

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

LOCAMETZ™

25 micrograms, kit for radiopharmaceutical preparation of gallium (⁶⁸Ga) gozetotide solution for injection

Read this carefully before you start taking **LOCAMETZ™**. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LOCAMETZ**.

Serious Warnings and Precautions

- Because gallium (⁶⁸Ga) gozetotide solution for injection is a radiopharmaceutical (radioactive substance), it can only be given by doctors and other health professionals who are specially trained and experienced in the safe use and handling of these substances.

What is LOCAMETZ used for?

This medicine is a radiopharmaceutical product for diagnostic use only.

LOCAMETZ contains gozetotide. Before use, the powder in the vial is mixed with a radioactive substance called gallium-68 to make gallium (⁶⁸Ga) gozetotide solution (this procedure is called radiolabeling).

- After radiolabeling, gallium (⁶⁸Ga) gozetotide is used in adult patients to identify prostate cancer lesions expressing a protein called prostate-specific membrane antigen (PSMA).

How does LOCAMETZ work?

By binding to cells that express PSMA, gallium (⁶⁸Ga) gozetotide makes these parts of the body visible to doctors during a medical imaging procedure called positron emission tomography (PET). PET allows your doctor to obtain images of your organs to help locate abnormal cells or tumors 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.

What are the ingredients in LOCAMETZ?

Medicinal ingredient: gozetotide. One vial contains 25 micrograms of gozetotide.

Non-medicinal ingredients: gentisic acid, sodium acetate trihydrate and sodium chloride.

LOCAMETZ comes in the following dosage forms:

Kit for radiopharmaceutical preparation of gallium (⁶⁸Ga) gozetotide solution for injection, 25 micrograms.

Do not use LOCAMETZ if:

- If you are allergic to gallium (^{68}Ga) gozetotide or any of the other ingredients of this medicine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LOCAMETZ. Talk about any health conditions or problems you may have, including if you:

- If you have any other type of cancer or any other non-malignant condition as these could affect the interpretation of the image;
- Have signs of dehydration (feeling very thirsty) before or after the examination;
- Have any other medical condition as these could affect the interpretation of the image.

Other warnings you should know about:

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 How to take LOCAMETZ).

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 product from your body.

Children and adolescents (below 18 years)

The safety and efficacy of this medicine have not been established in children and adolescents under 18 years of age.

Older people (65 years of age or above)

You can use LOCAMETZ if you are aged 65 years or over at the same dose as for other adults.

Pregnancy and breast-feeding

LOCAMETZ is not indicated for use in women. All radiopharmaceuticals, including LOCAMETZ, have the potential to cause harm to an unborn baby.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**The following may interact with LOCAMETZ:**

- There is no information available about the use of LOCAMETZ in combination with other medicines.

How to take LOCAMETZ:

- There are strict laws on the use, handling and disposal of radiopharmaceutical products. LOCAMETZ will only be used in special controlled areas. This medicine will only be handled and given to you by healthcare professionals who are trained and qualified to use it safely. They will take special care for the safe use of this medicine and will keep you informed of their actions.

Usual dose:

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 recommended dose for an adult is 1.8 to 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 procedure

After radiolabeling, LOCAMETZ is administered by slow intravenous injection. One injection is sufficient to conduct the test that your nuclear medicine doctor needs.

Duration of the procedure

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

After administration of LOCAMETZ

Drink plenty of water to urinate frequently during the first hours after the examination in order to eliminate the 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.

Overdose:

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 case of an overdose, you will receive the appropriate treatment. You may be asked to drink and urinate frequently, in order to eliminate the product from your body.

If you have any further questions on the use of LOCAMETZ, ask the nuclear medicine doctor who supervises the procedure.

What are possible side effects from using LOCAMETZ?

These are not all the possible side effects you may have when taking LOCAMETZ. If you experience any side effects not listed here, tell your healthcare professional.

LOCAMETZ will deliver low amounts of ionizing radiation associated with the least risk of cancer and hereditary abnormalities.

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
- diarrhea
- dry mouth
- a reaction at the site where an injection was given, which may cause some redness, swelling and warmth (injection site reactions)
- chills

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in the hospital. Storage of radiopharmaceuticals are in accordance with national regulations on radioactive materials.

If you want more information about LOCAMETZ:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (<https://www.novartis.ca>) or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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LOCAMETZ is a trademark.