of application.

Swissmedic has therefore authorised the medicinal product Locametz, containing the active substance gozetotide, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Locametz®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.