FLYRCADO™ (flurpiridaz F 18) injection, for intravenous use important safety information

IMPORTANT SAFETY INFORMATION

Indications and Usage

FLYRCADO is a radioactive diagnostic drug indicated for positron emission tomography (PET) myocardial perfusion imaging (MPI) under rest or stress (pharmacologic or exercise) in adult patients with known or suspected coronary artery disease (CAD) to evaluate for myocardial ischemia and infarction.

Contraindications

None

Warnings and Precautions

- Risk associated with exercise or pharmacologic stress: Patients evaluated with exercise or pharmacologic stress may experience serious adverse reactions such as myocardial infarction, arrhythmia, hypotension, bronchoconstriction, stroke, and seizure. Perform stress testing in the 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: FLYRCADO 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 to minimize radiation exposure to patients and health care providers. Advise patients to hydrate before and after administration and to void.

Adverse Reactions

- Most common adverse reactions occurring during FLYRCADO PET MPI under rest and stress (pharmacologic or exercise) (incidence ≥ 2%) are dyspnea, headache, angina pectoris, chest pain, fatigue, ST segment changes, flushing, nausea, abdominal pain, dizziness, and arrhythmia.

Use in Specific Populations

- **Pregnancy**

There are no data on use of flurpiridaz F 18 in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. If considering FLYRCADO administration to a pregnant woman, inform the patient about the potential for adverse pregnancy outcomes based on the radiation dose from flurpiridaz F 18 and the gestational timing of exposure.
FLYRCADO contains ethanol (a maximum daily dose of 337 mg anhydrous ethanol). If considering FLYRCADO administration to a pregnant woman, inform the patient about the potential for adverse pregnancy outcomes associated with ethanol exposure during pregnancy.

- **Lactation**

Temporarily discontinue breastfeeding. A lactating woman should pump and discard breastmilk for at least 8 hours after FLYRCADO administration.

- **Pediatric Use**

Safety and effectiveness of FLYRCADO in pediatric patients have not been established.

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800-654-0118 (option 2 then option 1) or by email at GPV.drugsafety@gehealthcare.com or FDA at 800-FDA-1088 or www.fda.gov/medwatch