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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Product Details for NDA 203971

XOFIGO (RADIUM RA-223 DICHLORIDE)
162mCi/6ML (27mCi/ML)

Marketing Status: Prescription

Active Ingredient: RADIUM RA-223 DICHLORIDE

Proprietary Name: XOFIGO

Dosage Form; Route of Administration: SOLUTION; INTRAVENOUS

Strength: 162mCi/6ML (27mCi/ML)

Reference Listed Drug: Yes

TE Code:

Application Number: N203971

Product Number: 001

Approval Date: May 15, 2013

Applicant Holder Full Name: BAYER HEALTHCARE PHARMACEUTICALS INC

Marketing Status: Prescription

[Patent and Exclusivity Information \(patent_info.cfm?](#)

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