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**WARNINGS:**

Infants and Children: Technetium Tc 99m should be administered to children only when the expected benefits to be gained clearly outweigh the potential hazards.

**PRECAUTIONS:**

Infants and Children: Technetium Tc 99m should be administered to children only when the expected benefits to be gained clearly outweigh the potential hazards.

**INDICATIONS AND USAGE:**

Sodium Pertechnetate Tc 99m is used in adults as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; salivary gland imaging; placental localization; blood pool imaging including radionuclide angiography; and urinary bladder imaging (direct isotopic cystography) for detection of vesicoureteral reflux. Sodium Pertechnetate Tc 99m is used in children as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; blood pool imaging including radionuclide angiography; and urinary bladder imaging (direct isotopic cystography) for detection of vesicoureteral reflux.

**CONTRAINDICATIONS:**

None known.

**WARNINGS:**

Radiation risks associated with the use of Sodium Pertechnetate Tc 99m are greater in children than in adults. 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.

**PRECAUTIONS:**

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to insure minimum radiation exposure to occupational workers. Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m may affect fertility in males or females.

Pregnancy Category C

Animal reproductive studies have not been conducted with Technetium Tc 99m. It is also not known whether Technetium

June, 1983

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Pulse Sequences for NMR Imaging Using Multidimensional Reconstruction Techniques
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DESCRIPTION: Each reagent ampoule of the kit contains 2.2 ml of a sterile, pyrogen-free aqueous solution containing 1.2 mg of succimer and 0.45 mg of anhydrous stannous chloride in aqueous solution under a nitrogen gas atmosphere. When sterile, oxygen-free, pyrogen-free sodium per technetate Tc 99m in sterile saline is combined with the reagent, following the instructions provided with the kit, a complex is formed. Administration is by intravenous injection for diagnostic use.

The succimer component of MPI Kidney Reagent consists of more than 99% meso isomer and less than 10% d,l isomer.

INDICATIONS AND USAGE: MPI DMSA Kidney Reagent is to be used as an aid in the scintigraphic evaluation of renal parenchymal disorders.

CONTRAINDICATIONS: None known.

WARNINGS: None.

PRECAUTIONS: General

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to insure minimum radiation exposure to occupational workers.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: No long-term animal studies have been performed to evaluate carcinogenesis potential or whether Technetium Tc 99m Succimer affects fertility in males or females.

PREGNANCY CATEGORY C: Animal reproduction studies have not been conducted with the MPI DMSA Kidney Reagent either with or without Tc 99m.

It is also not known whether Technetium Tc 99m alone or with Succimer can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m should be administered to a pregnant woman only if clearly needed.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menstruation.

NURSING MOTHERS: Technetium Tc 99m is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast-feeding.

PEDiATRIC USE: Safety and effectiveness in children have not been established. Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

MPI DMSA Kidney Reagent should be reformulated within 30 minutes prior to clinical use. The product must be used within 30 minutes after preparation. Any unused portion should be discarded after that time.

Some patients with advanced renal failure may exhibit poor renal intake of Tc 99m DMSA. It has been reported that satisfactory images may be obtained in some of these patients by delaying imaging for up to 24 hours.

ADVERSE REACTIONS: Rare instances of syncope, fever, nausea and maculopapular skin rash have been reported.

HOW SUPPLIED: Each kit package contains the following components:

1. Five sealed glass reagent ampoules, each containing 2.2 ml of a sterile, pyrogen-free aqueous solution of 1.2 mg succimer and 0.45 mg anhydrous stannous chloride. The solution is under a nitrogen gas atmosphere.
2. Five sterile and pyrogen-free mixing vials (10 ml).
3. Five mixing via labels.
4. Five courtesy record labels.
5. One package insert.