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Xofigo (*radium-223 dichloride*)

An overview of Xofigo and why it is authorised in the EU

What is Xofigo and what is it used for?

Xofigo is a radiopharmaceutical (a medicine containing a radioactive substance) that is used to treat adults with cancer of the prostate (a gland of the male reproductive system).

Xofigo is used when castration (to stop the production of male hormones) by surgery or with medicines does not work, and when the cancer has spread to the bones (bone metastases) and is causing symptoms such as pain, but has not spread to other internal organs. It should be used only for patients who have had at least two previous treatments for prostate cancer or who cannot receive other treatments.

Xofigo is used on its own or in combination with a medicine known as an 'LHRH analogue'.

Xofigo contains the active substance radium-223 dichloride.

How is Xofigo used?

Xofigo can only be obtained with a prescription and should only be handled and given by someone who is authorised to use radioactive medicines and after evaluation of the patient by a qualified doctor.

The dose of Xofigo is calculated to provide a specific dose of radioactivity based on the patient's body weight. The medicine is slowly injected into a vein usually for up to one minute. Injections are repeated every 4 weeks for a total of 6 injections.

For more information about using Xofigo, see the package leaflet or contact your doctor or pharmacist.

How does Xofigo work?

The active substance in Xofigo, radium-223, emits short-range radiation known as alpha particles. The bones in the body take up radium in the same way as calcium. The radioactive radium builds up in bone tissues where the cancer has spread, and the alpha particles destroy surrounding cancer cells and help to control the associated symptoms.

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What benefits of Xofigo have been shown in studies?

Xofigo was compared with placebo (a dummy treatment) as an addition to standard care in a main study involving 921 men with cancer of the prostate that had spread to the bones and for which suppression of male hormones using medicines or surgery did not work. Patients were given up to 6 injections at 1-month intervals and were followed up for 3 years from the first injection. Patients given Xofigo lived on average for 14.9 months, compared with 11.3 months for those given placebo. The signs and symptoms of progressive disease such as bone pain also took longer to develop in patients given Xofigo.

What are the risks associated with Xofigo?

The most common side effects with Xofigo (which may affect more than 1 in 10 people) are diarrhoea, nausea (feeling sick), vomiting, thrombocytopenia (low blood-platelet counts) and bone fractures. The most serious side effects were thrombocytopenia and neutropenia (low levels of neutrophils, a type of white blood cell that fights infection). For the full list of side effects of Xofigo, see the package leaflet.

Xofigo must not be used with the medicine abiraterone acetate and the corticosteroids prednisone or prednisolone. For the full list of restrictions, see the package leaflet.

Why is Xofigo authorised in the EU?

The European Medicines Agency decided that Xofigo's benefits are greater than its risks and it can be authorised for use in the EU. Xofigo has been shown to prolong life and delaying signs and symptoms of progressive disease. Regarding its safety, several measures have been put in place to minimise the risks of the medicine such as bone fractures[1] The radiation emitted by Xofigo has a shorter range than the radiation of currently available radiopharmaceuticals. This may limit the damage to nearby healthy tissues.

What measures are being taken to ensure the safe and effective use of Xofigo?

Xofigo can increase the risk of having fractures. The company that markets Xofigo will have to conduct studies to further characterise the safety profile of the medicine, in particular with regard to the risk of fractures and the risk of new metastases that do not affect the bone in patients treated with Xofigo.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Xofigo have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Xofigo are continuously monitored. Side effects reported with Xofigo are carefully evaluated and any necessary action taken to protect patients.

Other information about Xofigo

Xofigo received a marketing authorisation valid throughout the EU on 13 November 2013.

Further information on Xofigo can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

[1] See outcome of safety review carried out in 2018 here.

This overview was last updated in 09-2018.