

¹⁸F sodium fluoride

1. Indications

Sodium Fluoride ¹⁸F Injection is indicated for diagnostic positron emission tomography (PET) imaging of bone to define areas of altered osteogenic activity.

2. Preparation

Proton bombardment of enriched [¹⁸O]H₂O to produce [¹⁸F]]fluoride ion; [¹⁸F]]fluoride is then trapped on a Seppak QMA cartridge and eluted with normal saline. The final product is sterile filtrated over a 0,22 um filter.

3. Quality control

The drug product complies with the European Pharmacopeia (PhEur) monograph for Sodium Fluoride ¹⁸F Injection.

4. Interactions

The possibility of interactions of Sodium Fluoride ¹⁸F Injection with other drugs taken by patients undergoing PET imaging has not been studied.

5. Adverse reactions

No adverse reactions have been reported for Sodium Fluoride ¹⁸F Injection based on a review of the published literature, publicly available reference sources, and adverse drug reaction reporting systems.

6. Biodistribution & pharmacokinetics

Fluoride ¹⁸F ion normally accumulates in the skeleton in an even fashion, with greater deposition in the axial skeleton (e.g. vertebrae and pelvis) than in the appendicular skeleton and greater deposition in the bones around joints than in the shafts of long bones. Increased fluoride ¹⁸F ion deposition in bone can occur in areas of increased osteogenic activity during growth, infection, malignancy (primary or metastatic) following trauma, or inflammation of bone.

After intravenous administration, fluoride ¹⁸F ion is rapidly cleared from the plasma in a biexponential manner. The first phase has a half-life of 0,4 h, and the second phase has a half-life of 2,6 h. Essentially all the fluoride ¹⁸F that is delivered to bone by the blood is retained in the bone. One hour after administration of fluoride, ¹⁸F only about 10% of the injected dose remains in the blood. Fluoride ¹⁸F diffuses through capillaries into bone extracellular fluid space, where it becomes bound by chemisorption at the surface of bone crystals, preferentially at sites of newly mineralizing bone. Deposition of fluoride ¹⁸F in bone appears to be primarily a function of blood flow to the bone and the efficiency of the bone in extracting the fluoride ¹⁸F. Fluoride ¹⁸F does not appear to be bound to serum proteins. In patients with normal renal function, 20% or more of the fluorine ion is cleared from the body in the urine within the first 2 h after intravenous administration.

7. Stability

Store at 25°C in a shielded container; excursions permitted to 15-30°C. Use the solution within 12 h of the EOS reference time.