6. ADVERSE REACTIONS

Adverse reactions, generally mild, to moderate in severity, have been reported with Technetium Tc 99m Sestamibi. These include:
- Transient reactions: flushing, edema, injection site inflammation, hypotension, tachycardia, bradycardia, palpitations, nausea, vomiting, rash, fever, urticaria.
- More unusual reactions: angioedema, anaphylactic shock, respiratory distress, dyspnea, bronchospasm, hypoxia, chest pain, abdominal pain, Gastrointestinal tract disturbances, syncope, seizures, hypotension, tachycardia, bradycardia, palpitations, nausea, vomiting, rash, fever, urticaria.

7. DRUG INTERACTIONS

No pharmacokinetic studies have been performed to evaluate the potential for drug interactions with Technetium Tc 99m Sestamibi. However, due to Lantheus Medical Imaging's marketing exclusivity rights, a description of potential drug interactions is not included. Patients should be advised that Technetium Tc 99m Sestamibi should be administered according to the label and any concurrent medications should be discontinued if they are contraindicated for use with Technetium Tc 99m Sestamibi. Patients should also be advised about the possibility of allergic reactions to the drug.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

8.2 Nursing Mothers

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

8.3 Children

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

8.4 Geriatric Use

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

8.5 Pregnancy/Breastfeeding

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

8.6 Lactation

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

8.7 Female Reproductive Capacity

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

9. DRUG ABUSE AND DEPENDENCE

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

10. OVERDOSAGE

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

11. DESCRIPTION

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

12. CLINICAL PHARMACOLOGY

12.1 General

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

12.2 Pharmacokinetics

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

12.3 Metabolism and Excretion

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

12.4 Elimination

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

13. NONCLINICAL TOXICOLOGY

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

14. CLINICAL STUDIES

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.

15. REFERENCES

Clearance of Technetium Tc 99m Sestamibi in breast milk has not been determined. Because radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals, a decision should be made whether to discontinue breast feeding, or to discontinue the radiopharmaceutical, taking the usual precautions to minimize radiation exposure to the breast feeding infant.
8.4 Pediatric Use

The clinical consequences of overdosing with Technetium Tc 99m Sestamibi are not known. Not applicable.

Not applicable.

Not applicable.

The precise structure of the technetium complex is Tc 99m[MIBI]6+ where MIBI is 2-methoxyisobutylisonitrile. Asymptomatic, and one patient had an asthma exacerbation following administration. The type of the adverse events were similar to the ones observed in the studies of Technetium Tc 99m Sestamibi in adults. Those studies does not appear in this Technetium Tc 99m Sestamibi kit labeling. Labeling describing pediatric studies of Technetium Tc 99m Sestamibi kit is approved for Lantheus Medical Imaging's MIRALUMA® which are different names for the same drug (Kit for the Preparation of Technetium Tc 99m Sestamibi).

The pain appears to be associated with biopsy/surgical procedures. Pain appears to be associated with biopsy/surgical procedures.

Drugs and vectors generated in vitro are not known to be mutagenic in vivo. Mutagenicity studies in bacterial and mammalian cell systems have shown no evidence of mutagenicity. In vitro and in vivo cytogenetic studies have shown no evidence of chromosomal aberrations or sister chromatid exchanges. In vitro and in vivo chromosomal aberrations were noted in Chinese hamster ovary cells treated with Technetium Tc 99m Sestamibi. In vivo studies in both the female and male mouse and rat have shown no evidence of an increased incidence of congenital anomalies or postnatal abnormalities. In vivo studies in both the female and male mouse and rat have shown no evidence of an increased incidence of congenital anomalies or postnatal abnormalities.

8.5 Pregnancy

Technetium Tc 99m Sestamibi is classified in category B. Studies in pregnant women or in the rat have not disclosed evidence of impaired fertility, embryotoxicity or teratogenicity when the drug was administered intravenously in the rat at doses of up to 100 times the human dose as extrapolated from body weight. There were no signs of embryo or fetal toxicity in rats. Deformities have been produced in rat offspring given high doses of Technetium Tc 99m Sestamibi. The agent is excreted without any evidence of metabolism. The agent is excreted without any evidence of metabolism.

The precise structure of the technetium complex is Tc 99m[MIBI]6+ where MIBI is 2-methoxyisobutylisonitrile. The safety and effectiveness of the pediatric population have been not be established. In the clinical trials for pharmacokinetics, biodistribution, imaging and safety, Technetium Tc 99m Sestamibi was not approved for a pediatric use. In the clinical trials for pharmacokinetics, biodistribution, imaging and safety, Technetium Tc 99m Sestamibi was not approved for a pediatric use.

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries and the intestines within one hour of injection. Twenty-seven percent of the injected dose is excreted in the urine, and approximately 4% remains in the body as a whole. The effective half-life for the liver is approximately 30 minutes after a rest or exercise injection. The effective half-life for the liver is approximately 30 minutes after a rest or exercise injection.

The effective half-life for the liver is approximately 30 minutes after a rest or exercise injection. The ideal imaging time reflects the half-life of the radiopharmaceutical. The precise structure of the technetium complex is Tc 99m[MIBI]6+ where MIBI is 2-methoxyisobutylisonitrile. In the time and approximately by the time of the injected dose is cleared through the liver in less than 4 hours.

13.1.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In the clinical studies for pharmacokinetics, biodistribution, imaging and safety, Technetium Tc 99m Sestamibi had no evidence of carcinogenic, mutagenic or impairs fertility potential. There were no signs of embryo or fetal toxicity in rats. Deformities have been produced in rat offspring given high doses of Technetium Tc 99m Sestamibi. There were no signs of embryo or fetal toxicity in rats. Deformities have been produced in rat offspring given high doses of Technetium Tc 99m Sestamibi. The precise structure of the technetium complex is Tc 99m[MIBI]6+ where MIBI is 2-methoxyisobutylisonitrile.

The clinical consequences of overdosing with Technetium Tc 99m Sestamibi are not known. Technetium Tc 99m Sestamibi uptake can occur in both benign and malignant disease. THE CLINICAL CONSEQUENCES OF OVERDOSSING WITH TECHNETIUM Tc 99m SESTAMIBI ARE NOT KNOWN. THE PRECISE STRUCTURE OF THE TECHNETIUM COMPLEX IS Tc 99m[MIBI]6+ WHERE MIBI IS 2-METHOXYISOBUTYLISONITRILE. THE PROPER MAINTENANCE OF INJECTION TECHNIQUE IS CRUCIAL TO CONFIRM THE PRESENCE OR ABSENCE OF MALIGNANCY. EQUIVOCAL RESULTS DO NOT HAVE A CORRELATION WITH HISTOLOGY. THE PRECISE STRUCTURE OF THE TECHNETIUM COMPLEX IS Tc 99m[MIBI]6+ WHERE MIBI IS 2-METHOXYISOBUTYLISONITRILE. THE PROPER MAINTENANCE OF INJECTION TECHNIQUE IS CRUCIAL TO CONFIRM THE PRESENCE OR ABSENCE OF MALIGNANCY. EQUIVOCAL RESULTS DO NOT HAVE A CORRELATION WITH HISTOLOGY.