



April 30, 2015

**IMPORTANT DRUG INFORMATION UPDATE**

**Subject: Xofigo® (radium Ra 223 dichloride) Injection Drug Shortage Resolved;  
Temporary Filtration No Longer Required**

Xofigo® (radium Ra 223 dichloride) Injection is an alpha particle-emitting radioactive therapeutic agent indicated for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease.

With guidance from the FDA, the filter process temporarily implemented for Xofigo® is no longer required when preparing the patient-ready dose syringes. Cardinal Health Radiopharmacy, the central radiopharmacy in the United States for Xofigo® will no longer be required to use a filter during the preparation of Xofigo® patient-ready doses.

As previously announced, some batches of Xofigo® produced in September 2014 did not pass routine quality checks because they were found to contain small fibrous particles. This quality issue resulted in a temporary drug product shortage.

To resume distribution of the approved product during the drug shortage period, an enhanced visual inspection procedure was implemented and FDA required on a temporary basis a filtration step during the preparation of Xofigo® patient-ready doses at Nuclear Pharmacy Group at Cardinal Health.

The root cause was identified and corrective and preventive actions (CAPAs) were successfully implemented. As a part of the program to resolve the particulate matter issue Bayer: (1) submitted and received approval by FDA to use an alternative stopper to seal the Xofigo® vial and (2) produced recent Xofigo® batches with the alternative stoppers showing consistent and acceptable results. The normal product manufacturing procedure for Xofigo® has resumed, and the filtration step during the preparation of Xofigo® patient-ready doses at Nuclear Pharmacy Group at Cardinal Health should be discontinued.

If you have any questions or need further assistance please contact 1-888-842-2937.

Sincerely,

  
Dario Mirski, MD  
Vice President and Head, US Medical Affairs  
Bayer HealthCare Pharmaceuticals, Inc.