

APPENDIX. CONSIDERATIONS FOR PATIENTS RECEIVING SM-153 LEXIDRONAM

Before Administration

- Before administering samarium (Sm)-153 lexidronam, careful consideration must be given to a patient's bone marrow function, performance status, recent use of other marrow-suppressing agents such as chemotherapy or radiotherapy, and anticipated life expectancy.
- Caution should be used when treating patients with low white blood cells (WBC) or platelet counts. One study of Sm-153 lexidronam excluded patients with WBC counts <2000 μL , platelet counts $<50,000$ μL , or hemoglobin levels <5.0 g/dL.

Dosage and Administration

- The recommended dose of Sm-153 lexidronam is 1.0 millicuries (mCi) per kilogram of body weight, administered intravenously over a period of 1 minute through a secure, indwelling catheter, followed by a saline flush.
- Patients should drink at least 16 ounces of fluid *prior to injection* and they should urinate as often as possible during the first 6 to 12 hours after injection.
- Patients should be instructed to flush the toilet 2 times after each voiding.

Special Precautions

- Because radiopharmaceuticals are excreted in both urine and feces, patients should have adequate hepatic and renal function.
- Sm-153 lexidronam is excreted in the urine for ≤ 12 hours after injection, with 35% occurring during the first 6 hours; therefore, patients should be instructed to urinate as often as possible during the first 6 to 12 hours after injection to minimize radiation exposure to the bladder.
- Patients should be instructed to use a toilet rather than a urinal and to flush the toilet 2 times after each voiding to minimize the chance of radiation exposure to themselves and others. Patients should also be instructed to wash their hands thoroughly each time they void.
- Spilled urine should be cleaned up completely. If blood or urine gets onto clothing or bed linens, they should be washed separately or stored for 1 to 2 weeks to allow for decay of Sm-153 lexidronam.
- A transient increase in bone pain may occur within 72 hours of injection. The pain is usually mild and self-limiting and generally responsive to analgesics.
- Patients may notice the onset of pain relief within 1 week of injection, with maximal pain relief occurring at 3 to 4 weeks after injection. Patients who experience pain relief may be encouraged to decrease their use of opioid analgesics.
- Sm-153 lexidronam should not be given to women who are pregnant or breast-feeding.
- Sm-153 lexidronam is a chelating agent; therefore, caution and appropriate monitoring of electrocardiographic changes (with or without the presence of hypocalcemia) should be given when administering this agent to patients with a history of severe cardiac disease.
- Patients with a history of congestive heart failure or renal insufficiency should be monitored and supportive treatment should be considered to assure adequate hydration.
- This agent should be used only by those who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.
- Sm-153 lexidronam, like other radiopharmaceutical agents, must be handled with care and appropriate safety measures to minimize radiation exposure to clinical personnel and others in the patient's environment.

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(Continued)

Repeat Treatments

- Preliminary studies suggest that patients can be treated a second time with Sm-153 lexidronam, if needed, offering the potential for sustained pain relief for patients with multiple bone lesions. However, adequate time for marrow recovery should be allowed before retreatment.
- Factors that may rule out retreatment with Sm-153 lexidronam include rapid systemic progression of disease; mechanical bone pain secondary to pathologic fracture from metastases or osteoporosis from hormonal therapy; underlying degenerative disease such as osteoarthritis; impending or established pathologic fracture; or impending or established spinal cord compression.

REFERENCES

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