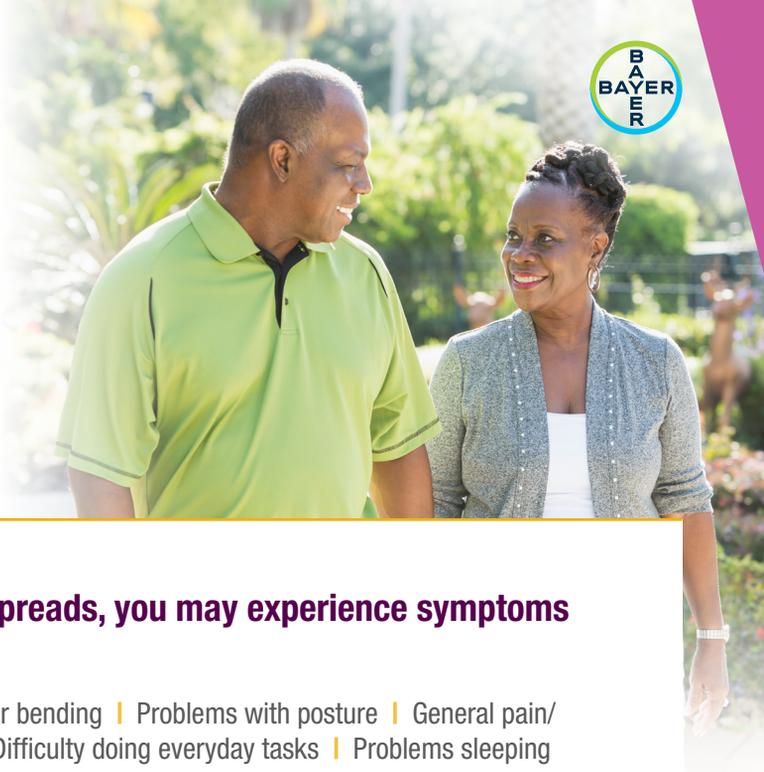




# For patients with prostate cancer that has spread to the bones...



## 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



## Xofigo® can help extend life by more than 30%

**14.9 months** in Xofigo-treated men vs 11.3 in placebo-treated men, as seen in a clinical trial.

Xofigo was studied in a clinical trial with 921 men with metastatic castration-resistant prostate cancer (mCRPC) with bone metastases. 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.

## Indication

Xofigo® (radium RA 223 dichloride) 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.

## 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 on page 2, and pages 3 and 4 for the consumer brief summary of full [Prescribing Information](#).



# IMPORTANT SAFETY INFORMATION (cont'd)

## Before taking Xofigo<sup>®</sup>, 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 another extensive radiation therapy
- are taking Zytiga<sup>®</sup> (also known as abiraterone) with prednisone/prednisolone, as this may increase the risk of bone fractures (breaks) and death
- have any other medical conditions

## 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

## The most common side effects of Xofigo include:

- nausea
- diarrhea
- vomiting
- swelling of the arms or legs (peripheral edema)
- low blood cell counts

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

*For important risk and use information about Xofigo, please see the Full Prescribing Information.*

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

**Please see additional Important Safety Information on page 1, and pages 3 and 4 for the consumer brief summary of full Prescribing Information.**



# 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.

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

Please see Important Safety Information on pages 1 and 2, and page 4 for additional consumer brief summary of full Prescribing Information.



# IMPORTANT FACTS ABOUT XOFIGO® (zo-FEEG-oh) (cont'd)

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

- 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](http://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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

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