# NEXT STEPS WITH XOFIGO

This booklet is intended for patients who have been prescribed Xofigo.





For more information please refer to the Package Leaflet that can be provided by your healthcare professional.

Reporting of side-effects. This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in the package leaflet. You can also report side-effects directly via the Yellow Card Scheme at www.mhra.gov.uk/ yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store. By reporting side-effects you can help provide more information on the safety of this medicine.

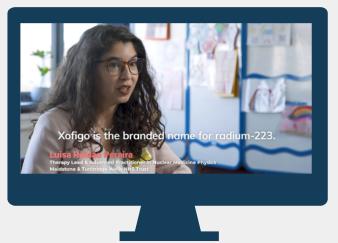
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# UNDERSTANDING YOUR TREATMENT WITH XOFIGO – WATCH OUR 'COMMON QUESTIONS' VIDEO

Visit the URL below to watch a short video, featuring Specialist Nurse Luisa Roldao Pereira. She answers common questions posed by men about to start treatment on Xofigo.

#### www.mcrpcpatientvideo.co.uk



XOFIGO IS A TREATMENT FOR METASTATIC CASTRATION-RESISTANT PROSTATE CANCER, WHICH IS ALSO KNOWN AS mCRPC.

#### BUT WHAT DOES THAT MEAN?

mCRPC is cancer that started in your prostate – a small gland at the base of your bladder, which makes a fluid that forms part of your semen.

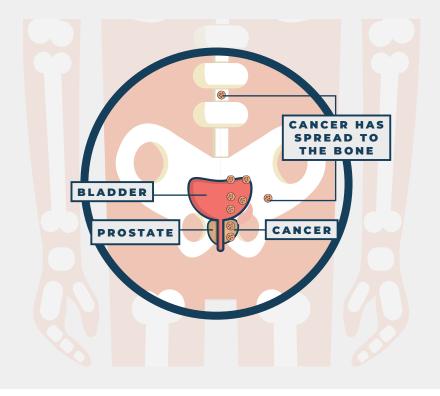
Your cancer has progressed and become metastatic. This means that it has spread from your prostate to a different part of your body. In your case, it has spread to your bones.



# HOW DOES CANCER BECOME METASTATIC?

Sometimes, cancer cells break away from the main cancer and travel in the blood to a different part of the body, where they start to grow. This can happen with any type of cancer, and any location in the body. Some types of cancer tend to spread to a specific part of the body, for example prostate cancer often spreads to the bones.

Even though it has spread to a different part of the body, metastatic cancer is not a different type of cancer. So your cancer is still prostate cancer, even if it's now in your bones too, and it will continue to be treated as prostate cancer.



# WHAT ARE THE SYMPTOMS OF mCRPC?

If your cancer has become metastatic, you will continue to experience many of the same symptoms as you did before, but may have some new ones caused by the cancer in your bones.

These symptoms will vary between people, and will depend on the location and size of your tumour. Some common symptoms of bone metastases are:

**Bone pain** - the most common symptom



Weakened bones - your bones may fracture or break more easily, even if you don't have an accident or fall



Raised calcium levels - this can cause increased tiredness. feeling sick (nausea), constipation, increased thirst and confusion



**Anaemia** - if your bone marrow is affected it may stop making enough red blood cells, which can make you feel tired and breathless



**Pressure on the spinal cord** - when cancer affects the bones in the spine, which can cause back or neck pain, muscle weakness, problems controlling your bladder or bowels, and numbness and weakness in your legs



**Increased infections** - also due to effects on your bone marrow; if it makes too few white blood cells, you may be more likely to get an infection



Increased bruising or bleeding - due to a low number of platelets in the blood, which is also caused by effects on the bone marrow

This may mean that you start to struggle with some every-day activities. For example, you may find that you:

- Struggle to sleep due to pain
- Worry about falling • Have to change your
- Have less energy than usual Get out of breath more guickly
  - socialising habits
- Get stiff more easily

It's important that you let your healthcare team know about anything you experience that might be a symptom of your cancer, even if it's not bothering you at the moment. They will be able to advise you on how you should manage the symptom and may prescribe additional medication if necessary.

If you experience weakness, pain, tingling or numbness in your arms or legs, you should contact your healthcare team as soon as possible.

If you can't contact your healthcare team, or if you develop problems controlling your bladder and bowels, go to your local accident and emergency department (A&E) straight away.

# WHAT IS XOFIGO?

Xofigo is a treatment option for men with prostate cancer that has become metastatic and spread to their bones, but not to other organs. It contains a medicine called radium-223 dichloride, which is a type of radioactive treatment.

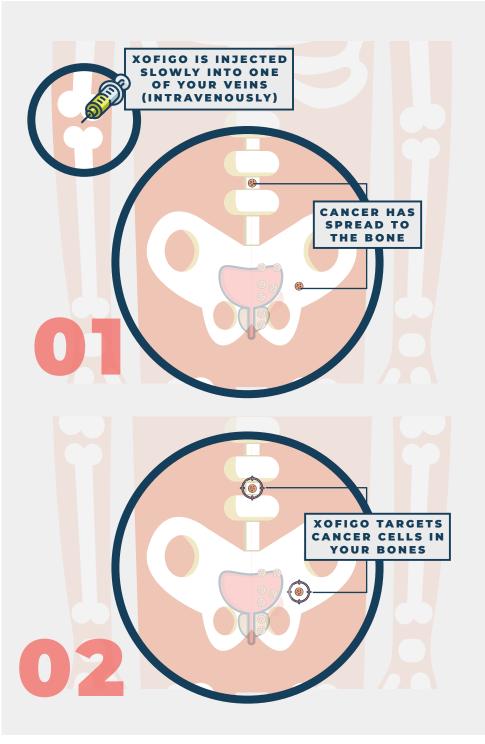
Xofigo is not a cure for mCRPC, but it can help you to live longer, reduce pain and improve your quality of life.

Xofigo was tested in a clinical trial of over 900 men with mCRPC. During the trial, two thirds of these men received Xofigo and the rest received a placebo – a dummy medicine that contains no active drug, but was made to look identical to Xofigo. The clinical trial found that people who take Xofigo (compared to those that took placebo) tend to:

Live longer than those who don't take Xofigo
Go longer without symptoms relating to their bones
Have a better quality of life

#### HOW DOES Xofigo Work?

Xofigo is a radioactive treatment that specifically targets cancer cells in your bones. It sends out strong but controlled radiation that travels only very short distances. So there is only a very small amount of damage to neighbouring, healthy cells and the radiation doesn't travel out through your skin.



# HOW IS Xofigo given?

Xofigo is given as an injection into a vein, usually through a small tube (cannula) that is put into a vein in your hand or arm every time you have treatment. The injection itself takes about a minute and you will be able to go home soon afterwards.

You will need to go to hospital for the injection. You may not be able to have the injection at your usual hospital, so may need to go to a different one.

#### HOW OFTEN WILL I GET XOFIGO?

You can have a maximum of 6 injections of Xofigo. These are usually given 4 weeks apart.

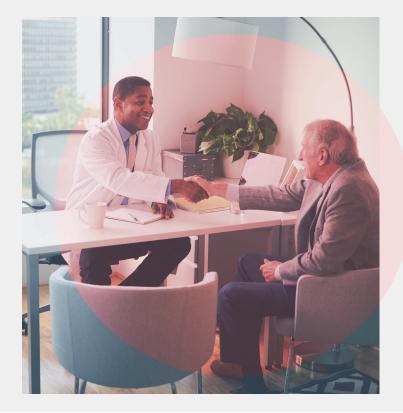
You will need to have a blood test before each injection to check that you are well enough to receive the treatment.



#### HOW DO I KNOW THAT Xofigo is working?

Because Xofigo targets cancer in your bones, and not in your prostate, tests like PSA (prostate specific antigen) level aren't useful to see how well the treatment is working. You may continue to have PSA tests to monitor your prostate cancer, but the cancer in your bones will need to be monitored in a different way.

Your doctor may repeat some of the scans and tests they did to diagnose your bone metastases to see how well Xofigo is working. They may also use your overall well-being, symptoms and blood tests to monitor your condition. You could use the Xofigo treatment diary booklet to keep track of all your appointments and any changes to your symptoms.



# WHAT ARE THE SIDE EFFECTS?

As with all medicines, Xofigo has some side effects. The most common ones are:





Feeling and

being sick



Reactions at

the site of the injection, such as redness, pain and swelling

Diarrhoea





Bone fractures C

Changes in blood test results

There are also some other side effects that you need to watch out for. Contact your healthcare team immediately if you experience:<sup>5</sup>



Unusual bruising



More bleeding than usual after a cut



A fever



A lot of colds or infections



Pain, swelling or numbness of the jaw, a heavy jaw feeling or a loose tooth

You may also experience some unusual side effects that are unique to you. If you notice anything listed above, or anything that you think may be connected to your treatment for prostate cancer, let your healthcare team know, even if it's not bothering you at the moment.

You could use the space in the Xofigo treatment diary to keep track of your side effects. Make a note of your symptoms in the space on the relevant day and take it with you to your next appointment to show your healthcare team.

You could also report your side effects to the Medicines & Healthcare products Regulatory Agency using their Yellow Card scheme.

This can be accessed at yellowcard.mhra.gov.uk.



# SOME THINGS TO CONSIDER WHEN TAKING XOFIGO

### 01

#### SOCIAL CONTACT WITH FAMILY AND FRIENDS

You can have normal contact with other people while receiving Xofigo, including immediately after your injections. So feel free to socialise with family and friends as you usually do.

If you have any questions or concerns about this or about contact with young children or pregnant women, please speak with your doctor or another member of your healthcare team.

### 02

#### **OTHER MEDICATIONS AND SUPPLEMENTS**

Some other medications used to treat prostate cancer can't be taken at the same time as Xofigo. If you are taking anything else for your prostate cancer, or any medication for another condition, it's important that you let your healthcare team know.

Additionally, if you are taking calcium, phosphate or vitamin D supplements, you may need to stop taking them before starting treatment with Xofigo. If you have to stop taking another treatment in order to receive Xofigo, your doctor and healthcare team will manage this to ensure it's done safely.

### 03

#### **SEX AND FERTILITY**

You can continue to have sex while receiving Xofigo, however the treatment may affect your sperm. So if you have sex with a woman who could become pregnant, it's important to use effective contraception during your treatment with Xofigo

and for 6 months after it has ended.

Xofigo may affect your sperm in a way that it makes you infertile. Therefore, you may not be able to have children in the future, so may wish to seek advice on sperm conservation before starting treatment. Your healthcare team will be able to advise you on this.

#### 04 DRIVING

It's fine to drive and use machines while receiving Xofigo. However, if you experience fatigue, or other side effects that could affect your concentration, you should be cautious.

### 05

#### WORK

You can continue to work while receiving Xofigo, however it's a good idea to let your employer know about your treatment so they can make some reasonable adjustments to support you,

for example giving you time off on appointment days or reduced working hours. They will also be able to tell you if there are any relevant company policies, or if there is an occupational health service or employee assistance programme that you could benefit from.

#### 06 TRAVEL

If you are planning on going on holiday, overseas or in the UK, let your healthcare team know. They will be able to help you to identify the best time to go based on your treatment schedule, and will let you know what to do if you need medical assistance while you are away.

### 07

#### **BATHROOM HYGIENE**

After each Xofigo injection, some radioactivity may remain in your faeces and urine for up to 1 week. The amount of radioactivity is very small, and will get lower each day, however it's necessary to take some precautions:

- · Drink plenty of water for a few days after each injection
- · Sit on the toilet when urinating, instead of standing
- Wear disposable gloves to wipe yourself or when cleaning up faeces or urine
- Flush the toilet twice after using it
- Wipe the toilet seat after using it if you share it with other people
- Wash your hands thoroughly after using the toilet
- Wash clothing separately and immediately if it becomes soiled with faeces or urine

# AFTER XOFIGO

### 01

#### **CAN I HAVE XOFIGO AGAIN?**

Unfortunately, not. You can only receive one course of Xofigo treatment – a maximum of 6 injections.

### 02

#### **IS THERE ANOTHER TREATMENT I CAN HAVE?**

You may be able to have chemotherapy after the end of your treatment with Xofigo. This will depend on your individual circumstances, and your healthcare team will be able to tell you more.

### 03

#### HOW LONG WILL THE RADIOACTIVITY STAY IN MY BODY?

It's difficult to say exactly how long the radioactivity will stay in your body. It has been estimated that about 15% of the radioactivity will have disappeared 1 day after each injection ,

and about 70% will have disappeared 7 days after each injection.

### 04

#### **CONSIDERATIONS FOR CREMATION**

If death occurs unexpectedly in someone who has recently had Xofigo, a delay to cremation may be needed. This is because the radioactivity in Xofigo is taken up and breaks down in bones at a set rate; a delay may be needed until a certain, low level of radioactivity has been reached. This would depend on the timing of the last injection. Your specialist healthcare team can discuss cremation in more detail, but it's important to ensure your family and friends are informed so that know what to expect.



# COPING WITH Emotions

Receiving treatment for advanced cancer can be an emotional time. Although you may have known that you have prostate cancer for a while, being told your condition has progressed and that you need additional treatment can be a shock.

There is no right or wrong way to feel, and you may experience a whole range of emotions.



Everyone copes with their emotions in a different way. It's important you find a way that works well for you. Some ideas are:





Joining a support group and meeting others like you



Relaxation techniques like yoga, massage, meditation and mindfulness



**Regular exercise** like going for a short walk or doing some gardening **Eating well** to keep your energy levels up



**Keeping a journal** of your emotions to see how they change

Hobbies provide an outlet for stress and a positive challenge

-

**Listening to** music can help you relax



Shouting, screaming and crying are all good ways of releasing tension

But even the strongest of people will struggle at times. If you start to feel overwhelmed by your emotions and struggle to cope, let your healthcare team know. They will be able to provide further support and advice, and could refer you to a counsellor if you would like.

Avoiding alcohol as it can negatively affect your emotions

#### STAYING POSITIVE

Despite your cancer, you can still keep a positive frame of mind. The goals you aim for now may be different to those you did in the past, and may now include feelings like comfort, dignity, love, peace and even joy. Or you may aim to be able to visit a place that you love, or that you can enjoy being with family and friends.

Some ideas to help build a sense of positivity are:

- Plan your days and set goals to look forward to
- Don't stop doing the things you enjoy
- Find small things to enjoy each day
- Set dates and events to look forward to
- Share your hopes with others so they can help you to fulfil them

Staying positive may give you a sense of purpose, which may in turn help you to feel better.

#### DISCUSSING YOUR CONDITION AND TREATMENT WITH YOUR HEALTHCARE TEAM

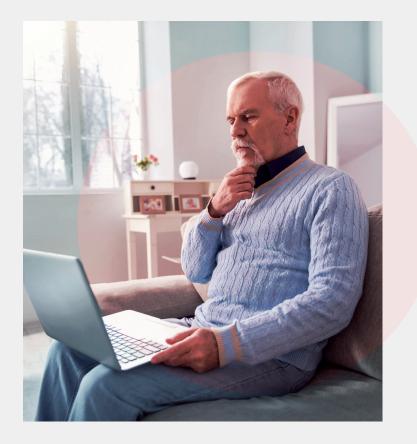
It's important that you understand what is going on with your health and care. Therefore, you should discuss any questions and concerns with your healthcare team. During an appointment, it can often be difficult to remember the questions you want to ask, so it's a good idea to write them down and take your list with you. You could use your Xofigo treatment diary booklet for this.

#### SOME IDEAS OF QUESTIONS YOU MAY WANT TO ASK ARE:

- How advanced is my cancer?
- Can you tell how quickly my cancer is progressing?
- Can I get a second opinion?
- Can I have a copy of my results?
- · Can you explain my results to me?
- Do I need more tests?
- · Has anything changed since my last appointment?
- Why have you chosen Xofigo for me?
- Are there any other treatments I could have?
- How does Xofigo work?
- How often will I have injections?
- Will I need any other appointments?
- What is radioactivity?
- Why can't I have more than 6 doses of Xofigo?
- What happens if I have a side effect?
- What should I do if I have a new symptom?
- Can I still spend time with young children?
- Can I travel abroad?
- Can I claim financial benefits?
- · Should I make any changes to my lifestyle?
- How could I connect with other people being treated with Xofigo?

# FURTHER INFORMATION AND SUPPORT

There are a number of organisations that could provide you with further information and support. Your healthcare team may be able to suggest a local organisation that could help you to connect with other people in a similar situation to yourself, or that could provide you with further support.



#### Other places to look are:

#### **PROSTATE CANCER UK**

Provides information and support for people with prostate cancer, including local support groups and an online forum. prostatecanceruk.org Contact a specialist nurse: 0800 074 8383

#### **TACKLE PROSTATE CANCER**

Supports people with prostate cancer and works to raise awareness of the condition. Also provides links to local support groups. <u>tackleprostate.org</u> National helpline: 0800 035 5302 helpline@tackleprostate.org

#### ORCHID

Promotes awareness of and pioneers research into testicular, prostate and penile cancers. <u>orchid-cancer.org.uk</u> National male cancer helpline: 0808 802 0010

#### **MACMILLAN CANCER SUPPORT**

Provides information about many different types of cancer, as well as emotional, physical and financial support. <u>macmillan.org.uk</u> 0808 808 0000

#### **CANCER RESEARCH UK (CRUK)**

Provides information about many different types of cancer, and funds scientists, doctors and nurses to help beat cancer sooner. cancerresearchuk.org Nurse helpline: 0808 800 4040





For further information about Xofigo please contact Bayer at: Bayer plc, 400 South Oak Way, Reading, Berkshire, RG2 6AD, United Kingdom. Tel: 0118 206 3000. For any medical information requests, please contact: medical.information@bayer.co.uk © Bayer plc November 2020. ® Registered trademark of Bayer AG, Germany.

PP-XOF-GB-0484 Date of preparation: November 2023