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INFORMATION



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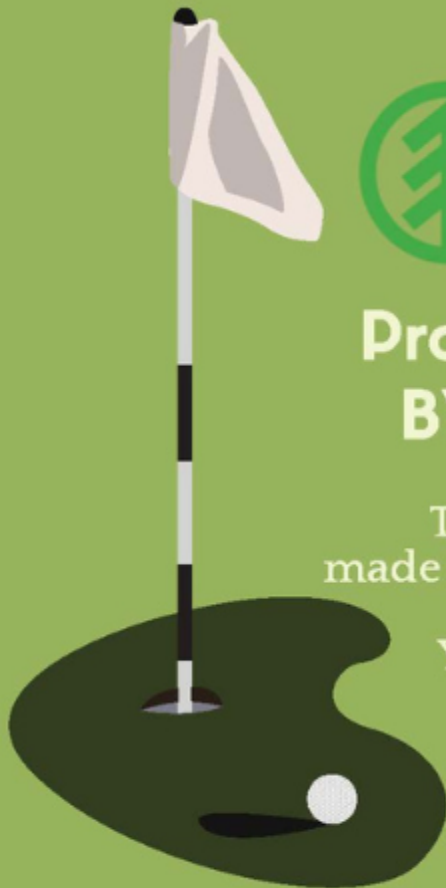


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References: 1. illuccix (kit for the preparation of gallium Ga 68 gozetotide injection) prescribing information. 2. Hope TA, Elbar M, Armstrong WR, et al. Diagnostic accuracy of ⁶⁸Ga-PSMA-11 PET for pelvic nodal metastasis detection prior to radical prostatectomy and pelvic lymph node dissection: a multicenter prospective phase 3 imaging trial. *JAMA Oncol.* 2021;7(10):1635-1642. 3. Hofmeier MS, Laurentschuk N, Francis RJ, et al. Prostate-specific membrane antigen PET-CT in patients with high-risk prostate cancer before curative-intent surgery or radiotherapy (proPSMA): a prospective, randomised, multicentre study. *Lancet.* 2020;395(10231):1208-1216. 4. Velikyan I. ⁶⁸Ga-based radiopharmaceuticals: production and application relationship. *Molecules.* 2015;20(7):12813-12943. 5. Data on File. Isotope Decay Rates. Telix Pharmaceuticals. 2022. 6. Massat MB. Nuclear medicine prepares for greater ⁶⁸Ga demand. *Appl Radiat.* 2022;50(2):30-31. <https://appliedradiology.com/articles/nuclear-medicine-prepares-for-greater-ga-68-demand>. Accessed June 9, 2023. 7. Data on File. Activated Sites. Telix Pharmaceuticals. 2023. 8. Data on File. Distribution Metrics. Telix Pharmaceuticals. 2023. 9. Data on File. Delivery. Telix Pharmaceuticals. 2022.

INDICATIONS AND USAGE

ILLUCIX, after radiolabeling with Ga-68, is for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- With suspected metastasis who are candidates for initial definitive therapy
- With suspected recurrence based on elevated serum prostate-specific antigen (PSA) level
- For selection of patients who are indicated for PSMA-directed therapy as described in the prescribing information of the therapeutic products

IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS

Risk for Misinterpretation

Image interpretation errors can occur with ILLUCIX PET. A negative image does not rule out the presence of prostate cancer, and a positive image does not confirm the presence of prostate cancer. Gallium Ga-68 gozetotide uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes such as Paget's disease, fibrous dysplasia, and osteomyelitis. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended.

Imaging Prior to Initial Definitive or Suspected Recurrence Therapy

The performance of ILLUCIX for imaging of biochemically recurrent prostate cancer seems to be affected by serum PSA levels and by site of disease. The performance of ILLUCIX for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by Gleason score.

Radiation Risks

Gallium Ga-68 gozetotide contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Ensure safe handling to minimize radiation to the patient and healthcare providers. Advise patients to hydrate before and after administration and to void frequently after administration.

Adverse Reactions

The safety of gallium Ga-68 gozetotide was evaluated in 360 patients in the PSMA-Pivotal and PSMA-ECIS studies, each receiving one dose of gallium Ga-68 gozetotide. The average injected activity was 188.7 ± 40.7 MBq (5.1 ± 1.1 mCi). The most commonly reported adverse reactions were nausea, diarrhea, and dizziness, occurring at a rate of <1%.

In the VISION study, 1003 patients received one dose of gallium Ga-68 gozetotide intravenously with the amount of radioactivity 1071 ± 231 MBq (4.52 ± 0.62 mCi). Adverse reactions occurring at ≥0.5% in patients with metastatic prostate cancer who received gallium Ga-68 gozetotide injection in the clinical study were fatigue (3.2%), nausea (0.05%), constipation (0.5%), and vomiting (0.5%).

Adverse reactions occurring at a rate of < 0.5% in the VISION study were diarrhea, dry mouth, injection site reactions, including injection site hematoma and injection site warmth and chills.

Injection site pain has been identified during postapproval use of ILLUCIX.

Drug Interactions

Androgen deprivation therapy and other therapies targeting the androgen pathway, such as androgen receptor antagonists, can result in changes in uptake of gallium Ga-68 gozetotide in prostate cancer. The effect of these therapies on performance of gallium Ga-68 gozetotide PET has not been established.

Please note that this information is not comprehensive.

Please see the full Prescribing Information at illuccix.com/prescribinginformation

You are encouraged to report suspected adverse reactions of prescription drugs to the FDA. Visit MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report adverse reactions to Telix Pharmaceuticals (US) by calling 1-844-455-0600 or emailing pharmacovigilance@telixpharma.com.



*It's often said that laughter
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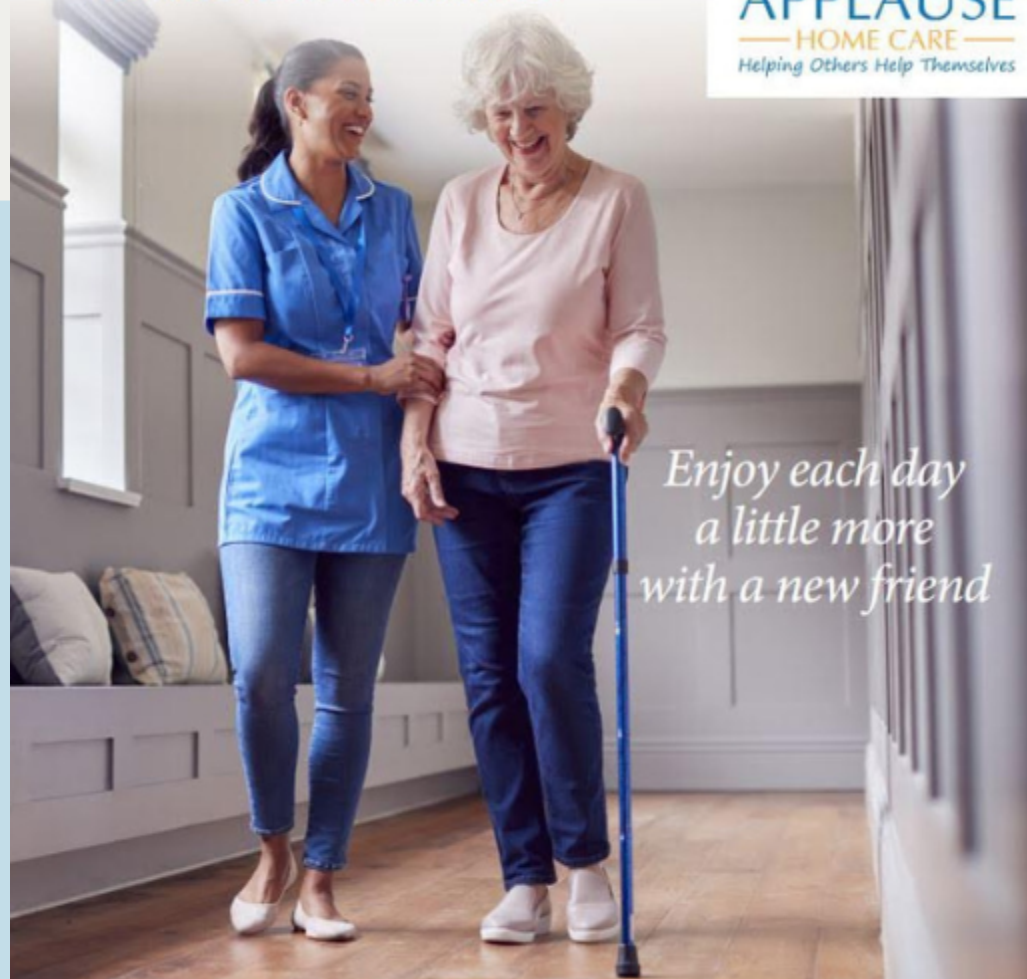
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