Fludeoxyglucose F 18 Injection is indicated for positron emission tomography (PET) imaging in the following settings:

- **Oncology (1.1):** For assessment of abnormal glucose metabolism to assist in the evaluation of malignancy in patients with known or suspected abnormalities found by other testing modalities, or in patients with an existing diagnosis of cancer.

- **Cardiology (1.2):** For the identification of left ventricular myocardium with residual glucose metabolism and reversible loss of systolic function in patients with coronary artery disease and left ventricular dysfunction, when used together with myocardial perfusion imaging.

- **Neurology (1.3):** For the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures.

**DOSAGE AND ADMINISTRATION**
Fludeoxyglucose F 18 Injection emits radiation. Use procedures to minimize radiation exposure. Screen for blood glucose abnormalities.

- In the oncology and neurology settings, instruct patients to fast for 4 – 6 hours prior to the drug’s injection. Consider medical therapy and laboratory testing to assure at least two days of normoglycemia prior to the drug’s administration (5.2).

- In the cardiology setting, administration of glucose-containing food or liquids (e.g., 50 – 75 grams) prior to the drug’s injection facilitates localization of cardiac ischemia (2.3). Aseptically withdraw Fludeoxyglucose F 18 Injection from its container and administer by intravenous injection (2). The recommended dose:
  - for adults is 5 – 10 mCi (185 – 370 MBq), in all indicated clinical settings (2.1).
  - for pediatric patients is 2.6 mCi (95 MBq) in the cardiology setting (2.2).

Initiate imaging within 40 minutes following drug injection; acquire static emission images 30 – 100 minutes from time of injection (2).

**DOSAGE FORMS AND STRENGTHS**
Multiple-dose glass vial containing 0.74 – 7.40 GBq (20 – 200 mCi/mL) of Fludeoxyglucose F18 Injection and 4.5 mg of sodium chloride in citrate buffer (approximately 25 mL volume), for intravenous administration (3).

**CONTRAINDICATIONS**
None

**WARNINGS AND PRECAUTIONS**
- Radiation risks: use smallest dose necessary for imaging (5.1).

**ADVERSE REACTIONS**
Hypersensitivity reactions have occurred; have emergency resuscitation equipment and personnel immediately available (6).

To report SUSPECTED ADVERSE REACTIONS, contact Lantheus Medical Imaging, Inc. at 1-800-362-2668 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**USE IN SPECIFIC POPULATIONS**
- Pregnancy Category C: No human or animal data. Consider alternative diagnostics; use if clearly needed (8.1).

- Nursing Mothers: Use alternatives to breast feeding (e.g., stored breast milk or infant formula) for at least 10 half-lives of radioactive decay, if Fludeoxyglucose F 18 Injection is administered to a woman who is breast-feeding (8.3).

- Pediatric Use: Safety and effectiveness in pediatric patients have not been established in the oncology and cardiology settings (8.4).

See 17 for PATIENT COUNSELING INFORMATION.
Fludeoxyglucose F 18 Injection is provided as a ready to use sterile, pyrogen free, clear, colorless citrate buffered solution. Each mL contains between 0.74 to 7.40 MBq (20 - 200 mCi) of 2-deoxy-2-[18F]fluoro-D-glucose at the EOS of 4.5 mg sodium citrate in citrate buffer. The pH of the solution is between 4.5 and 7.5. The solution contains 0.15% w/v disodium phosphate and 0.1% w/v sodium chloride and does not contain any preservative.

### Pharmacokinetics

**Distribution:** In healthy male volunteers, receiving an intravenous administration of 30 minutes in duration, the arterial blood level profile for Fludeoxyglucose F 18 decayed triexponentially. The effective half-life of the three phases were 0.2-0.3 minutes, 10-13 minutes with a mean and standard deviation (STD) of 11.6 (±) 1.1 min, and 80-95 minutes with a mean and STD of 88 (±) 4 min.

**Plasma protein binding of Fludeoxyglucose F 18 has not been studied.**

**Fludeoxyglucose F 18 is transported across biological membranes by facilitated diffusion.** The phosphorylated deoxy-glucose analogs are phosphorylated and the resulting compounds (FDG, FOM, FDG-D, and FDG-D-alt) presumably leave cells by passive diffusion. Fludeoxyglucose F 18 and related compounds are cleared from non-cardiac tissues within 5 to 24 hours after administration. Clearance from the cardiac tissue may require a longer time period post-administration suggesting that 20-40% (mean) of the radioactive dose was present in the blood.

**Pharmacokinetics:** The pharmacokinetics of Fludeoxyglucose F 18 Injection have not been studied in animals. Fludeoxyglucose F 18 is eliminated through the renal system. Avoid excessive radiation exposure to this organ system and adjacent tissues.

**Fludeoxyglucose F 18 accumulation may be increased, normally in any tissue in which F 18 is then excreted in the urine.**

### NONCLINICAL TOXICOLOGY

#### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies have not been performed to evaluate the Fludeoxyglucose F 18 Injection carcinogenic potential, mutagenic potential or effects on fertility.

### 14 CLINICAL STUDIES

#### 14.1 Oncology

The efficacy of Fludeoxyglucose F 18 Injection in position emission tomography imaging cancer imaging was demonstrated in 16 independent studies. Three of these studies have been published in the literature. Fludeoxyglucose F 18 is a substance that is distributed in the normal or neoplastic small cell lung cancer, colorectal, pancreatic, breast, thyroid, melanoma, Hodgkin’s and non-Hodgkin’s lymphomas, and various types of metastatic cancers to lung, liver, bone, and axillary nodes. All these studies had at least 50 patients and used pathology as a standard of reference. A total of 65 patients in the Fludeoxyglucose F 18 injection studies reported from 200 MBq with a median and mean dose of 370 MBq.

In the studies, the diagnostic performance of Fludeoxyglucose F 18 Injection varied with the type of cancer, size of cancer, and other clinical conditions. False negative and false positive scans were observed. Positive Fludeoxyglucose F 18 injection PET scans do not exclude the diagnosis of cancer. Positive Fludeoxyglucose F 18 PET scans can be equivocal in a multi-dose, cardiac 30 mL glass vial containing between 0.74 – 7.40 MBq/mL (20 – 200 mCi/mL), of no added carrier 2-deoxy-2-[18F] Fluorodeoxyglucose, at end of synthesis, in approximately 25 mL. The contents of each vial are sterile, pyrogen-free and preservative-free.

This radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to the Code of Federal Regulations (CFR) for radioactive material specified in 10 CFR 35, as appropriate, or under equivalent regulations of an Agreement State or a Licensing State.

Store and dispose of Fludeoxyglucose F 18 Injection in accordance with the regulations and a general license, or its equivalent, of an Agreement State or a Licensing State.

### 15 REFERENCES


### 16 HOW SUPPLIED/STORAGE AND DRUG HANDLING

Fludeoxyglucose F 18 PET imaging depends on successful coronary revascularization. Therefore, in patients with suspected or known malignancies, including non-small cell lung cancer, colorectal, pancreatic, breast, thyroid, melanoma, Hodgkin’s and non-Hodgkin’s lymphomas, various types of metastatic cancers to lung, liver, bone, and axillary nodes, all these studies had at least 50 patients and used pathology as a standard of reference. A total of 65 patients in the Fludeoxyglucose F 18 injection studies reported from 200 MBq with a median and mean dose of 370 MBq.

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### 17 PATIENT COUNSELING INFORMATION

Instruct patients in procedures that increase renal clearance of radioactivity. Encourage patients to:

- void as soon as the imaging study is completed and as often as possible thereafter for at least one hour in patients with normal renal function.
- drink sufficient water and other fluids (as tolerated) in the 4 hours before their PET study.
- avoid as soon as the imaging study is completed and as often as possible thereafter for at least one hour.

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