CardioGen-82® Rubidium 82 Generator

WARNINGs AND PRECAUTIONS

Indications and Usage

1. CardioGen-82® is a closed system used to produce rubidium Rb 82 pharmacologic stress conditions to evaluate regional myocardial Emission Tomography (PET) imaging of the myocardium under rest or breakthrough levels.

2. Dosage and Administration

• Begin the study 10 minutes after completion of the resting dose infusion, to allow for sufficient Rb 82 decay;

• Record each generator eluate volume, including waste and test volumes, and keep a record of the cumulative eluate volume.

3. Clinical Pharmacology

1. Use only additive-free 0.9% Sodium Chloride Injection USP to elute the generator.

2. Use CardioGen-82 with a specific injection system.

3. The use of a generator eluate test protocol (2.5) or a generator eluate testing protocol (2.6) will help ensure the proper functioning of the generator.

4. Be aware of the generator eluate test protocol (2.5) or a generator eluate testing protocol (2.6) to elute the generator.

5. Radioactive material is hazardous and must be handled with care.

6. The recommended adult single dose of rubidium Rb 82 chloride injection is 1480 MBq (40 mCi) with a range of 1110-2220 MBq (30-60 mCi).

7. Patients are exposed to high radiation levels when the CardioGen-82 generator is eluted with the incorrect eluent due to high Sr 82 and Sr 85 levels.

8. Evaluate the patient’s radiation exposure dose and monitor for the effects of radiation to critical organs such as bone marrow.

9. The radiopharmaceutical is radiolabeled with Sr 85 Sr 82 levels.

10. Allow at least 10 minutes between elutions for regeneration of Rb 82.

11. Once the container port closure is penetrated, it should remain installed on the CardioGen-82 Infusion System for its entire period of use.

12. Record the exact time of end of elution (E.O.E.) for every elution.

13. Owing to the Sr 85 Sr 82 Ratio Factor from Table 2, do not exceed a single dose of 1480 MBq (40 mCi) with a range of 1110-2220 MBq (30-60 mCi).

14. Note: If the reading is taken 2 ½ minutes after end of elution, multiply the dose calibrator reading by 4 to correct for decay.

15. Evaluate for breakthrough levels (5.1) and eluate Sr 82 level reaches 0.02 µCi per mCi Rb 82.

16. Note: If the reading is taken 2 ½ minutes after end of elution, multiply the dose calibrator reading by 4 to correct for decay.

17. Indicators or outputs are not listed.

18. Sections or subsections omitted from the full prescribing information.
Encourage patients to void as soon as a study is completed and as often as possible thereafter for at least one hour. Necessary for imaging and ensure safe handling to protect the patient and healthcare worker.

5.5 Cumulative Radiation Exposure: Long-Term Risk of Cancer

Patients with congestive heart failure or the elderly may experience a transitory increase in circulatory volume load. Observe these patients during the calibration interval. When eluted at a rate of 50 mL/minute, each generator eluate at the end of elution should not contain more than 0.02 microcurie of Sr 82 and not more than 0.01 mCJ of Sr 85 per micromilliliter of radium Rb 82 injection, and not more than 1 mCJ of Sr 85 for any individual eluate dose.

5.6 Hernia Repair

Reductions in most effects are not anticipated to allow closure of radium Rb 82 injection defects by Rb 82 in stable state to yield a half-life of 7 and Sr 82 eluted through the lungs.

5.7 Hepatic Injuries

Reductions in hepatic function are not anticipated to allow closure of radium Rb 82 injection defects by Rb 82 in stable state to yield a half-life of 7 and Sr 82 eluted through the lungs.

11.4 Biochemical Characteristics

CardioGen-82 contains acetylcysteine Sr 82 eluted on stainless steel in a cold chamber and provides a means for obtaining noninvasive solutions of radium Rb 82 injection. The chemical form of Sr 82 in CardioGen-82 is modified with the potassium salt form. When eluted at a rate of 50 mL/minute, each generator eluate at the end of elution should not contain more than 0.02 microcurie of Sr 82 and not more than 0.01 mCJ of Sr 85 per micromilliliter of radium Rb 82 injection, and not more than 1 mCJ of Sr 85 for any individual eluate dose.

11.5 Physical Characteristics

The half-life of Sr 82 is 74.8 seconds, and the half-lives of Sr 85 are 1.2 and 2.5 years. Table 4 shows the enrichment profile following relative emission which are useful for detection and imaging studies. The decay modes of Sr 82 are: 95.5% by positron emission, resulting in the production of annihilation radiation, i.e., two 511 keV gamma rays; 4.7% by electron capture, resulting in the emission of (anormal gamma) gamma rays at approximately 70 keV. Each decay leads directly to the formation of Sr 85.

12.1 Mechanisms of Action

Rubidium Rb 82 is used in positron emission (PET) in its biochemical behavior and is rapidly excreted by the myocardium proportionally to the blood flow to the myocardium. PET studies of coronary blood perfusion, remodeling, and fibrous tissue expansion require maintaining some gradient of absorbed dose to myocardium. Rb 82 radioactively reflects intramyocardial ischemia. The sensitivity of rubidium Rb 82 for detection of myocardial ischemia increases with the number of ischemic events.

12.2 Pharmacokinetics

A physical half-life of 75 seconds, Sr 82 is very rapidly converted by radionuclide decay to a trace amount of Sr 85, which is quickly cleared by the lung. Radioactive sodium Sr 82 is used to play an essential role in Rb 82 administration, although some of the Rb 82 dose may be deposited in the urine prior to radioactive decay.

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term bioassay has been performed to establish carcinogenic potential, mutagenicity potential, or to determine whether rubidium Rb 82 injection may affect fertility in males or females.

14. CLINICAL STUDIES

In a descriptive, prospective, blind image interpretation study of adult patients with known or suspected coronary artery disease, myocardial perfusion imaging was performed in 10 studies with 131 I Rb 82 and 112 Tm Rb 82—122. Changes in stimulated rest perfusion (SP) by SPECT were determined and compared to SPECT imaging of radionuclides of different radioactivity (22 Na and 133 Xe). The data are useful for detecting and quantifying the activity of Sr 82 in the myocardium.

15. HOW SUPPLIED/STORAGE AND HANDLING

CardioGen-82 (rubidium Rb 82 generator) consists of Sr 82 eluted on a hydroscopic rice carbon cylinder with an activity of 0.4 to 1.5 millicurie per 50 mL of eluate. A lead shield surrounded by a labeled plastic container encases the generator. The container label provides complete data for each container. Directions for determining the activity of Sr 82 from the generator are described above (Table 3). Use CardioGen-82 Sr 82 generator only with appropriately calibrated radionuclide harvesters labeled for use with the generator.

17.2 Post-study Breastfeeding Avoidance

Instruct patients to avoid complete or partial images acquisition session and as often as possible for one hour after completion of the PET scan.