

Xofigo® is used to treat prostate cancer that no longer responds to hormonal or surgical treatment that lowers testosterone. It is for men whose prostate cancer has spread to the bone with symptoms but not to other parts of the body.



LIFE CAN BE LONGER

Xofigo can help extend life by more than 30%

(14.9 months in Xofigo-treated men vs 11.3 months in placebo-treated men, in an updated analysis)

Xofigo was studied in a clinical trial with 921 men with mCRPC. In addition to the other medication they were taking, some of the men in the study were given Xofigo. Others were given an injection that did not contain an active drug.

Important Safety Information

It is not known if Xofigo is safe and effective in women. Xofigo can harm unborn babies when given to a pregnant woman. Men should use condoms and make sure female partners who may become pregnant use birth control (contraception) during treatment and for 6 months after completing treatment with Xofigo.

Please see additional Important Safety Information throughout this brochure, and pages 11-12 for the consumer brief summary of full [Prescribing Information](#).

 **Xofigo**[®]
radium Ra 223 dichloride
INJECTION

EVERYONE'S PROSTATE CANCER STORY IS DIFFERENT— BUT TREATMENT GOALS REMAIN THE SAME

There are thousands of men, just like you, who are fighting prostate cancer that has spread to the bones. One of the reasons it may have spread is because your cancer is no longer responding to therapies aimed at lowering testosterone. The medical term for this condition is metastatic castration-resistant prostate cancer (mCRPC).

When prostate cancer spreads to your bones, a treatment change may be necessary.



FOR **9** OUT OF **10**
MEN WITH mCRPC

PROSTATE CANCER
SPREADS TO
THE BONES

It is important to know that even if the cancer has spread to your bones and you may no longer have a prostate, it is still considered **prostate cancer, not bone cancer**.

Your doctor may also refer to mCRPC as “advanced” or “late-stage” disease.



WHEN CANCER SPREADS TO THE BONES, IT MAY BE TIME TO THINK ABOUT
ADDITIONAL THERAPIES

MONITORING YOUR DISEASE



Ask your doctor if a bone scan or checking your ALP levels should be considered. ALP is a substance that may be released into the bloodstream when bones break down. High levels of ALP give your doctor a better idea if your disease has spread to the bone.



In metastatic castration-resistant prostate cancer (mCRPC), PSA tests alone should not be used to determine long-term outcomes.

When prostate cancer spreads, you may experience symptoms such as:



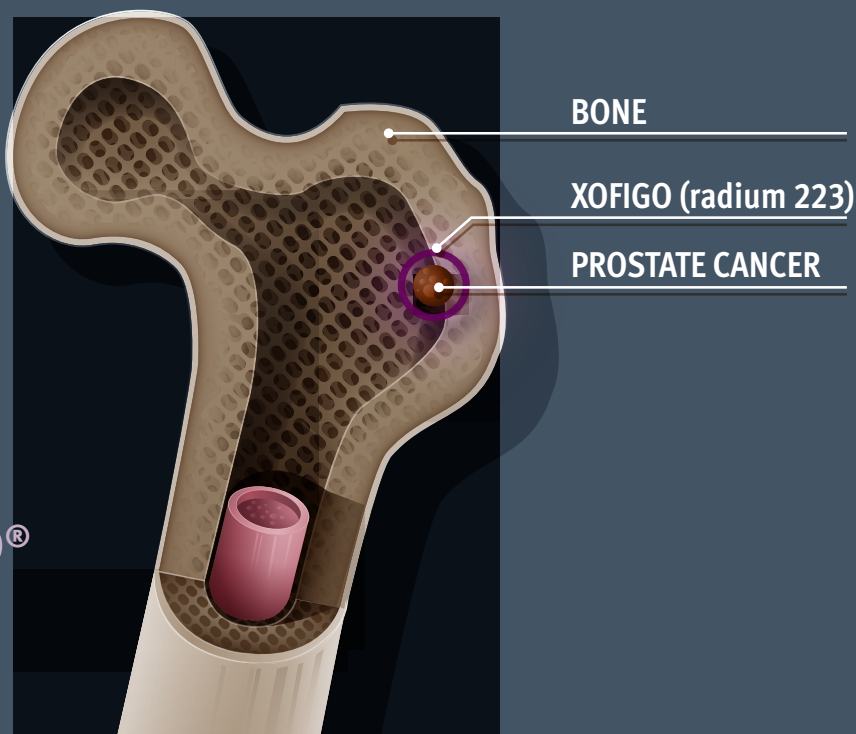
- Exhaustion
- Difficulty moving or bending
- Problems with posture
- General pain/discomfort in the lower back
- Difficulty doing everyday tasks
- Problems sleeping

ALP=Alkaline Phosphatase; PSA=Prostate-Specific Antigen.

BE OPEN AND HONEST WITH YOUR DOCTORS.
THIS WILL HELP THEM DETERMINE IF YOU ARE
ADVANCING ON YOUR CURRENT TREATMENT



WHEN PROSTATE
CANCER GOES
TO THE BONE,
SO DOES XOFIGO®



Xofigo gives off radiation that helps kill cancer cells

- Xofigo contains the radioactive material radium 223. It goes to areas in your bones that are growing quickly, just like calcium does. Bone metastases are one of those rapidly growing areas
- Even though Xofigo gives off a strong energy, it has a short range that does limited damage to healthy cells around it
 - Xofigo can be absorbed by other organs, primarily the bone marrow and digestive system, which may result in side effects in those healthy tissues

IF YOUR DISEASE IS ADVANCING
ON HORMONAL THERAPY,
TALK TO YOUR DOCTOR
TO SEE IF XOFIGO IS
RIGHT FOR YOU



Indication

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INJECTION

XOFIGO[®] CAN HELP YOU LIVE LONGER

Xofigo can help extend life by more than 30%

(14.9 months in Xofigo-treated men vs 11.3 months in placebo-treated men, in an updated analysis)

Xofigo was studied in a clinical trial with 921 men with mCRPC. In addition to the other medication they were taking, some of the men in the study were given Xofigo. Others were given an injection that did not contain an active drug.



IF YOUR DISEASE IS ADVANCING ON HORMONAL THERAPY,
TALK TO YOUR DOCTOR TO SEE IF XOFIGO IS RIGHT FOR YOU

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 **Xofigo[®]**
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INJECTION

SAFETY WITH XOFIGO®

- It is not known if Xofigo is safe and effective in women. Xofigo can harm unborn babies when given to a pregnant woman. Men should use condoms and make sure female partners who may become pregnant use birth control (contraception) during treatment and for 6 months after completing treatment with Xofigo



Tell your healthcare provider if you:

- Have bone marrow problems. Xofigo can cause your blood cells counts to go down, including red blood cells, white blood cells, and/or platelets. In a clinical trial, some patients had to permanently discontinue therapy because of bone marrow problems. In addition, there were some deaths and blood transfusions that occurred due to severe bone marrow problems. Your healthcare provider will do blood tests before and during treatment with Xofigo
- Are receiving any chemotherapy or any extensive radiation therapy. The use of chemotherapy while taking Xofigo is not recommended
- Are taking Zytiga® (also known as abiraterone) with prednisone/prednisolone, as this may increase the risk of bone fractures (breaks) and death
- Have any other medical conditions



The most common side effects of Xofigo include:

- Nausea
- Diarrhea
- Low blood cell counts
- Vomiting
- Swelling of the arms or legs (peripheral edema)



While you are on Xofigo:

- Make sure you keep your blood cell count monitoring appointments and tell your healthcare provider about any symptoms or signs of low blood cell counts. Report symptoms or signs of shortness of breath, tiredness, bleeding (such as bruising), or infection (such as fever)
- Stay well hydrated and report any signs of dehydration (such as dry mouth and increased thirst), or urinary or kidney problems (such as burning when urinating)
- There are no restrictions regarding personal contact (visual or physical proximity) with other people after receiving Xofigo
- People who are handling fluids such as urine, feces, or vomit of a man taking Xofigo should wear gloves and wash their hands as precaution
- Follow good hygiene practices in order to minimize radiation exposure from spills of bodily fluids to household members and caregivers for a period of one week after each injection

It's also important that you—and those who care for you—talk to your healthcare provider about any side effects you may have while receiving your treatment that bother you or do not go away. If you have any questions about your care, be sure to discuss them with your healthcare provider.

You are encouraged to report side effects or quality complaints of products to the FDA by visiting www.fda.gov/medwatch, or call 1-800-FDA-1088.

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WHAT TO KNOW BEFORE AND AFTER YOUR TREATMENT



BEFORE EACH TREATMENT

You will get a blood test so your doctor can be sure your blood counts are normal and it is okay for you to receive your injection.

1
MIN

ON YOUR DAY OF TREATMENT

Receive a 1-minute injection in the vein every 4 weeks, for a total of 6 injections.



INJECTION
EVERY



TOTAL **6** INJECTIONS

- You will receive your injection at a location where healthcare providers or technicians are qualified to give Xofigo®
- Visit www.xofigo-us.com to find a treatment facility near you



AFTER EACH TREATMENT

Once the injection is finished, you can leave the office and go about your daily activities. There are no restrictions regarding personal contact (visual or physical proximity) with other people, so you may hug your friends and family.

While you are being treated with Xofigo you will continue to see the doctor who manages your cancer treatment. This way, he or she can keep track of your progress.

There are additional considerations to keep in mind following treatment with Xofigo. This important information is on page 8 of this brochure.

Blood cell count monitoring appointments are very important. Be sure to tell your doctor or nurse if you have signs of low blood cell counts, such as:

- More bleeding or bruising than usual after an injury
- Catching more colds than usual
- Fever
- Feeling short of breath
- Feeling tired

Drink enough fluids

Tell your doctor if you become dehydrated or experience urinary or kidney problems.

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WHAT TO KNOW BEFORE AND AFTER YOUR TREATMENT (cont'd)

BATHROOM HYGIENE IS IMPORTANT

Your body removes radioactivity mostly through feces. So, while you are being treated with Xofigo®—until at least 1 week after the last injection—you should:

- Wash your hands well every time you go to the bathroom
- Flush the toilet several times after each use
- Make sure that if bodily waste is spilled, it is removed completely and quickly. If bodily waste gets on clothing, wash it right away by itself. Afterward, you should wash your hands very well. Anyone who helps you should wash their hands well, too
- Wear one-use gloves or gowns any time you clean up bodily waste. Dispose of gloves or gowns as directed by your healthcare provider
- Keep your bathroom area clean

SEXUAL RELATIONS DURING XOFIGO THERAPY

You can have sexual relations while being treated with Xofigo. Because of the possible effect that radiation can have on sperm, you should always use a condom. Also, your female partners should use effective contraception during your treatment and for 6 months after treatment is over.

TALK TO YOUR DOCTOR ABOUT
STAYING ON XOFIGO FOR ALL
6 INJECTIONS



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TREATMENT SUPPORT IS JUST A PHONE CALL AWAY

Xofigo® Access Services offers additional support:

- Helps you pay for Xofigo®, if you qualify
- Assists in finding treatment sites near you
- Helps provide travel assistance to and from your treatment site^a

Xofigo is covered by most health insurance plans, including Medicare.

Call our Xofigo Access Service Counselors to see if you are eligible for the \$0 copay.*



We look forward to speaking with you

Live counselors are available from 9:00 AM to 7:00 PM ET,
Monday through Friday, at 1-855-6XOFIGO (1-855-696-3446)

For more information, visit www.xofigo-us.com.

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

*Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible. As a condition precedent of the co-payment support provided under this program, e.g., co-pay refunds, participating patients and pharmacies are obligated to inform insurance companies and third-party payors of any benefits they receive and the value of this program, as required by contract or otherwise. Void where prohibited by law, taxed, or restricted. Patients enrolled in Bayer's Patient Assistance Program are not eligible. Bayer may determine eligibility, monitor participation, equitably distribute product and modify or discontinue any aspect of the Xofigo Access Services at any time, including but not limited to this commercial co-pay assistance program. Only patients not currently enrolled in the Xofigo Access Services are eligible; current participants may enroll upon their annual renewal date.

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SUPPORTING YOU ALONG THE WAY

PATIENT AND CAREGIVER SUPPORT ORGANIZATIONS

CancerCare®

www.cancercares.org

1-800-813-HOPE
(1-800-813-4673)

Malecare

www.malecare.org

1-212-673-4920

Men's Health Network

www.menshealthnetwork.org

1-202-543-MHN-1
(1-202-543-6461)

National Cancer Institute

www.cancer.gov

1-800-4-CANCER
(1-800-422-6237)

Patient Advocates for Advanced Cancer Treatments (PAACT) Inc.

www.paact.help

1-616-453-1477

Prostate Conditions Education Council (PCEC)

www.prostateconditions.org

1-866-4PROST8
(1-866-477-6788)

Prostate Cancer Research Institute

www.pcri.org

1-310-743-2116

Prostate Health Education Network (PHEN)

www.prostatehealthed.org

1-617-481-4020

Us TOO International Prostate Cancer Education & Support

www.ustoo.org

1-800-808-7866

ZERO—The End of Prostate Cancer

www.zerocancer.org

1-202-463-9455

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IMPORTANT FACTS ABOUT XOFIGO[®] (zo-FEEG-oh)

About Xofigo

Xofigo is used to treat prostate cancer that no longer responds to hormonal or surgical treatment that lowers testosterone. It is for men whose prostate cancer has spread to the bone with symptoms but not to other parts of the body.

Warnings about Xofigo

Xofigo can cause your blood cell counts to go down, including red blood cells, white blood cells, and/or platelets. In a clinical trial, some patients had to stop therapy because of bone marrow problems. In addition, there were some deaths and blood transfusions that occurred due to severe bone marrow problems. Your healthcare provider will do blood tests before and during treatment with Xofigo.

It is not known if Xofigo is safe and effective in women. Xofigo can harm unborn babies when given to a pregnant woman. Men should use condoms and make sure female partners who may become pregnant use birth control (contraception) during treatment and for 6 months after completing treatment with Xofigo.

Before starting Xofigo

Tell your healthcare provider if you:

- Suffer from bone marrow problems (a decrease in blood cell production in the bone marrow). Your healthcare provider will decide if treatment is right for you
- Are receiving any chemotherapy or another broad radiation therapy
- Are taking Zytiga[®] (also known as abiraterone) with prednisone/prednisolone, as this may increase the risk of bone fractures (breaks) and death
- Have any other medical conditions

How to take Xofigo

If Xofigo is right for you, your healthcare provider will refer you to a clinic or facility where healthcare providers or technicians are qualified to give Xofigo.

Xofigo is given as a 1-minute IV injection. Over the course of your therapy, you will receive 1 injection every 4 weeks until you reach a total of 6 injections.

What you should know while taking Xofigo

Blood cell count monitoring appointments are very important. Make sure you keep your appointments, and tell your healthcare provider about any of the following symptoms: shortness of breath, tiredness, bleeding or bruising, or infection (such as a fever). These may be signs or symptoms of low blood cell counts.

Please see the consumer brief summary of full [Prescribing Information](#) continued on the next page.



What you should know while taking Xofigo® (cont'd)

Stay well hydrated and report any signs of dehydration (such as dry mouth, increased thirst, no urination, or urine that is darker than normal) or kidney problems (such as reduced urine output, shortness of breath, drowsiness, inability to empty your bladder despite the urge to urinate, or swelling of your legs, ankles, or feet).

There are no limits regarding personal contact (visual or physical proximity) with other people after receiving Xofigo; however, you should follow good hygiene to reduce radiation contact from spills of bodily fluids to household members and caregivers. Whenever possible, here are some things you should do while receiving Xofigo and for at least 1 week after the last injection:

- Be sure to wash your hands well every time you go to the bathroom
- Flush the toilet several times after each use
- If you spill bodily waste, it should be removed completely and quickly, and you or the person helping you should wash hands thoroughly
- Remember to wear disposable gloves and gowns any time you or your caregiver cleans up bodily waste. Dispose of gloves as directed by the healthcare provider who gave you your Xofigo treatment
- If bodily waste gets into clothing, make sure the clothing is quickly washed separate from other clothing
- Keep your bathroom area clean

Use condoms and make sure female partners who may become pregnant use birth control (contraception) during treatment and for 6 months after completing treatment with Xofigo.

Possible side effects of Xofigo

The most common side effects seen in people receiving Xofigo were:

- Nausea (feeling sick to your stomach)
- Diarrhea
- Vomiting
- Swelling of the arms or legs, known as peripheral edema
- Low blood cell counts

Tell your healthcare provider if you have any side effects that bother you or do not go away.

The risk information provided here is not comprehensive.

How to get more information:

- Talk to your healthcare provider or pharmacist
- Visit www.xofigo-us.com to obtain the FDA-approved product labeling
- Call 1-888-842-2937

You are encouraged to report side effects or quality complaints of products to the FDA by visiting www.fda.gov/medwatch, or call 1-800-FDA-1088.



LIFE CAN BE LONGER

WHEN PROSTATE CANCER GOES TO THE BONE, SO DOES XOFIGO®

- Xofigo gives off radiation that helps kill cancer cells

XOFIGO MAY HELP YOU LIVE LONGER

- It can help extend life by **more than 30%** (14.9 months in Xofigo-treated men vs 11.3 months in placebo-treated men, in an updated analysis)

XOFIGO® ACCESS SERVICES: TREATMENT SUPPORT IS JUST A PHONE CALL AWAY

- Live counselors are available from 9:00 AM to 7:00 PM ET, Monday through Friday, at 1-855-6XOFIGO (1-855-696-3446)

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Print, cut out, and bring this card to your next appointment.

I'D LIKE TO KNOW MORE ABOUT

 **Xofigo**[®]
radium Ra 223 dichloride
INJECTION

(zo-FEEG-oh)



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