PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

XOFIGO®

1100 kBq/ ml corresponding to 0, 58 ng radium-223, at the reference date

Solution for injection

Read all of this leaflet carefully before you are given XOFIGO.

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask the doctor who will supervise the procedure.

1. WHAT XOFIGO CONTAINS:

The active ingredient is radium Ra 223 dichloride (radium-223 dichloride)

Each ml of solution contains 1100 kBq radium Ra 223 dichloride (radium-223 dichloride), corresponding to 0,58 ng radium-223, at the reference date. Radium is present in the solution as a free ion.

Each ml contains 0,194 mmol (equivalent to 4,5 mg) of sodium.

The other ingredients are hydrochloric acid, sodium chloride, sodium citrate and water for injection

2. WHAT XOFIGO IS USED FOR:

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

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

3. BEFORE YOU ARE GIVEN XOFIGO:

You should not be given XOFIGO:

- If you are hypersensitive (allergic) to radium-223 dichloride or any of the other ingredients of XOFIGO.
- If you are below 18 years of age.

Take special with XOFIGO:

Tell your doctor or healthcare professional before being given the injection:

- 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.
- 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, can be continued, or needs to be postponed or discontinued.
- 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.

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).

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.

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.

Driving and using machines:

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

Important information about some of the ingredients of XOFIGO:

If you are on a controlled sodium diet, take into consideration that XOFIGO can contain up to 54 mg of sodium per dose, depending on the volume of XOFIGO you are given.

Using other medicines with XOFIGO:

If you are using other medicines on a regular basis, including complementary or traditional medicines, the use of XOFIGO with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

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.

4. HOW TO RECEIVE XOFIGO:

For intravenous use.

There are strict laws on the use, handling and disposal of products like XOFIGO. It will only be used in special controlled areas.

You will not be expected to give yourself XOFIGO. It will be given to you by a person who is qualified to do so.

After receiving XOFIGO:

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:

Since a healthcare professional will administer XOFIGO, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

However, in the case of an accidental overdose, your doctor will initiate 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).

5. 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 being given XOFIGO, please consult your doctor, pharmacist or other healthcare professional 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.

6. STORING AND DISPOSING OF XOFIGO:

You will not have to store this medicine. XOFIGO is stored under the responsibility of the specialist or the health care professional in appropriate premises. Storage of XOFIGO will be in accordance with national regulation on radioactive materials.

7. PRESENTATION OF XOFIGO:

Solution for injection in a 10 mL colourless glass bottle, glass type I for injection, closed with a chlorobutyl gray siliconised stopper for injection and fixed with a flanged closure made of an aluminium shell.

Each sealed vial is wrapped with an adhesive transparent film. A plastic bottom and top cap provides a cylindrical form to support the wrapping process.

The wrapped vial is inserted in a lead shielded container. The lead shielded container is then packed in a shipping cardboard box.

8. IDENTIFICATION OF XOFIGO:

XOFIGO solution for injection is clear, colourless and free of particulate matter.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

48/32.15/0715

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Bayer (Pty) Ltd

Reg. No.: 1968/011192/07

27 Wrench Road

ISANDO, 1609

11. DATE OF PUBLICATION:

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