

# <sup>153</sup>Sm lexidronam

<sup>153</sup>Sm-lexidronam-pentasodium (EDTMP) (Quadramet®)

## 1. Indications

<sup>153</sup>Sm injection is approved to reduce bone pain at patients with multiple osteoblastic skeletal metastases, who took up technetium (<sup>99m</sup>Tc) labeled bisphosphonates during bone scan.

## 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

Samarium may not be administered concomitantly with myelotoxic chemotherapy or external radiation therapy due to possible cumulative effects on the bone marrow. Do not administer at the same time as biphosphonates.

## 5. Adverse reactions

Decrease of the white blood cells en blood plates, anaemia. Transient increase in bone pain, shortly after the injection (flare reaction).

Also reported in clinical studies: asthaenia, nausea, vomiting, diarrhea, peripheral oedema, headache, hypotension, dizziness, myasthenia, confusion and perspiration.

## 6. Biodistribution & pharmacokinetics

The total uptake of <sup>153</sup>Sm in bone is  $65,5 \pm 15,5\%$  in study with 453 patients with different multiple primary malignancies of the administered activity. There is a positive correlation between the uptake in bone and the number of metastatic sites. On the other hand the uptake in bone is inversely proportional to the radioactivity in plasma after 30 min.

<sup>153</sup>Sm is cleared from the blood in patients rapidly. In 22 patients is only  $9,6 \pm 2,8\%$  of the administered activity in the plasma present after 30 min of the injection.

After 4 and 24 h the radioactivity of the plasma is decreased from  $1,3 \pm 0,7\%$  to  $0,05 \pm 0,03\%$ . Urinary excretion occurs predominantly during the first 4 h ( $30,3 \pm 13,5\%$ ).

After 12 h  $35,3 \pm 16,6\%$  is excreted of the administered activity via the urine. Patients with many bone metastases have a lower excretion in the urine, regardless of the administered amount of radiopharmaceutical.

Analysis of urine samples have shown that the measured radioactivity belongs to the intact complex.

### **7. Stability**

The product has a shelf-life of 1 day after the activity reference time. It has to be used within 6 h after defrosting. It has to be stored at -10 to -20°C.

### **8. Literature**

- SmPC Samarium-153; Sm-153-lexidronam-pentanatrium.
- KNMP kennisbank, Sm-153-lexidronam-pentanatrium.