

XOFIGO – INTRAVENOUS INFUSION OF RADIUM 223 DICHLORIDE FOR BONE METASTASES

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DISCLAIMER: Please recognize that I am not a Medical Doctor. I have been an avid student researching and studying prostate cancer as a survivor and continuing patient since 1992. I have dedicated my retirement years to continued research and study in order to serve as an advocate for prostate cancer awareness, and, from a activist patient's viewpoint, to voluntarily help patients, caregivers, and others interested develop an understanding of prostate cancer, its treatment options, and the treatment of the side effects that often accompany treatment. There is absolutely no charge for my mentoring – I provide this free service as one who has been there and hoping to make your journey one with better understanding and knowledge than was available to me when I was diagnosed so many years ago. Readers of this paper must understand that the comments or recommendations I make are not intended to be the procedure to blindly follow; rather, they are to be reviewed as my opinion, then used for further personal research, study, and subsequent discussion with the medical professional/physician providing your prostate cancer care.

Every day we can learn something new about the medications available to us for our various stages of prostate cancer.

My daughter, who is employed by the Wichita Urology Group here in Wichita, Kansas, and I were having a discussion as to the pronunciation of the word Xofigo. I had not heard it pronounced though have read quite a bit about it and had been saying "X"ofigo. She advised the "X" is pronounced in this case as a "Z." Thus, Xofigo should be pronounced "Zofigo."

She since called to advise that she had conversation with the local drug rep for Xofigo who mentioned that if one is currently taking either Zytiga/abiraterone acetate or Xtandi/enzalutamide and the physician is considering the infusion of Xofigo for bone metastases, several insurers will not cover Xofigo while taking these androgen deprivation medications, though they can be taken simultaneously with administration of Xofigo should the insurer approve coverage.

Importantly, chemotherapy medications must be stopped during the period of Xofigo infusion; or, alternatively, if already in the series of Xofigo infusion and it

is considered necessary to prescribe a chemotherapy medication, continued infusion of Xofigo must be stopped.

Please also note that if men are experiencing any visceral metastases (E.g., lung, liver), Xofigo is NOT to be prescribed.

Make sure if Xofigo is to be prescribed that your health insurer approves coverage since this is an expensive medication; the treating physician should get that approval before administering: <http://tinyurl.com/pmfw63> . A patient receiving his first injection in mid-June 2015 was able to read the label on the product – cost for this single injection was \$10,835.10. Likely health insurers who cover the injection have arranged lower costs to them. This medication is injected every four weeks for six administrations.

This paper describes more fully this new and important medication for patients with bone metastases:

<http://www.xofigo-us.com/product-information/>

Noted in the foregoing paper was the exclusion of hemibody radiation (external beam radiation) while administering Xofigo. However, a more recent presentation by Professor A. Oliver Sartor, M.D., of the Tulane University Medical Center, and involved in research and ALSYMPCA trials with Xofigo, has determined that EBRT can be used concomitant with Xofigo. See: <http://tinyurl.com/k6lthnq>

Xofigo is an intravenous (IV) infusion of a radioactive material that treats metastatic prostate cancer resistant to medical or surgical treatments.

If prostate cancer grows outside of the prostate gland, it spreads into nearby tissues or lymph nodes, and then nearly always spreads to the bones. Spread of cancer to the bones can be painful and result in bone fractures or high blood calcium levels, which can be dangerous or even life threatening. Preventing or slowing the spread of prostate cancer to the bones is a major goal of treatment if the cancer has grown outside of the prostate.

Xofigo resembles calcium in the body, which allows direct absorption into the bones adjacent to areas where prostate cancer has spread. Given the unique characteristics of the treatment, the radiation is very focused and precise, only traveling a short distance from the areas containing the prostate cancer spread to

bone and 20 times more potent than standard x-ray treatment. This protects the rest of the body from many of the possible damaging effects of treatment.

Patients and their caregivers should be thoroughly explained by the treating physician the reactions that might accompany – particularly initially – the administration of Xofigo/alpharadin/radium 223 so that they are not alarmed should such reactions occur. Information below is for those patients/caregivers not so informed,

With initial administration of Xofigo the reaction to the system can likely increase PSA levels for many men, thus causing alarm, but then abate as time and additional administration occurs. For others, there may be no initial PSA reaction to this medication.

There are several side effects that can accompany the administration of Xofigo as identified in the below two papers. Unfortunately, we have to set our minds to dealing with and tolerating those side effects as a matter of survival.

<http://www.rxlist.com/xofigo-side-effects-drug-center.htm>.

For some men the lowering of white blood cell (WBC) level occurs to the point that neutropenia and accompanying side effects are experienced. As noted in the following paper, “When your WBC’s are low, you are at higher risk for developing fever, chills, aches, and fatigue that are caused by infection. A low WBC count is usually a temporary condition, but can be life threatening.” Obviously, when noted, significantly low WBC should be immediately addressed by the treating physician.

http://www.cancer.duke.edu/btc/docs/your_guide_to_care/neutropenia.pdf.

A measure of whether Xofigo is being effective is the significant reduction of pain level experienced by most men. This is the result of Xofigo’s effect on reducing high level Bone Alkaline Phosphatase (BALP) likely responsible for the pain. Though the below paper regards Xofigo for Breast Cancer, it reports “The co-primary end points were change in urinary N-telopeptide of type 1 (uNTX-1) and serum bone alkaline phosphatase (bALP) after 16 weeks of treatment. Exploratory end-points included sequential FDG PET/CT to assess metabolic changes in osteoblastic bone metastases. Safety data were collected for all patients. Radium-223 significantly reduced uNTX-1 and bALP from baseline to end of treatment. Median uNTX-1 change was -10.1 nmol bone collagen equivalents/mmol

creatinine (-32.8 %; p = 0.0124); median bALP change was -16.7 ng/ml (-42.0 %; p = 0.0045).” I would expect the same improvement/reduction in BALP level for Prostate Cancer patients administered Xofigo.

See: http://www.aetna.com/cpb/medical/data/800_899/0874.html