Xofigo Therapy
For metastatic prostate cancer

This handout explains how the drug Xofigo is used to treat metastatic prostate cancer.

What is Xofigo?
Xofigo is a radioactive drug. It is used to treat prostate cancer that has spread (metastasized) to the bones. Xofigo therapy has helped men with this stage of cancer live longer.

This drug is not used with other treatments. If you choose to have Xofigo therapy, any chemotherapy or radiation therapy you may be having will be stopped.

Your dose of Xofigo will be based on your weight. Most men receive 1 infusion every 4 weeks for a total of 6 infusions.

How does it work?
Xofigo is injected into a vein. From your bloodstream, the radioactive material in Xofigo (Ra-223 dichloride) goes directly to your bones.

The body treats Xofigo like calcium. The drug is taken into the bone, especially where there are cancer cells. It then destroys tissue cells in a very small area around the bone. This means it will have only a small effect on normal cells in the area.

But, Xofigo may affect your bone marrow, where red blood cells are made. This is called myelosuppression. Your doctor will closely monitor your blood cell levels while you are having Xofigo therapy.

Xofigo leaves the body with other waste products in the intestines. How quickly Xofigo leaves your body will depend on how your stomach and intestines (your gastrointestinal system) are working.

Your blood cell levels will be closely monitored while you are having Xofigo treatments.
Before Your Treatment

Before your Xofigo treatment, you must:

- **Have a blood draw** to see if this type of treatment will work for you. Another blood draw will be done 2 to 3 days before your first injection.
- **Have a Nuclear Medicine bone scan.** This scan is required before treatment. It must be done within 8 weeks of your first injection.
- **Stop any chemotherapy treatments** for 3 to 4 weeks before your first injection.
- **Be weighed.** Your dose of Xofigo is based on your weight. We must have a recent and accurate weight so that we give you the right amount.

Your Treatment Day

- Drink plenty of water before and after your injections so that you stay hydrated.
- Bring 2 forms of identification (ID) with you to the hospital, with at least 1 photo ID.
- A Nuclear Medicine attending doctor will oversee your injection.
- A technologist will place an intravenous (IV) line in your arm. It will take 1 to 2 minutes to inject the Xofigo. After that, you will receive a saline flush.
- You will stay in the Nuclear Medicine department for 30 minutes after your injection. We will monitor you and watch for any reactions.

After Your Treatment

Radiation Safety

- It is safe to be around other people after your Xofigo treatments.
- Your feces and urine will be radioactive for about 1 week after your injection. Because of this, after you use the toilet, you must:
  - Flush the toilet.
  - Clean up any spills.
  - Wash your hands well with soap and warm water.
- If you are sexually active:
  - Use condoms for at least 6 months after your treatment.
  - Your female partners within childbearing age should also use effective birth control methods.
- You will need to have follow-up blood draws to monitor your blood cell levels.
Side Effects
You will probably not have most of the following side effects, but if you have any talk to your doctor or nurse. They can help you understand the side effects and cope with them.

Common
- Nausea
- Diarrhea
- Low blood platelet count (with increased risk of bleeding)*
- Low red blood cell count (anemia)*
- Low white blood cell count (with increased risk of infection)*

Less Common
- Vomiting
- Swelling in the hands or feet

Rare
- Pain, redness, or swelling at the injection site
- Dehydration
- Severe bone marrow damage resulting in low blood cell counts*
- Kidney damage or kidney failure*
- Death due to severe bone marrow damage or other causes

*See “Precautions” on page 5 for more detailed information.

There are other side effects not listed above that can also occur in some patients. Tell your doctor or nurse if you develop these or any other problems.

Before Taking this Medicine
Tell Your Doctor:
- If you are allergic to anything, including medicines, dyes, additives, or foods.
- If you have any type of kidney disease. This drug might affect the kidneys (see “Precautions” on page 5).
- If you have any other medical conditions such as heart disease, liver disease, diabetes, gout, or infections. Your doctor may need to monitor you more closely during treatment.
• If you are sexually active and there is any chance your partner could become pregnant. This drug is not approved for use in women at this time. In men, it might damage sperm, which could affect pregnancy (see “Precautions” on page 5).

• If you think you might want to have children in the future. This drug might affect fertility. Talk with your doctor about the possible risk with this drug and the options that may preserve your ability to have children.

• About any other prescription or over-the-counter medicines you are taking, including vitamins and herbs. In fact, keeping a written list of each of these medicines (including the doses of each and when you take them) with you in case of emergency may help prevent complications if you get sick.

**Interactions with Other Drugs**

This drug is not known to interact directly with other drugs at this time, but this does not necessarily mean that it will not interact with other drugs. Be sure your doctor knows about all of the drugs and supplements you are taking.

This drug can lower your blood platelet count, which can increase your risk of uncontrolled bleeding (see “Precautions” on page 5). If your platelet count becomes low, you might need to avoid other drugs or supplements that interfere with blood clotting, because they could further raise the risk of bleeding. These include:

• **Non-steroidal anti-inflammatory drugs** (NSAIDs) such as aspirin, ibuprofen (Advil, Motrin), naproxen (Aleve, Naprosyn) and many others

• Warfarin (Coumadin), dabigatran (Pradaxa), rivaroxaban (Xarelto), apixaban (Eliquis), or other blood thinners, including any type of heparin injections

• Anti-platelet drugs such as clopidogrel (Plavix) or prasugrel (Effient)

• Vitamin E

Note that many cold, flu, fever, and headache remedies contain aspirin or ibuprofen. Ask your pharmacist if you are not sure what is in the medicines you take.

Check with your doctor, nurse, or pharmacist about your other medicines, herbs, and supplements, and whether alcohol can cause problems with this medicine.
Precautions

• **This drug contains radiation**, which will leave your body slowly over time. There are no restrictions about contact with other people after getting this drug, but your health care team will tell you to take some precautions during treatment and for at least 1 week after the last dose to lower the chance of exposing other people to radiation. These will include using a toilet to dispose of urine, feces, and vomit whenever possible and then flushing the toilet several times after each use. Your caregivers should wear gloves when handling body fluids (such as urine) or soiled clothes and wash their hands afterward.

• **This drug can damage your bone marrow**, which is where new blood cells are made. This could lead to a drop in your blood cell counts. In rare cases, the damage may be severe enough to be life threatening. Your doctor will test your blood before each treatment, looking for possible effects of the drug on blood cell counts or on other body organs. Based on the test results, you might get treatment to help with any effects. Your doctor may also need to delay your next dose of this drug, or even stop it altogether. It is very important that you keep all of your appointments for lab tests and doctor visits.

• **This drug can lower your blood platelet count**, which can raise your risk of uncontrolled bleeding. Your doctor will check your platelet count before each treatment, and your dose might need to be delayed if you have a low platelet count. Be sure your doctor knows if you are taking any medicines that could affect your body's ability to stop bleeding (see “Interactions with other drugs”). Tell your doctor or nurse right away if you cough up blood or have unusual bruising, nosebleeds, bleeding gums when you brush your teeth, vomit that is bloody or looks like coffee grounds, or black, tarry stools.

• **This drug might lower your red blood cell count**. If this occurs, it will usually happen a few months after starting treatment. A low red blood cell count (known as anemia) can cause shortness of breath, or make you feel weak or tired all the time. Be sure to let your doctor or nurse know right away if you have any of these symptoms. If you do become anemic, you might need blood transfusions or other treatments to help with this.

• **This drug can lower your white blood cell count**. This can increase your chance of getting an infection. Be sure to let your doctor or nurse know right away if you have any signs of infection, such as fever of 100.5°F (38°C) or higher, chills, pain when passing urine, new onset of cough, or bringing up sputum.
• **Do not get any immunizations (vaccines),** either during or after treatment with this drug, without your doctor’s OK. This drug might affect your immune system. This could make vaccinations ineffective, or even lead to serious infections if you get live vaccines during treatment or for some time afterward. Try to avoid contact with people who have recently received a live virus vaccine, such as the oral polio vaccine or smallpox vaccine. Check with your doctor about this.

• **In rare cases, this drug might damage the kidneys.** Your health care team will advise you to drink a lot of fluids during your treatment to help protect your kidneys, and to keep track of how much urine you are making. Be sure to tell your health care team if you notice any possible signs of dehydration or kidney problems, such as excessive thirst, feeling dizzy or fainting when standing, dark-colored urine, or a drop in urine output.

• **Because this drug contains radiation, it might raise the risk of getting another type of cancer, such as osteosarcoma (a type of bone cancer), later in life.** If this were to happen, it would likely be many years after treatment, but studies of this drug have not been going on long enough to know for sure.

• **This drug is not approved for use in women or children at this time.**