PART III: CONSUMER INFORMATION

XOFIGO®

radium Ra 223 dichloride

This leaflet is Part 3 of a three-part "Product Monograph" published when XOFIGO was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about XOFIGO. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

XOFIGO is used in men to treat advanced (castration-resistant) prostate cancer that has spread mainly to the bone and is causing symptoms (eg, pain).

What it does:

XOFIGO is known as a radiopharmaceutical drug that contains small amounts of the radioactive isotope radium-223 which as a substance can act similar to calcium, a major component of bones. XOFIGO goes to where the cancer has spread in the bone and gives off radiation (alpha particles) which kills the tumour cells without major effects to the healthy cells.

When it should not be used:

Your doctor will monitor your blood cell counts; if they are too low, XOFIGO will not be administered.

What the medicinal ingredient is:

Radium-223 dichloride

What the nonmedicinal ingredients are:

Hydrochloric acid, sodium chloride, sodium citrate and water for injection

What dosage forms it comes in:

XOFIGO is a clear and colorless solution for injection.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Radiopharmaceuticals such as XOFIGO should be used only by those health professionals who are appropriately qualified in the use of radioactive prescribed substances in or on humans.

BEFORE you are given XOFIGO talk to your doctor if:

- You suffer from bone marrow suppression (decreased blood cell production in the bone marrow). In this case your physician will treat you with caution. Your doctor will assess your individual situation by doing blood lab tests before you receive this drug and also during therapy to monitor these matters; if results from the lab tests are too low, you may not receive this product or a delay may be needed.
- You suffer from untreated spinal cord compression (severe back pain spreading to the legs or arms) or if it is thought likely that you are developing spinal cord compression (which can be caused by a tumour or other lesion) your doctor will first treat this disease with standard treatment before starting or continuing treatment with XOFIGO
- You experience a broken bone, your doctor will first stabilize the fractured bone before starting or continuing treatment with XOFIGO
- You tend to suffer from constipation (infrequent or difficult emptying of your bowels); for example, if going to the bathroom to empty your bowels only once every few days is the normal for you, tell your doctor.

XOFIGO can lead to a decrease in the number of your white blood cells and blood platelets. Before starting treatment and before each subsequent treatment, your doctor will perform blood tests. Depending on the results of these tests your doctor will decide if the treatment can be started, can be continued, or needs to be postponed or discontinued.

There is no data available on the use of XOFIGO in patients with Crohn's disease (a chronic inflammatory disease of the intestines) and with ulcerative colitis (a chronic inflammation of the colon). If you have either of these conditions, be sure to speak to your doctor about this matter.

XOFIGO is not for use in women and must not be given to women who are, or may be, pregnant or who are breast-feeding.

If you are having sex, you should use condoms to prevent transfer of bodily fluids. If your partner is a woman who can become pregnant, you should use effective birth control methods during and for 6 months after your treatment to prevent pregnancy.

There is a potential risk that radiation from XOFIGO could harm your testicles and this can impact your ability to have children. Please ask your doctor how this may affect you, especially if you are planning on having children in the future.

INTERACTIONS WITH THIS MEDICATION

No interaction studies to determine how XOFIGO behaves with other medicinal products have been done. There is no data on the use of XOFIGO at the same time as chemotherapy (other medicines to kill your cancer cells). XOFIGO and chemotherapy used together may enhance the decrease in the number of your blood cells and blood platelets. The doctors monitor your blood cell counts while you are on XOFIGO.

Please tell your physician if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription.

See also ABOUT THIS MEDICATION: When it should not be used, and SIDE EFFECTS AND WHAT TO DO ABOUT THEM**.**

PROPER USE OF THIS MEDICATION

XOFIGO will be administered under the supervision of a health professional who is experienced in the use of radiopharmaceuticals.

There are strict laws on the use, handling and disposal of products like XOFIGO. It will only be used in special controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

Usual dose

The dose you receive depends on your body weight. The physician supervising the procedure will calculate the quantity of XOFIGO to be used in your case.

The recommended quantity to be administered is 55 kBq (kilobecquerel, the unit used to express radioactivity) of XOFIGO per kilogram of your body weight.

No dosage adjustment is considered necessary if you are 65 years of age or older or if you have poor kidney or liver function.

You will usually have an injection into a vein once every 4 weeks for a total of 6 injections. There are no data available on the use of treatment with more than 6 cycles of XOFIGO.

XOFIGO will be injected slowly via a needle into one of your veins (a process known as intravenous injection).

XOFIGO is removed from the body mainly by going through the bowels and into the feces (and then passed when going to the bathroom to empty your bowels). The physician will tell you if you need to take any special precautions after receiving this medicine. Contact your physician if you have any questions or if you develop a change in your usual bowel habit, such as a change in bowel frequency or constipation (difficult or less frequent bowel movements).

As your doctor will want to monitor your blood cell counts, it is important that you keep any appointments to give the blood samples needed for the tests.

Be sure to report to your doctor any signs of bleeding or infections such as unusual bruising, bleeding more than usual after a minor cut, a fever, or if you seem to be catching a lot of infections (cold, flu, or so on).

It is important to remember to maintain good fluid intake during treatment with XOFIGO (e.g., drinking water, juice, etc); this can be particularly important if you develop diarrhea (loose and frequent bowel movements) or vomiting (throwing up) as these unwanted effects can cause you to become dehydrated (have too little water in your system); if you have questions, ask your doctor.

Be sure to report to your doctor if you experience nausea and vomiting (not feeling well and throwing up), or diarrhea.

There are no special restrictions regarding contact with other people after receiving XOFIGO (there are with some other types of radiopharmaceuticals). Follow good personal cleanliness and hand-washing practices while receiving XOFIGO and for at least 1 week after the last injection in order to minimize the potential for radiation exposure received from bodily fluids (such as vomit or fecal matter) to household members and caregivers. Whenever possible, you should use a toilet and the toilet should be flushed twice after each use. Clothing soiled with patient fecal matter or urine should be washed promptly and separately from other clothing. Your healthcare providers will use some standard precautions and procedures such as gloves and barrier gowns when handling your bodily fluids to avoid contamination (getting radiation on themselves from the body fluids); this approach is normal under these circumstances and should not be upsetting for you. When handling bodily fluids, wearing gloves and hand washing will help protect healthcare providers from any unnecessary radiation dose they might otherwise be exposed to.

Overdose

There have been no reports of accidental overdose of XOFIGO during clinical studies.

However, in the case of an accidental overdose, your physician will initiate appropriate supportive treatment and will check you for changes in the number of blood cells, and for gastrointestinal symptoms (eg diarrhea, nausea (feeling sick), vomiting).

If you have any further questions on the use of XOFIGO, please ask the physician who supervises the procedure.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, this medicine can cause side effects, although not everybody gets them. The most serious side effects in patients receiving XOFIGO were:

- Thrombocytopenia (decrease in the number of blood platelets)
- Neutropenia (decrease in the number of a specific type of white blood cells (neutrophils))

Your physician will perform blood tests before starting treatment and before each treatment cycle to check your number of blood cells and platelets. It is important that you keep any appointments to give the blood samples needed for the tests.

Contact your physician immediately if you notice the following symptoms as they may be signs of thrombocytopenia (decrease in the number of blood platelets) or neutropenia (decrease in the number of a specific type of white blood cells):

- Any unusual bruising
- More bleeding than usual after injury
- Fever
- If you seem to be catching a lot of infections

The most frequently seen side effects in patients receiving XOFIGO (may affect more than 1 in 10 people) are: diarrhea, nausea (feeling sick), vomiting and thrombocytopenia (decrease in the number of blood platelets).

Possible side effects are listed below by how likely they are.

Very common (may affect more than 1 in 10 people)

- Thrombocytopenia (decrease in the number of blood platelets)
- Diarrhea
- Vomiting
- Nausea (feeling sick)

Common (may affect up to 1 in 10 people)

- Neutropenia (decrease in the number of a specific type of white blood cells (neutrophils))
- Pancytopenia (decrease in the number of red and white blood cells and blood platelets)
- Leukopenia (decrease in the number of white blood cells)
- Injection site reactions (eg erythema (redness of the skin), pain and swelling)

Uncommon (may affect up to 1 in 100 people)

- Lymphopenia (decrease in the number of a specific type of white blood cells (lymphocytes))

XOFIGO contributes to your overall long-term cumulative radiation exposure (the amounts of radiation that an individual typically receives from different sources over a longer period of time). Long-term cumulative radiation exposure may increase your risk for developing new cancers and increase the chances for your future children to have hereditary (from a parent) abnormalities. No cases of cancer caused by XOFIGO have been reported in clinical trials with a follow-up of up to three years but this is a short follow-up period and such cancers, if they occur, are expected to take many years to form or be detected.

If you get any side effects talk to your physician. This includes any possible side effects not listed in this leaflet.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/ Effect		Talk with your doctor or pharmacist	
		Only if severe	**In all cases**
Common	Thrombocytopenia (marked by unusual bruising, more bleeding than usual after injury, fever, catching infections more frequently)		✓
	Neutropenia (marked by unusual bruising, more bleeding than usual after injury, fever, catching infections more frequently)		✓

This is not a complete list of side effects. For any unexpected effects while taking XOFIGO, contact your doctor or pharmacist.

HOW TO STORE IT

You will not have to store this medicine as it is kept at the hospital or clinic and it will be administered to you by the doctor or staff.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online:	www.healthcanada.gc.ca/medeffect
Call toll-free at:	866-234-2345
Complete a Canada Vigilance Reporting Form and:	
Fax toll-free to:	866-678-6789
Mail to:	Canada Vigilance Program Health Canada Postal Locator 0701E Ottawa ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada website at: www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of the side effect, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or Canada.medinfo@bayer.com.

This document plus the full Product Monograph, prepared for health professionals can be found at: http://www.bayer.ca or by contacting the manufacturer at the above-mentioned phone number and email address.

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