Kit for the Preparation of Technetium Tc 99m Sestamibi Injection

For INTRAVENOUS USE

For DIAGNOSTIC USE

HIGHLIGHTS OF PREScribing INFORMATION

These highlights do not include all the information needed to use this kit for the Preparation of Technetium Tc 99m Sestamibi Injection safely and effectively. See full prescribing information for this kit for the Preparation of Technetium Tc 99m Sestamibi Injection.

Kit for the Preparation of Technetium Tc 99m Sestamibi Injection

Kit for use in nephrology.

Initial U.S. Approval: 1990

RECENT MAJOR CHANGES

- Kit for the Preparation of Technetium Tc 99m Sestamibi Injection is supplied as a 10 mL vial in kits of five (5) (NDC # 45548-141-05), ten (10) (NDC # 45548-141-10), and thirty (30) vials, is a package insert and a sufficient number of vial shield labels and radiation warning labels.
- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

Technetium Tc 99m Sestamibi, is a myocardial perfusion agent indicated for:

1. Cardiac Imaging: The indicated dose range for 1 ml of Technetium Tc 99m Sestamibi is a single dose to be employed in the average patient (75 kg) injected at 1110 MBq (30 mCi) and 1110 MBq (30 mCi).

2. Clinical Pharmacology

2.1 Image Acquisition

- Technetium Tc 99m Sestamibi has been rarely associated with acute severe allergic and anaphylactic events of angioedema and generalized urticaria. In some patients the allergic symp-

2.2 Radiation Dosimetry

- Technetium Tc 99m Sestamibi is not indicated for breast cancer screening, to confirm the presence or absence of malignancy, and it is not an alternative to biopsy.

3. Dosage Form and Strengths

- The potential for cracking and significant contamination exists whenever vials containing radioactive material are heated.

4. Contraindications

- Technetium Tc 99m Sestamibi has been rarely associated with acute severe allergic and anaphylactic events of angioedema and generalized urticaria. In some patients the allergic symp-

5. Warnings and Precautions

- Ambulatory or decubitus ulcer.

6. Adverse Reactions

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

7. Use in SPECIFIC POPULATIONS

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

8. Dosage and Administration

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

9. Abuse

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

10. Radiation Exposure

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

11. Dosage and Strengths

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

12. Use in SPECIFIC POPULATIONS

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

13. Contraindications

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

14. Clinical Studies

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

15. Reference

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

16. ODYSSEY

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

17. PATIENT COUNSELING INFORMATION

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

18. Radiation Exposure

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

19. WARNINGS

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

20. ADVERSE REACTIONS

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

21. DRUG INTERACTIONS

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

22. CONTRAINDICATIONS

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

23. DOSAGE FORM AND STRENGTHS

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

24. DOSAGE AND ADMINISTRATION

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

25. INDICATIONS AND USAGE

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

26. DRUG INTERACTIONS

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

27. USE IN SPECIFIC POPULATIONS

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.

28. WARNINGS AND PRECAUTIONS

- The radiation doses to organs and tissues of an average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi injected intravenously are shown in Table 1.


**Table 2**

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