

XOFIGO® IS INDICATED for the treatment of patients with castration-resistant prostate cancer (CRPC), symptomatic bone metastases and no known visceral metastatic disease.



Introduce Xofigo at progression to mCRPC with symptomatic bone metastases and no visceral disease on an AR pathway inhibitor^{1*}

Routine monitoring requirements for your patients with mCRPC on Xofigo



*In ALSYMPCA, best standard of care (BSOC) was defined as antiandrogens, local external beam radiation therapy (EBRT), ketoconazole, and treatment with glucocorticoids.²

Important Safety Information

Warnings and Precautions:

- **Bone Marrow Suppression:** In the phase 3 ALSYMPCA trial, 2% of patients in the Xofigo arm experienced bone marrow failure or ongoing pancytopenia, compared to no patients treated with placebo. There were two deaths due to bone marrow failure.

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Important Safety Information for Xofigo®

Important Safety Information (cont'd)

Warnings and Precautions (cont'd):

- **Bone Marrow Suppression** (cont'd): For 7 of 13 patients treated with Xofigo bone marrow failure was ongoing at the time of death. Among the 13 patients who experienced bone marrow failure, 54% required blood transfusions. Four percent (4%) of patients in the Xofigo arm and 2% in the placebo arm permanently discontinued therapy due to bone marrow suppression. In the randomized trial, deaths related to vascular hemorrhage in association with myelosuppression were observed in 1% of Xofigo-treated patients compared to 0.3% of patients treated with placebo. The incidence of infection-related deaths (2%), serious infections (10%), and febrile neutropenia (<1%) was similar for patients treated with Xofigo and placebo. Myelosuppression—notably thrombocytopenia, neutropenia, pancytopenia, and leukopenia—has been reported in patients treated with Xofigo.

Monitor patients with evidence of compromised bone marrow reserve closely and provide supportive care measures when clinically indicated. Discontinue Xofigo in patients who experience life-threatening complications despite supportive care for bone marrow failure

- **Hematological Evaluation:** Monitor blood counts at baseline and prior to every dose of Xofigo. Prior to first administering Xofigo, the absolute neutrophil count (ANC) should be $\geq 1.5 \times 10^9/L$, the platelet count $\geq 100 \times 10^9/L$, and hemoglobin ≥ 10 g/dL. Prior to subsequent administrations, the ANC should be $\geq 1 \times 10^9/L$ and the platelet count $\geq 50 \times 10^9/L$. Discontinue Xofigo if hematologic values do not recover within 6 to 8 weeks after the last administration despite receiving supportive care
- **Concomitant Use With Chemotherapy:** Safety and efficacy of concomitant chemotherapy with Xofigo have not been established. Outside of a clinical trial, concomitant use of Xofigo in patients on chemotherapy is not recommended due to the potential for additive myelosuppression. If chemotherapy, other systemic radioisotopes, or hemibody external radiotherapy are administered during the treatment period, Xofigo should be discontinued

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Follow appropriate drug handling

- Xofigo® injection should be received, used, and administered by authorized persons in designated clinical settings¹
- The receipt, storage, use, transfer, and disposal of Xofigo are subject to the regulations and/or appropriate licenses of the competent official organization¹
- Follow normal procedures for the handling of radiopharmaceuticals and use precautions, such as gloves and barrier gowns, when handling blood and bodily fluids, to avoid contamination¹
- In case of contact with skin or eyes, flush immediately with water¹
- If spillage occurs, contact the local radiation safety officer immediately to initiate decontamination¹
 - 0.01 M EDTA solution is recommended to remove contamination

EDTA=Ethylene-Diamine-Tetraacetic Acid.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd):

- **Increased Fractures and Mortality in Combination With Abiraterone Plus Prednisone/ Prednisolone:** Xofigo is not recommended for use in combination with abiraterone acetate plus prednisone/prednisolone outside of clinical trials. At the primary analysis of the phase 3 ERA-223 study that evaluated concurrent initiation of Xofigo in combination with abiraterone acetate plus prednisone/prednisolone in 806 asymptomatic or mildly symptomatic mCRPC patients, an increased incidence of fractures (28.6% vs 11.4%) and deaths (38.5% vs 35.5%) have been observed in patients who received Xofigo in combination with abiraterone acetate plus prednisone/prednisolone compared to patients who received placebo in combination with abiraterone acetate plus prednisone/prednisolone. Safety and efficacy with the combination of Xofigo and agents other than gonadotropin-releasing hormone analogues have not been established
- **Embryo-Fetal Toxicity:** The safety and efficacy of Xofigo have not been established in females. Xofigo can cause fetal harm when administered to a pregnant female. Advise pregnant females and females of reproductive potential of the potential risk to a fetus. Advise male patients to use condoms and their female partners of reproductive potential to use effective contraception during and for 6 months after completing treatment with Xofigo

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Contact Xofigo® Access Services to order today

Ordering Xofigo®:

A simple 3-step process

1. Contact Xofigo Access Services
 - Submit appropriate enrollment form
 - Xofigo Access Services completes benefits investigation
2. Receive confirmation
 - Confirms patient treatment date
3. Order Xofigo
 - Your call is transferred to Cardinal Health Nuclear Pharmacy Services for actual order placement



To contact Xofigo Access Services, call **1-855-6XOFIGO (1-855-696-3446)** or visit **www.hcp.xofigo-us.com**

Counselors are available from 9:00 AM to 7:00 PM ET, Monday through Friday

Patient Support

- Patient copay and reimbursement support for eligible patients
- Travel assistance for patients to and from the treatment site^a
- Scheduling and logistics

^aXofigo Access Services offers referrals to third-party travel assistance programs; eligibility criteria apply.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd):

Administration and Radiation Protection: Xofigo should be received, used, and administered only by authorized persons in designated clinical settings. The administration of Xofigo is associated with potential risks to other persons from radiation or contamination from spills of bodily fluids such as urine, feces, or vomit. Therefore, radiation protection precautions must be taken in accordance with national and local regulations

References: 1. Xofigo® (radium Ra 223 dichloride) injection [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; December 2019. 2. Parker C, Nilsson S, Heinrich D, et al. Alpha emitter radium-223 and survival in metastatic prostate cancer. *N Engl J Med.* 2013;369(3):213-223. 3. United States Nuclear Regulatory Commission. Revision to the National Institute of Standards and Technology standard for radium-223 and impact on dose calibration for the medical use of radium-223 dichloride. <https://www.nrc.gov/docs/ML1526/ML15264B095.pdf>. Accessed June 6, 2018. 4. Data on file. Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ, 2012.

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Patient guidance while on treatment

- Patients should be compliant with blood cell count monitoring appointments and understand their importance. Patients should report signs of bleeding or infections¹
- Injections should be administered by authorized persons in a designated clinical setting. Patients may return home after the injection^{1,3,4}
- There are no restrictions regarding personal contact (visual or physical proximity) with other people after receiving Xofigo^{®1}
- Patients should maintain good hygiene while receiving Xofigo and for at least 1 week after the last injection; radioactivity will be present in excreted bodily waste¹
 - Whenever possible, patients should use a toilet and flush it several times after each use
 - Caregivers should use universal precautions for patient care to avoid contamination. When handling bodily fluids, caregivers should wear gloves and wash their hands
 - Clothing soiled with patient fecal matter or urine should be washed promptly and separately from other clothing
- Male patients should use a condom and their female partners of reproductive potential should use effective contraception during and for 6 months following the completion of Xofigo treatment¹
- Patients undergoing treatment should¹
 - Stay hydrated and monitor oral intake, fluid status, and urine output
 - Report signs of dehydration, hypovolemia, urinary retention, or renal failure/insufficiency

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Routine monitoring requirements

Perform standard hematologic evaluations before and during treatment with Xofigo^{®1}

Before **FIRST**
administration of Xofigo:

CONFIRM

- Absolute neutrophil count is $\geq 1.5 \times 10^9/L$
- Platelet count is $\geq 100 \times 10^9/L$
- Hemoglobin is ≥ 10 g/dL

Before **SUBSEQUENT**
administrations of Xofigo:

CONFIRM

- Absolute neutrophil count is $\geq 1 \times 10^9/L$
- Platelet count is $\geq 50 \times 10^9/L$

- If hematologic values do not recover within 6 to 8 weeks after last administration, despite supportive care, discontinue further treatment

Important Safety Information (cont'd)

Warnings and Precautions (cont'd):

Adverse Reactions: The most common adverse reactions ($\geq 10\%$) in the Xofigo arm vs the placebo arm, respectively, were nausea (36% vs 35%), diarrhea (25% vs 15%), vomiting (19% vs 14%), and peripheral edema (13% vs 10%). Grade 3 and 4 adverse events were reported in 57% of Xofigo-treated patients and 63% of placebo-treated patients. The most common hematologic laboratory abnormalities in the Xofigo arm ($\geq 10\%$) vs the placebo arm, respectively, were anemia (93% vs 88%), lymphocytopenia (72% vs 53%), leukopenia (35% vs 10%), thrombocytopenia (31% vs 22%), and neutropenia (18% vs 5%)

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