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EPAR summary for the public

Xofigo

radium-223 dichloride

This is a summary of the European public assessment report (EPAR) for Xofigo. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Xofigo.

For practical information about using Xofigo, patients should read the package leaflet or contact their doctor or pharmacist.

What is Xofigo and what is it used for?

Xofigo is a radiopharmaceutical (a medicine containing a radioactive substance) that contains the active substance radium-223 dichloride. It is used to treat adult men with cancer of the prostate (a gland of the male reproductive system). Xofigo is used when medical or surgical castration (stopping the production of male hormones in the body using medicines or surgery) does not work, and when the cancer has spread to the bones and is causing symptoms such as pain but is not known to have spread to other internal organs.

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.

Xofigo is available as a solution for injection. The dose of Xofigo is calculated based on the patient's body weight to provide a specific dose of radioactivity. The medicine is given into a vein by slow injection usually lasting around one minute. Injections are repeated every 4 weeks for a total of 6 injections. For further information, see the package leaflet.

How does Xofigo work?

The active substance in Xofigo, radium-223, emits short-range radiation known as alpha particles. In the body, radium is handled like the calcium naturally found in the bones. It accumulates in bone

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

tissues where the cancer has spread, and the alpha particles destroy surrounding cancer cells and help to control the associated symptoms.

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. The main measure of effectiveness was how long the patients survived. The average survival in patients given Xofigo was 14.9 months, compared with 11.3 months in those given placebo. Patients given Xofigo also took longer for signs and symptoms of progressive disease such as fractures and bone pain to develop.

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 and thrombocytopenia (low blood-platelet counts). The most serious effects were thrombocytopenia and neutropenia (low levels of neutrophils, a type of white blood cell that fights infection). For the full list of all side effects reported with Xofigo, see the package leaflet.

Why is Xofigo approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Xofigo's benefits are greater than its risks and recommended that it be approved for use in the EU. Xofigo had shown a clinically relevant benefit in prolonging life and delaying signs and symptoms of progressive disease. Its main short-term side effects were reversible and considered manageable. 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?

A risk management plan has been developed to ensure that Xofigo is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Xofigo, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Xofigo

The European Commission granted a marketing authorisation valid throughout the European Union for Xofigo on 13 November 2013.

The full EPAR for Xofigo can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Xofigo, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 9-2015.