# $^{223}$Ra dichloride

(Xofigo®)

**1. Indications**

Treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases.

**2. Preparation**

Approved product, see summary of product characteristics (SmPC).

**3. Quality control**

Approved product, see summary of product characteristics (SmPC) and the European Pharmacopeia.

**4. Interactions**

No clinical interaction studies have been performed.
As interactions with calcium and phosphate cannot be excluded, pausing supplementation with these substances and/or Vitamin D should be considered some days before starting with $^{223}$Ra-dichloride treatment.
Concomitant chemotherapy with $^{223}$Ra-dichloride may have additive effects on bone marrow suppression.

**5. Contraindications**

Bone marrow suppression, pregnancy and breastfeeding

**6. Adverse reactions**

| | Very common (≥1/10) | Common (≥1/100 to <1/10) | Uncommon (≥1/1,000 to <1/100) |
|---|---|---|---|
| Blood and lymfatic system disorders | thrombocytopenia | neutropenia, pancytopenia, leukopenia | lymphopenia |
| Gastrointestinal disorders | | diarrhoea, vomiting, nausea | |
| Administration site conditions | | injection site reactions | |

*Injection site reactions*

Grade 1 and 2 injection site reactions, such as erythema, pain and swelling, were reported in 1,2% of patients.

*Thrombocytopenia and Neutropenia*

Thrombocytopenia (all grades) occurred in 11,5% of patients. Grade 3 and 4

thrombocytopenia was observed in approximately 6,3% of patients.
Neutropenia (all grades) was reported in 5% of patients. Grade 3 and 4 neutropenia was observed in 2,2% of patients.
Neutrophil and platelet count nadirs occurred mostly at 2-3 weeks after intravenous administration of a single dose of $^{223}$Ra-dichloride.

**7. Biodistribution & pharmacokinetics**

After intravenous injection, $^{223}$Ra is rapidly cleared from the blood and is incorporated primarily into bone and bone metastases, or is excreted into the intestine.
Fifteen minutes post injection, about 20% of the injected activity remained in the blood. At 4 h, about 4% of the injected activity remained in the blood, decreasing to less than 1% at 24 h after the injection. The volume of distribution was higher than the blood volume indicating distribution to peripheral compartments.
At 10 min post injection, activity was observed in the bone and in the intestine. The level of activity in the bone was in the range of 44-77% at 4 h post injection.
No significant uptake was seen in other organs such as heart, liver, kidneys, urinary bladder and spleen at 4 h post injection.
Faecal excretion is the major route of elimination from the body. About 5% is excreted in the urine and there is no evidence of hepatobiliary excretion.

**8. Stability**

The shelf-life of this product is 28 days.

**9. Literature**


- SmPC Xofigo 1100 kBq/mL solution for injection 05-2016