GB Prescribing Information: Locametz®▼ (gozetotide) 25 micrograms kit for radiopharmaceutical preparation

Important note: Before prescribing, consult Summary of Product Characteristics (SmPC).

Presentation: Kit for radiopharmaceutical preparation containing one vial of white lyophilised powder (powder for solution for injection). For radiolabelling with gallium-68 chloride solution.

Indication(s): This medicinal product is for diagnostic use only. Locametz, after radiolabelling with gallium-68, is a radioactive diagnostic agent for the identification of prostate-specific membrane antigen (PSMA)-positive lesions by positron emission tomography (PET) in adult patients with prostate cancer.

Dosage and administration: The recommended dose of gallium (^{68}Ga) gozetotide is 1.8-2.2 MBq/kg body weight (minimum dose 111 MBq, maximum dose 259 MBq). After reconstitution, gallium (^{68}Ga) gozetotide solution should be administered by slow intravenous injection, in order to avoid local extravasation resulting in inadvertent radiation exposure to the patient and imaging artefacts. Accidental extravasation may cause local irritation, due to the acidic pH of the solution. The total radioactivity in the syringe should be verified with a dose calibrator immediately before and after administration to the patient. Gallium (^{68}Ga) gozetotide PET image acquisition should be performed by scanning the whole body starting at mid-thigh and proceeding to skull base. PET images should be acquired 50 to 100 minutes after the intravenous administration of gallium (^{68}Ga) gozetotide solution.

Contraindications: Hypersensitivity to the active substance, or excipients or to any of the components of the labelled product.

Warnings/Precautions: For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should be as low as reasonably achievable to obtain the required diagnostic information. Gallium (^{68}Ga) gozetotide contributes to the patient's overall long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Safe handling and reconstitution procedures should be ensured to protect patients and healthcare professionals from unintentional radiation exposure.

While the uptake of gallium (^{68}Ga) gozetotide reflects the levels of PSMA expression in prostate cancer, gallium (^{68}Ga) gozetotide uptake is not specific to prostate cancer and may occur in other types of cancers, non-malignant processes and normal tissues. Interpretation of gallium (^{68}Ga) gozetotide PET imaging findings in the context of histopathology and/or other diagnostic procedures is recommended. The diagnostic performance of gallium (^{68}Ga) gozetotide may be affected by serum PSA levels.

Patients should be well hydrated prior to gallium (^{68}Ga) gozetotide administration and should be advised to void immediately prior to and frequently during the first hours after image acquisition in order to reduce radiation exposure.

This medicinal product contains 28.97 mg sodium per injection, equivalent to 1.5% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Interactions: Based on *in vitro* interaction studies, gallium (^{68}Ga) gozetotide is not expected to have any clinically significant interaction with other medicinal products.

Fertility, pregnancy and lactation: Locametz is not indicated for use in females. There are no data on the effect of gallium (^{68}Ga) gozetotide on human fertility.

Undesirable effects: Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 0.0166 mSv/MBq, with a maximal recommended dose of 259 MBq (4.3 mSv), these adverse reactions are expected to occur with a low probability.

Common (≥1/100 to <1/10): fatigue. *Uncommon (≥1/1,000 to <1/100)*: nausea, constipation, vomiting, diarrhoea, dry mouth, injection site reactions, chills

Other Adverse Effects: Please consult the Summary of Product Characteristics for a detailed listing of all adverse events before prescribing.

Legal classification: POM

Marketing Authorisation (MA) number, quantities and price: PLGB 35903/0002 – 1 vial: £1,950.00

Date of last revision of prescribing information: 15.08.2022

Marketing Authorisation (MA) address: Advanced Accelerator Applications (UK and Ireland) Ltd, Edison House,223-231, Old Marylebone Road, Marylebone, London NW1 5QT, United Kingdom. Telephone: +44 (0)20 7258 5200

Full Prescribing Information available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

Adverse Event Reporting:
Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis via uk.patientsafety@novartis.com or online through the pharmacovigilance intake (PVI) tool at www.report.novartis.com

If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com