XOFIGO®

(zo-fee-go)

Radium (223Ra) dichloride

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about XOFIGO. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given XOFIGO against the benefits your doctor expects it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

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

WHAT XOFIGO IS USED FOR

XOFIGO is used to treat prostate cancer that has not responded to hormone therapy. XOFIGO is only used when the disease has spread to the bone but is not known to have spread to other internal organs, and is causing symptoms (e.g. pain).

XOFIGO contains small amounts of the radioactive isotope radium-223 [223Ra] (as radium-223 dichloride) which mimics calcium.

Radium-223 goes to where the tumour cells are growing in the bone and releases short-ranging radioactivity (alpha particles) which is toxic to the cells.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Your doctor may have prescribed it for another reason.

BEFORE YOU ARE GIVEN XOFIGO

When you must not be given it

If you are not sure whether you should be given this medicine, talk to your doctor.

There are no known medical conditions in which you must not be given XOFIGO.

You must not be given XOFIGO if:

- the packaging is torn or shows signs of tampering
- the expiry date printed on the pack after "EXP" has passed

If you are given XOFIGO after the expiry date has passed, it may not work as well.

The hospital or clinic where you will be receiving XOFIGO will make sure that XOFIGO is not used if the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

XOFIGO is not to be used in women.

The safety and efficacy in children and adolescents under 18 years of age have not been studied.

Before you are given it

Tell your doctor if you have any of the following medical conditions:

- bone marrow suppression (a severe problem with your bone marrow which can lead to a decreased production of blood cells)
- untreated spinal cord compression which is already established or is about to happen (this can be caused by a tumour or other lesion)
- a bone fracture
- Crohn's disease (chronic inflammatory disease of the intestines)
- ulcerative colitis (chronic inflammation of the colon)

XOFIGO can lead to a decrease in the number of white blood cells (which are necessary to help fight infection) and/or platelets (which are necessary to control blood clotting).

Before starting treatment with XOFIGO, your doctor will perform blood tests to check your blood cells and platelet levels. Some of these tests will be repeated before each subsequent treatment (injection). 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.

Tell your doctor if you are intending to have children.
Radiation may have an effect on the production or development of your sperm.

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 prior to treatment.

If you have not told your doctor about any of the above, tell your doctor before you are given XOFIGO.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket, naturopath or health food shop.

Tell your doctor if you are taking chemotherapy (other medicines to treat your cancer).
In some cases, using XOFIGO and chemotherapy together may cause a more severe decrease in the number of your white blood cells and/or platelets.

Your doctor or treatment provider has more information on medicines to be careful with or avoid when you are given XOFIGO.

HOW XOFIGO IS GIVEN

There are strict laws on the use, handling and disposal of products like XOFIGO. XOFIGO can only be used in specialised hospitals or clinics.

XOFIGO must only be handled and given to you by a qualified doctor or other qualified healthcare professional who is trained and licensed to use it safely.

If you have any questions, ask your doctor.

Follow all directions given to you by your doctor carefully.
They may differ from the information contained in this leaflet.

If you do not understand the instructions given, ask your doctor for help.

How much is given

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

The recommended quantity to be administered is 55 kBq of XOFIGO per kilogram of your body weight.

No dosage adjustment is needed in elderly patients, or if you have poor kidney or liver function.

How it is given

XOFIGO is injected slowly (generally up to 1 minute) into your veins (intravenously).

The healthcare professional administering XOFIGO will flush the intravenous access line or cannula before and after the injection with a saline solution.

XOFIGO is a ready-to-use solution and should not be diluted or mixed with any solutions.

When it is given

Your doctor will decide when you will be given XOFIGO.

How long to continue treatment

Continue treatment with XOFIGO for as long as your doctor tells you.

You will usually be given an injection of XOFIGO once every 4 weeks for a total of 6 injections.

If you forget a treatment

If you miss a treatment with XOFIGO, contact your doctor to make a new appointment for injection as soon as possible.

Do not stop treatment with XOFIGO unless your doctor tells you to do so.

If you are given too much (overdose)

It is unlikely that you will be given too much XOFIGO. The dose of XOFIGO you will receive will be calculated by a qualified doctor and given to you in a highly specialised setting by the qualified doctor or other qualified healthcare professional.

If you receive too much XOFIGO, you will need to be monitored for gastrointestinal symptoms and your doctor will need to perform blood tests on you to check for any changes in your blood counts.

If an overdose is suspected, immediately telephone your doctor or the Poisons Information Centre (Australia: 13 11 26 or New Zealand: 0800 POISON or 0800 764 766) or go to Accident and Emergency at your nearest hospital.

WHILE YOU ARE BEING TREATED WITH XOFIGO

Things you must do

Your doctor who supervises the procedure will let you know if you need to take any special precautions after receiving XOFIGO.

Follow good hygiene after receiving XOFIGO.

XOFIGO is excreted from your body mainly via the faeces.

You should adhere to good personal hygiene practices while receiving XOFIGO and for at least 4 weeks after the last injection in order to minimise radiation exposure from bodily fluids to household members and caregivers.

Flush the toilet twice and wash your hands well after going to the bathroom.

Clothing soiled with bodily fluids, such as faecal matter or urine, should be washed promptly and separately from other clothing.

When handling bodily fluids, you and your caregiver should wear protective gloves and wash your hands thoroughly afterwards.

Contact your doctor if you have any questions.

Make sure you keep all your doctor's appointments so your progress can be checked.
Your doctor will need to perform blood tests to check your blood cells and platelet levels before giving each dose of XOFIGO.

If you are told that your blood count has become abnormally low, ask your doctor for advice on the precautions you can take to reduce the risk of infection or bleeding.

Use an effective birth control method during and for 6 months after treatment with XOFIGO if you are having sex with a woman who can become pregnant.
Your partner should also use an effective contraceptive method.

SIDE EFFECTS

Tell your doctor as soon as possible if you do not feel well while you are being treated with XOFIGO.

XOFIGO helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.
You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- diarrhoea
- vomiting
- nausea (feeling sick)

Tell your doctor as soon as possible if you notice any of the following:

- redness of the skin, pain and swelling at the injection site
- symptoms of anaemia like tiredness, being short of breath and looking pale

The most serious side effects in patients receiving XOFIGO are:

- low platelet count in the blood (thrombocytopenia)
- low number of neutrophils which are a class of white blood cells (neutropenia)

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- bleeding or bruising more easily than normal
- frequent infections such as fever, severe chills, sore throat or mouth ulcers

The above side effects may be signs that your blood cells and/or platelet levels are too low. You may need urgent medical attention.

Tell your doctor if you notice anything else that is making you feel unwell.
Other side effects not listed above may also occur in some people.

AFTER YOU ARE TREATED WITH XOFIGO

Storage

You will not have to store XOFIGO.
The hospital or clinic where you will be receiving XOFIGO will be responsible for storing XOFIGO properly.

Disposal

Each XOFIGO vial is to be used for one injection only and then discarded.

The hospital or clinic where you will be receiving XOFIGO will be responsible for discarding any unused contents properly.

PRODUCT DESCRIPTION

What it looks like

XOFIGO is a clear and colourless solution for injection, supplied in a glass vial and packed in a lead container.

Each pack of XOFIGO contains one single-dose vial. Each vial contains 6 mL of radium-223 solution for injection corresponding to a total activity of 6.6 MBq (1100 kBq/mL) at the reference date.

Ingredients

Active ingredient:

- radium (223Ra) dichloride

Inactive ingredients:

- hydrochloric acid
- sodium chloride
- sodium citrate dihydrate
- water for injection

Supplier

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

Australian registration number

AUST R 208905

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See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.