APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

XOFIGO 1100 kBq/mL solution for injection
radium Ra 223 dichloride
Sugar free

Read all of this leaflet carefully before you start taking XOFIGO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What XOFIGO is and what it is used for

This medicine contains the active ingredient radium Ra 223 dichloride (radium-223 dichloride).

XOFIGO contains the radioactive isotope radium-223 which mimics calcium. Radium-223 goes to where the cancer has spread in the bone and gives off short-ranging radioactivity (alpha particles) which kills the tumour cells

XOFIGO is used to treat advanced (castration-resistant) prostate cancer that has spread to the bone.

2. What you need to know before you use XOFIGO

XOFIGO should not be administered to you:

- if you are hypersensitive (allergic) to radium-223 dichloride or any of the other ingredients of XOFIGO (listed in section 6).
- if you are below 18 years of age.

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Warnings and precautions

Tell your doctor or health care provider before being given the injection:

Take special care / Special care should be taken with XOFIGO

- XOFIGO can lead to a decrease in the number of your blood cells and blood platelets. Before you start treatment and before each subsequent treatment, your doctor will need to perform blood tests. Depending on the results of these tests, your doctor will decide if the treatment can be started, continued, or needs to be postponed or discontinued.
- If you suffer from bone marrow suppression (decreased blood cell production in the bone marrow).
- If you suffer from untreated spinal cord compression 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.
- If you experience a bone fracture, your doctor will first stabilise the fractured bone before starting or continuing treatment with XOFIGO.
- There is a potential risk that radiation from XOFIGO could harm your testicles. Please ask your doctor how this may affect you, especially if you are planning on having children in the future.
- XOFIGO is not recommended if you are already taking abiraterone together with prednisone/prednisolone (medicines used to treat prostate cancer) due to a possible increase in the risk of bone fracture or death. If you are already taking these medicines, please tell your doctor.

There is no data 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).

Children and adolescents

This medicine is not for use in children and adolescents.

Other medicines and XOFIGO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

No interaction studies 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.

Pregnancy, breastfeeding and fertility

Pregnancy and Breastfeeding:

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 their babies.

Contraception in males and females
If you are having sex with women who can become pregnant you are advised to use a condom and your female partners of reproductive potential are advised to use a highly effective contraceptive method during and up to 6

months after treatment with XOFIGO.

Fertility
There is a potential risk that radiation from Xofigo could affect your fertility. Please ask your doctor how this may affect you, especially if you are planning to have children in the future. You may wish to seek advice on conservation of sperm before treatment starts.

Driving and using machines

There is no evidence and it is considered unlikely that XOFIGO will affect your ability to drive or use machines.

XOFIGO contains sodium

Depending on the volume administered, this medicine can contain up to 54 mg sodium (main component of cooking/table salt) per dose. This is equivalent to 2.7% of the recommended maximum daily dietary intake of sodium for an adult.
If you are on a controlled sodium diet, take this into consideration.

3. How to use XOFIGO

There are strict laws on the use, handling and disposal of medicines 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.

The dose you receive depends on your body weight. The doctor supervising the procedure will calculate the quantity of XOFIGO to be used in your case.
The recommended dose of XOFIGO is 55 kBq (Becquerel, the unit used to express radioactivity) per kilogram body weight.
No dose adjustment is necessary if you are 65 years of age or older or if you have reduced kidney or liver function.

Administration of XOFIGO and conduct of the procedure
XOFIGO will be injected slowly via a needle into one of your veins (intravenously). The healthcare professional will flush the intravenous access line or cannula before and after injection with a saline solution.

Duration of the procedure
- XOFIGO is given once every 4 weeks for a total of 6 injections.
- There is no data available on the safety and efficacy of treatment with more than 6 injections of XOFIGO.

After administration of XOFIGO
- Care should be taken when handling materials, such as bed linen, that come into contact with body fluids (such as spill of urine, faeces, vomiting etc.). XOFIGO is excreted mainly via the faeces. The doctor will tell you if you need to take any special precautions after receiving this medicine. Contact your doctor if you have any questions.

If you have been given more XOFIGO than you should
An overdose is unlikely.
However, in the case of an accidental overdose, your doctor will start appropriate supportive treatment and will check you for changes in the number of blood cells, and for gastrointestinal symptoms (e.g. diarrhoea, nausea [feeling sick], vomiting).
If you have any further questions on the use of XOFIGO, please ask the doctor who supervises the procedure.

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4. Possible side effects

XOFIGO can have side effects.

Not all side effects reported for XOFIGO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking XOFIGO, please consult your health care provider for advice.

If any of the following happens, stop taking XOFIGO and tell your doctor immediately or go to the casualty department at your nearest hospital:
These maybe signs or symptoms of thrombocytopaenia (decrease in the number of blood platelets) or neutropaenia (decrease in the number of a specific type of white blood cells):

- any unusual bruising
- more bleeding than usual after injury
- fever
- or if you seem to be catching a lot of infections.

These are all serious side effects. You may need urgent medical attention.

Your doctor will perform blood tests before starting treatment and before each treatment cycle to check your number of blood cells and platelets.

More frequent side effects:

- thrombocytopenia (decrease in the number of blood platelets)
- diarrhoea
- vomiting
- nausea (feeling sick)

Frequent side effects:

- 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 (e.g. erythema - redness of the skin), pain and swelling)

Less frequent side effects:

- lymphopenia (decrease in the number of a specific type of white blood cells - lymphocytes)) If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of XOFIGO.

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5. How to store XOFIGO

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulations on radioactive materials.

The following information is intended for the specialist only:
XOFIGO must not be used after the expiry date which is stated on the vial and the lead pot.
Store at or below 40 °C.
XOFIGO must not be used if discolouration, the occurrence of particulate matter or a defective container is noticed.

6. Contents of the pack and other information

What XOFIGO contains

The active ingredient is: radium Ra 223 dichloride (radium-223 dichloride).
Each mL of solution contains 1100 kBq radium-223 dichloride, corresponding to 0.58 ng radium-223 at the reference date.
Each vial contains 6 mL of solution (6600 kBq radium-223 dichloride at the reference date).

The other ingredients are: water for injections, sodium citrate, sodium chloride and hydrochloric acid (see end of Section 2 for further information on sodium).

What XOFIGO looks like and contents of the pack

XOFIGO is a clear and colourless sterile isotonic solution for injection with a pH between 6.0 and 8.0. It is supplied in a colourless glass vial closed with a grey rubber stopper and aluminium seal. The vial contains 6 mL of solution. It is stored in a lead pot.

Holder of Certificate of Registration

Bayer (Pty) Ltd
Reg. No.: 1968/011192/07
27 Wrench Road
Isando
1609

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