Product Indications and Important Safety Information – Myoview

PRODUCT INDICATIONS AND USE

MYOVIEW™ (Kit for the Preparation of Technetium Tc99m Tetrofosmin Injection) is indicated for myocardial perfusion imaging under rest and/or exercise or pharmacologic stress conditions to delineate regions of reversible myocardial ischemia or infarcted myocardium in patients with known or suspected coronary artery disease. MYOVIEW is also indicated for the assessment of left ventricular function (left ventricular ejection fraction and wall motion) in patients with known or suspected heart disease.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Risks Associated With Exercise or Pharmacologic Stress**: Patients evaluated with exercise or pharmacologic stress may experience serious adverse reactions such as myocardial infarction, arrhythmia, hypotension, and bronchoconstriction, as well as cerebrovascular reactions such as headache, paraesthesias, convulsions, somnolence, and cerebrovascular accident, including hemorrhage. Perform stress testing in a setting where cardiac resuscitation equipment and trained staff are readily available. When pharmacologic stress is selected as an alternative to exercise, perform the procedure in accordance with the pharmacologic stress agent's Prescribing Information

- **Radiation Risks:** Technetium Tc99m contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Ensure safe handling and preparation radiolabeling procedures to protect patients and healthcare workers from unintentional radiation exposure. Encourage adequate hydration; instruct patients to void when the examination is completed and as often thereafter as possible

- **Hypersensitivity Reactions:** Hypersensitivity reactions, including anaphylaxis, dyspnea, bronchospasm, throat tightness, coughing, tachycardia, chest pain, hypotension, abdominal pain, and cutaneous reactions (rash, urticuria, pruritus, erythema, and swelling or angiodema) have been observed after the administration of MYOVIEW. Always have cardiopulmonary resuscitation equipment and personnel available, and monitor all patients for hypersensitivity reactions

ADVERSE REACTIONS

- Serious episodes of angina, ventricular tachycardia, and respiratory arrest were reported. Other events included angina, hypertension, torsades de pointes, vomiting, abdominal discomfort, cutaneous allergy, hypotension, dyspnea, metallic taste, burning of the mouth, and smell alteration. The following were reported when used with pharmacological stress: Angina, flushing, dyspnea, headache, abdominal pain, dizziness, palpitations, nausea, hypotension, pain, cough, arrhythmia, bronchospasm, ECG (electrocardiogram) abnormalities, hypertension, vomiting, and asthenia. Postmarketing adverse reactions included rash, urticaria, abnormal vision, hypersensitivity reactions, and fever

USE IN SPECIFIC POPULATIONS

- **Nursing Mothers:** Technetium Tc99m tetrofosmin is present in human milk in small amounts (<1% of maternal dose). There are no data available regarding the effects of technetium Tc99m tetrofosmin on the breastfed infant or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for MYOVIEW and any other potential adverse effects on the

breastfed child from MYOVIEW or from the underlying maternal condition. To decrease radiation exposure to the breastfed infant, advise a lactating woman to pump and discard for 60 hours (10 half-lives) after technetium Tc99m tetrofosmin administration.

- **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established

- **Geriatric Use:** No overall differences in safety were observed between these subjects and younger subjects. Other reported clinical experience has not identified differences in responses between elderly patients and younger patients, but greater sensitivity regarding some older individuals cannot be ruled out

Prior to MYOVIEW administration, please read the full Prescribing Information for additional Important Safety Information.

To report SUSPECTED ADVERSE REACTIONS, contact GE Healthcare at 800 654 0118 (option 2, then option 1) or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.