



A guide to administering Strontium89

Radiopharmaceuticals like Strontium89 must be administered by clinicians trained and licensed to handle radionuclide therapy. Strontium89 must be handled with care and appropriate safety measures taken to minimize radiation to clinical personnel. To ensure the safety of the person administrating treatment, always use waterproof gloves and effective radiation shielding when handling Strontium89.1

Steps for administration:

Step 1: Test blood levels prior to administration. Strontium89 should be used with caution in patients with platelet counts below 60,000 and white cell counts below 2,400. Have patients complete the Patient Release Card if required by your institution.

Step 2: Review the Strontium89 Patient Counseling Tool and the post-administration information sheet with patients and answer any questions they may have.

Step 3: Assay the 4 mCi dose immediately before treatment and draw it into a syringe. Assay the syringe to confirm activity.

Step 4: Set up the injection environment by placing absorbent materials in the area where the injection will take place.

Step 5: Insert the IV cannula required by your institution for injection. Connect a 2- or 3-way stopcock to the IV device. Open the stopcock to flush the infusion set with isotonic saline to confirm IV patency.

Step 6: If IV patency is confirmed, administer Strontium89 by slow IV injection over 1 to 2 minutes. Flush the infusion system thoroughly with isotonic saline, remove the syringes and injection setup, and assay immediately for residual activity. Dispose of according to institutional policies.

Step 7: Handle product with appropriate safety measures to minimize radiation exposure. Remove the syringes and injection setup. Assay for residual activity and dispose of according to institutional policies.

Always use waterproof gloves and effective radiation shielding when handing Strontium89.

Before discharging patients:

- Provide them with the post-administration information sheet and remind them to follow the guidelines; ensure they know that it can take 7-21 days for pain relief to begin
- · Schedule bi-weekly blood tests
- · Encourage patients or caregivers to track their pain and report their results
- Remind them to visit **<u>Strontium89.com</u>** for more information

A single injection of Strontium89 may provide lasting pain relief. If pain returns, additional injections may be administered every 90 days, as long as hematologic testing confirms appropriateness.¹

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

Strontium Chloride Sr-89 Injection, USP is indicated for the relief of bone pain in patients with painful skeletal metastases. The presence of bone metastases should be confirmed prior to therapy.

WARNINGS

Use of Strontium-89 Chloride Injection in patients with evidence of seriously compromised bone marrow from previous therapy or disease infiltration is not recommended unless the potential benefit of the treatment outweighs its risks. Bone marrow toxicity is to be expected following the administration of Strontium-89 Chloride Injection, particularly white blood cells and platelets. The extent of toxicity is variable. It is recommended that the patient's peripheral blood cell counts be monitored at least once every other week. Typically, platelets will be depressed by about 30% compared to preadministration levels. The nadir of platelet depression in most patients is found between 12 and 16 weeks following administration of Strontium-89 Chloride Injection. White blood cells are usually depressed to a varying extent compared to preadministration levels. Thereafter, recovery occurs slowly, typically reaching preadministration levels six months after treatment unless the patient's disease or additional therapy intervenes. (Continued on next page).

Please see full Prescribing Information.





INDICATIONS AND IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS

In considering repeat administration of Strontium-89 Chloride Injection, the patient's hematologic response to the initial dose, current platelet level, and other evidence of marrow depletion should be carefully evaluated. Verification of dose and patient identification is necessary prior to administration because Strontium-89 Chloride Injection delivers a relatively high dose of radioactivity.

Strontium-89 Chloride Injection may cause fetal harm when administered to a pregnant woman. There are no adequate and well-controlled studies in pregnant women. If this drug is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant.

PRECAUTIONS

Strontium-89 Chloride Injection is not indicated for use in patients with cancer not involving bone. Strontium-89 Chloride Injection should be used with caution in patients with platelet counts below 60,000 and white cell counts below 2,400.

Radiopharmaceuticals should only be used by physicians 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. Strontium-89 Chloride Injection, like other radioactive drugs, must be handled with care and appropriate safety measures taken to minimize radiation to clinical personnel.

In view of the delayed onset of pain relief, typically 7 to 20 days post injection, administration of Strontium-89 Chloride Injection to patients with very short life expectancy is not recommended.

A calcium-like flushing sensation has been observed in patients following a rapid (less than 30 second injection) administration.

Special precautions, such as urinary catheterization, should be taken following administration to patients who are incontinent to minimize the risk of radioactive contamination of clothing, bed linen, and the patient's environment.

Strontium-89 Chloride Injection is excreted primarily by the kidneys. In patients with renal dysfunction, the possible risks of administering Strontium-89 Chloride Injection should be weighed against the possible benefits.

PREGNANCY

Teratogenic effects. Pregnancy Category D. See Warnings section.

NURSING MOTHERS

Because Strontium acts as a calcium analog, secretion of Strontium-89 Chloride into human milk is likely. It is recommended that nursing be discontinued by mothers about to receive intravenous Strontium-89 Chloride. It is not known whether this drug is excreted in human milk.

PEDIATRIC USE

Safety and effectiveness in children below the age of 18 years have not been established.

ADVERSE REACTIONS

A single case of fatal septicemia following leukopenia was reported during clinical trials. Most severe reactions of marrow toxicity can be managed by conventional means.

A small number of patients have reported a transient increase in bone pain at 36 to 72 hours after injection. This is usually mild and self-limiting, and controllable with analgesics. A single patient reported chills and fever 12 hours after injection without long-term sequelae.

Additional post-marketing reactions include hot flush.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information.