Bayer HealthCare

▼Xofigo: supply shortage and Special Temporary Preparation Instructions

Important information for all Healthcare professionals involved in the preparation and administration of Xofigo.

18th December 2014

Dear Healthcare professional**,**

Bayer Pharma AG in agreement with the Health Products Regulatory Agency and the European Medicines Agency would like to inform you of important information regarding drug shortage and new special temporary preparation instructions for Xofigo (radium-223 dichloride), used in the treatment of adults with castration-resistant prostate cancer.

Summary

- **Recently produced batches of Xofigo did not pass routine quality checks because they were found to contain small fibrous particles. No affected product was released for distribution. This resulted in a temporary drug shortage on which a Direct Healthcare Professional Communication Letter was issued.**

- **A temporary batch release procedure with additional product checks has been agreed in order to make Xofigo available to patients as quickly as possible. Priority should be given to patients currently on treatment until normal supply is resumed.**

- **As a precautionary measure Xofigo must be filtered prior to administration to the patient, following the instructions below. This temporary filtering procedure must be done in the nuclear medicines department in your facility.**

- **You will be notified when this filtration is no longer necessary and normal supply is resumed.**

Filtering Procedure:
This filtering step consists of drawing up the drug product solution through a syringe filter before administering it to the patient.

Bayer has qualified three filters for filtration of Xofigo, and will provide appropriate filters for you to use in the preparation of doses during the temporary batch release.

Specific instructions:

- Calculate the appropriate volume needed for the dose, based on the patient's body weight.
- Place a filter between the needle used to withdraw the solution from the vial and the syringe.
- Carefully withdraw the volume up from the vial through the filter into the syringe.
- Carefully remove and discard the filter and replace the needle (follow your normal procedure for discarding radioactive waste).
- The filter could absorb some of the product, reducing the radioactivity in the syringe (not more than 1%). Measure the amount of radioactivity in the syringe in a properly calibrated activimeter.
- Inspect the product visually before use. Xofigo is a clear, colourless solution and should not be used in case of discolouration or the occurrence of particulate matter.
- Administer the dose according to your local protocols.
- For clinical trials: assay and record the total radioactivity in the syringe before and after administration

Further information

Bayer has qualified three filters for filtration of Xofigo, and will provide appropriate filters for you to use in the preparation of doses during the temporary batch release. The list of filters is provided below:

Supplier	**Article / Pore size**	**Art-No.**	**Material (Filter)**	**Material (Housing)**
BBraun	Sterifix Injection Filter, 0.2 µm	4099206	PESU	MABS
Merck Millipore	Millex-GS, 0.22 µm	SLGL0250S	CME	PVC
RoweMed	RowePhil 18/5.0, 5 µm	A6227	PET	MABS

Company contact point

Contact point details for further information are given in the product information of the medicinal products (SmPC and PL) at: http://www.ema.europa.eu/ema/.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

Adverse events or quality complaints should also be reported to Bayer Limited Drug Safety on 01-2999313.

Yours sincerely,

Dr. Tristan P. Cooper MB BCh BAO FFPM
Medical Director

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.