Fludeoxyglucose F18 Injection for Intravenous Use*

INDICATIONS AND USAGE

Fludeoxyglucose F18 Injection is indicated for positron emission tomography (PET) imaging in the following settings:

- Oncology: 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: 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: For the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures

IMPORTANT SAFETY INFORMATION

Radiation Risk
Radiation-emitting products, including Fludeoxyglucose F 18 Injection, may increase the risk for cancer, especially in pediatric patients. Use the smallest dose necessary for imaging and ensure safe handling to protect the patient and health care worker.

Blood Glucose Abnormalities
In the oncology and neurology setting, suboptimal imaging may occur in patients with inadequately regulated blood glucose levels. In these patients, consider medical therapy and laboratory testing to assure at least two days of normoglycemia prior to Fludeoxyglucose F 18 Injection administration.

Adverse Reactions
Hypersensitivity reactions have occurred; have emergency resuscitation equipment and personnel immediately available

DOSAGE FORMS AND STRENGTHS

Available in 30 mL multiple-dose glass vials containing 0.74 – 11.1 GBq (20 – 300 mCi/mL) of Fludeoxyglucose F18 Injection and 4.5 mg of sodium chloride in citrate buffer for intravenous administration

*Please see accompanying full prescribing information