



About

XOFIGO[®] ▼

(radium-223 dichloride)

**Your
Guide to
Treatment**

This booklet is intended for patients who have been prescribed Xofigo[®].
For more information, please refer to the Patient Information Leaflet.

▼ This medicinal product is subject to additional monitoring. Adverse events and product complaints should be reported. To report an adverse event or a product complaint about a Bayer product, please call Bayer on 01 216 3300. Adverse events and product complaints may also be reported to HPRAs Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

Support during Xofigo® treatment

Your doctor has prescribed Xofigo as a treatment for your cancer. This booklet has been written to help you understand your treatment. It is not meant to replace talking to your doctor or a healthcare professional.

If you have additional questions that are not covered in this brochure, you will find further information in the Patient information Leaflet of your Xofigo pack. Or for detailed information about this medicine please visit www.medicines.ie

Also for further information and cancer support you can visit the Irish Cancer Society on www.cancer.ie or telephone **Freephone 1800 200 700**.

For any further information, please contact:

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What happens when prostate cancer spreads to the bones

Your doctor has told you that your prostate cancer no longer responds to medical or surgical treatments that lower testosterone. The medical term for this condition is castration-resistant prostate cancer (CRPC).

At this point, your prostate cancer may have spread to other parts of your body. When this happens, your doctor will say the cancer has “metastasised.” The medical term for this condition is metastatic castration-resistant prostate cancer (mCRPC). When prostate cancer has metastasised it most often spreads to the bones. Your doctor has spoken with you about other ways to treat the prostate cancer that has spread to your bones.



Prostate cancer
spreads to **the bones**

FOR **9** OUT OF **10** MEN WITH ADVANCED CRPC

When cancer spreads to your bones, it can cause them to weaken and even break. It's also possible you can experience numbness, weakness, difficulty moving, problems with your posture, or pain from this kind of cancer.

Make sure you tell your doctor about any numbness, weakness, or pain you are experiencing anywhere in your body – even if you think it's not related to your cancer. Such symptoms could guide your doctor to better evaluate your condition and treat you more effectively.

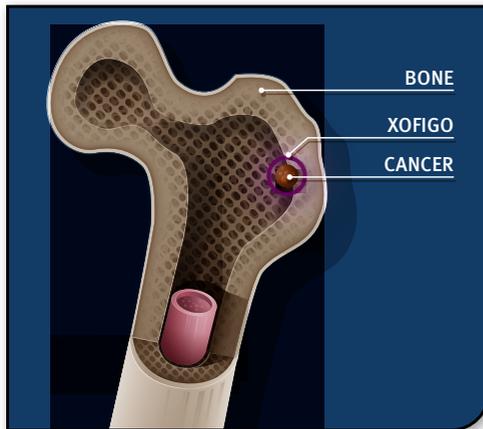
It's also important to tell your loved ones about any symptoms you are having. This way, those who care for you can help make sure your doctor is well informed.

What is Xofigo® and how does it work

Xofigo is used to treat prostate cancer that has spread to your bones. Xofigo contains the radioactive material radium-223 dichloride.

You may know that calcium is a major component of bones, and is needed to build new bone. Because radium acts like calcium, Xofigo goes to areas in your bones that are growing quickly. Bone metastases are one of those areas.

Xofigo sends out radiation that is powerful, but only travels a very short distance. Once Xofigo has reached the bones, the radiation helps to kill areas of cancer in your bones but minimises damage to the surrounding normal tissue.



Xofigo specifically targets areas of cancer in the bone.

Xofigo and your PSA



Xofigo has been proven effective and safe for your disease. While Xofigo may slow the rise of PSA, it may not reduce PSA levels significantly. In fact, even if there is no change in your PSA level, you may still be getting a benefit from Xofigo. Your doctor may use your overall well-being, symptoms, imaging studies, and blood work to monitor the effect of treatment.

Be sure to talk to your doctor if you have any questions about your PSA.

Stay on schedule



To get the most benefit from Xofigo, it is important for you to keep your appointments and stay on schedule with your treatments. If you cannot keep an appointment, make sure you give the facility at least 3 days' notice before the date of the visit.

Your steps along the treatment path with Xofigo®

You doctor has referred you to a clinic where other doctors or technicians have been trained to give Xofigo.

Before your treatment

You will always get a blood test before you go in for your Xofigo treatment. This way, your doctor can be sure your blood counts are normal and you can safely receive your next injection.

On the day of treatment

Over the course of your therapy, you will get a total of 6 intravenous injections of Xofigo – one injection every 4 weeks. The injection of Xofigo will be given over 1 minute.

The dose that you receive depends on your body weight and the exact amount will be calculated for your treatment.

Your dose is ordered just for you, so it is important that you show up for your treatments. Please let your oncologist and nuclear medicine department know as soon as you know about a possible schedule conflict that would require that your treatment be rescheduled.



After treatment

After your injection, you will be able to go about your normal day.

When being treated with Xofigo, you will continue to see the doctor who manages your cancer, just like you normally would. This way, he or she can continue to monitor your progress.

What does the usual dosing schedule for Xofigo look like? †

Pre-treatment oncologist appointment and blood test

This appointment will assess if Xofigo® is an appropriate treatment for you.



 Your Xofigo® treatments will always be given in the nuclear medicine department

Please note there are no data available on treatment with the use of more than 6 cycles of Xofigo®.

 Your oncologist will schedule a blood test and will check to see how you are feeling before your next treatment appointment

† Represents the usual Xofigo® dosing regimen and may not be representative of patients' individual experiences (appointments, tests, treatment duration, adverse events, etc.) while on Xofigo®.

Xofigo safety and you – possible side-effects

Like all medicines, Xofigo can cause side effects, although not everybody gets them. The table below lists potential side effects from most common to uncommon.

Very Common (may affect more than 1 in 10 people)	Common (may affect up to 1 in 10 people)	Uncommon (may affect up to 1 in 100 people)
Thrombocytopenia (decrease in the number of blood platelets)	Neutropenia (decrease in the number of a specific type of white blood cells [neutrophils])	Lymphopenia (decrease in the number of a specific type of white blood cells [lymphocytes])
Diarrhoea Vomiting Nausea (feeling sick)	Pancytopenia (decrease in the number of red and white blood cells and blood platelets)	Osteoporosis (weakened bones)
Bone fracture	Leukopenia (decrease in the number of white blood cells)	
	Injection-site reactions (e.g., erythema [redness of the skin], pain and swelling)	

The most serious side effects in patients receiving Xofigo are:

- Thrombocytopenia (decrease in the number of blood platelets) and
- Neutropenia (decrease in the number of a specific type of white blood cell called neutrophils).

This is not a complete list of side effects. Please refer to the Patient Information Leaflet found on www.medicines.ie. For any unexpected effects while taking Xofigo, contact your doctor.

Xofigo should not be used in women

If you suffer from bone marrow problems (a decrease in blood cell production in the bone marrow), your doctor will decide if treatment is appropriate. In a clinical trial, some patients had to permanently discontinue therapy because of bone marrow problems. In addition, there were some deaths (less than 1%) that occurred due to severe bone marrow problems.

It's important that both you – and those who care for you – talk to your doctor about any side effects you may have while receiving your treatment. Ask about ways you can manage them. If you have any questions about your care, be sure to discuss them with your doctor.



Sexual relations during Xofigo therapy

It's fine to have sexual relations with your partner. Because of the potential effect of radiation on sperm, you should always use effective contraceptive methods during treatment. It's important to continue this practice for a minimum of 6 months after Xofigo treatment is completed.

Be sure to tell your doctor about any signs of low blood cell counts

Signs of low blood cell counts include more bleeding or bruising than usual after injury, catching more colds than usual, fever, shortness of breath, and tiredness.

Key contacts

Contact 1

Hospital:

Doctor:

Nurse:

Contact 2

Hospital:

Doctor:

Nurse:

Contact 3

Hospital:

Doctor:

Nurse:

Contact 4

Hospital:

Doctor:

Nurse:

Appointments

Appointment 1

Date:

Time:

Appointment 2

Date:

Time:

Appointment 3

Date:

Time:

Appointment 4

Date:

Time:

Appointment 5

Date:

Time:

Appointment 6

Date:

Time:



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