Package leaflet: Information for the patient

Locametz® 25 micrograms kit for radiopharmaceutical preparation
gozetotide

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Locametz is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only.

Locametz contains a substance called gozetotide. Before use, gozetotide (the powder in the vial) is mixed with a radioactive substance called gallium-68 to make gallium (^{68}Ga) gozetotide solution (this procedure is called radiolabelling). After radiolabelling, gallium (^{68}Ga) gozetotide is used in adult patients to identify prostate cancer lesions that express a protein called prostate-specific membrane antigen (PSMA).

By binding to cells that express PSMA, gallium (^{68}Ga) gozetotide makes these parts of the body visible to doctors during a medical imaging procedure called positron emission tomography (PET). The images of your organs obtained with PET allow your doctor to locate abnormal cells or tumours, giving valuable information about your disease.

The use of Locametz involves exposure to a small amount of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

If you have any questions about how Locametz works or why this medicine has been prescribed for you, ask your nuclear medicine doctor.

2. What you need to know before Locametz is used

Locametz must not be used
- if you are allergic to gozetotide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your nuclear medicine doctor before you receive Locametz if you:
- have any other type of cancer or any other non-malignant condition, as these could affect the interpretation of the image. Your nuclear medicine doctor will take into account your serum level of PSA for Locametz imaging and interpretation.

The use of Locametz involves exposure to a small amount of radioactivity. Long-term cumulative radiation exposure contributes to an increased risk of cancer. Your nuclear medicine doctor will explain the necessary radioprotection measures to you (see section 3).

Before administration of Locametz you should
Drink plenty of water in order to urinate immediately before and as often as possible during the first hours after the examination, in order to eliminate the radiopharmaceutical product from your body.

Children and adolescents
This medicine should not be given to children or adolescents aged under 18 years because no data are available in this age group.

Pregnancy and breast-feeding
Locametz is not intended for use in women. All radiopharmaceuticals, including Locametz, have the potential to cause harm to an unborn baby.

Driving and using machines
It is considered unlikely that Locametz will affect your ability to drive or to use machines.

Locametz contains sodium
This medicine contains 28.97 mg sodium (main component of cooking/table salt) in each injection. This is equivalent to 1.5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Locametz is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Locametz will only be used in special controlled areas. This radiopharmaceutical product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this radiopharmaceutical product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of Locametz to be used in your case. It will be the smallest quantity necessary to get the desired information.

The quantity to be administered usually recommended for an adult is 1.8-2.2 MBq/kg of body weight, ranging from a minimum quantity of 111 MBq up to a maximum quantity of 259 MBq (MBq, megabecquerel, the unit used to express radioactivity).

Administration of Locametz and conduct of the procedure
After radiolabelling, Locametz is administered by slow intravenous injection. One injection is sufficient to conduct the test that your nuclear medicine doctor needs. You will undergo a PET scan starting 50 to 100 minutes after Locametz administration.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure.

After administration of Locametz, you should:
- drink plenty of water to urinate frequently during the first hours after the examination, in order to eliminate the radiopharmaceutical product from your body.

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more Locametz than you should
An overdose is unlikely because you will only receive a single dose of Locametz precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the event of an overdose, you will receive the appropriate treatment. You may be asked to drink and urinate frequently in order to eliminate the radiopharmaceutical product from your body.

Should you have any further question on the use of Locametz, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be serious

Side effects include the following listed below. If these side effects become serious, **tell your nuclear medicine doctor immediately.**

Common (may affect up to 1 in every 10 people)
- tiredness (fatigue)

Uncommon (may affect up to 1 in every 100 people)
- nausea
- constipation
- vomiting
- diarrhoea
- dry mouth
- a reaction at the site where an injection was given, which may cause some redness, swelling and warmth (injection site reactions)
- chills

This radiopharmaceutical product will deliver low amounts of ionising radiation associated with the least risk of cancer and hereditary abnormalities.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How Locametz is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceutical products will be in accordance with national regulations on radioactive materials.

The following information is intended for the specialist only.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Before reconstitution, store below 25°C.

After reconstitution, store upright below 30°C. Use within 6 hours.

6. Contents of the pack and other information

What Locametz contains
Locametz contains gozetotide. One vial contains 25 micrograms of gozetotide.
The other ingredients are: gentisic acid, sodium acetate trihydrate and sodium chloride. See "Locametz contains sodium" in section°2.

What Locametz looks like and contents of the pack
Locametz is a multidose kit for radiopharmaceutical preparation. It is supplied as one glass vial containing a white freeze-dried powder .

For radiolabelling with gallium-68 chloride solution. Gallium-68 is not part of the kit.

After reconstitution and radiolabelling, Locametz contains a sterile solution for injection of gallium (^{68}Ga) gozetotide at an activity of up to 1,369 MBq.

After reconstitution, the solution obtained also contains hydrochloric acid.

Pack size: 1 vial.

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The following information is intended for healthcare professionals only:

The complete SmPC of Locametz is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.