RADIOGENIX SYSTEM (technetium Tc 99m generator)
INDICATION AND IMPORTANT RISK INFORMATION
12 DECEMBER 2019

INDICATION

The RadioGenix® System is a technetium Tc-99m generator used to produce Sodium Pertechnetate Tc 99m Injection, USP. Sodium Pertechnetate Tc 99m Injection is a radioactive diagnostic agent and can be used in the preparation of FDA-approved diagnostic radiopharmaceuticals.

Sodium Pertechnetate Tc 99m Injection is also indicated in

- Adults for Salivary Gland Imaging and Nasolacrimal Drainage System Imaging (dacryoscintigraphy).
- Adults and pediatric patients for Thyroid Imaging and Vesicoureteral Imaging (direct isotopic cystography) for detection of vesicoureteral reflux.

IMPORTANT RISK INFORMATION

- Allergic reactions (skin rash, hives, or itching) including anaphylaxis have been reported following the administration of Sodium Pertechnetate Tc 99m Injection. Monitor all patients for hypersensitivity reactions.

- Radiation risks associated with the use of Sodium Pertechnetate Tc 99m Injection are greater in children than in adults and, in general, the younger the child, the greater the risk owing to greater absorbed radiation doses and longer life expectancy. These greater risks should be taken firmly into account in all benefit-risk assessments involving children. Long-term cumulative radiation exposure may be associated with an increased risk of cancer.

- Discard the first eluate from every new Potassium Molybdate Mo-99 Source Vessel to minimize the risk of unintended radiation exposure from Rhenium Re-186.

- Temporarily discontinue breastfeeding. A lactating woman should pump and discard breastmilk for 12 to 24 hours after Sodium Pertechnetate Tc 99m Injection administration.

- Sodium Pertechnetate Tc 99m Injection should be given to pregnant women only if the expected benefits to be gained clearly outweigh the potential hazards.

- Follow step by step directions for use provided in the RadioGenix® System Operator Guide. Only use potassium molybdate Mo-99, processing reagents, saline and other supplies, including kits, provided by NorthStar Medical Radioisotopes. Do not administer Sodium Pertechnetate Tc 99m Injection after the 0.15 microCi of Mo-99/mCi of Tc-99m limit has been reached or when the 12 hour expiration time from elution is reached, whichever occurs earlier.

- Sodium Pertechnetate Tc 99m Injection contributes to a patient's long-term cumulative radiation exposure. Ensure safe handling to protect patients and health care workers from unintentional radiation exposure. Use the lowest dose of Sodium Pertechnetate Tc 99m Injection necessary for imaging and ensure safe handling and preparation to protect the patient and health care worker from

unintentional radiation exposure. Encourage patients to drink fluids and void as frequently as possible after intravenous or intravesicular administration. Advise patients to blow their nose and wash their eyes with water after ophthalmic administration.

To report SUSPECTED ADVERSE REACTIONS, contact NorthStar® Medical Radioisotopes, LLC at 1-844-438-6659; or FDA at 1-800-332-1088 or www.fda.gov/medwatch.