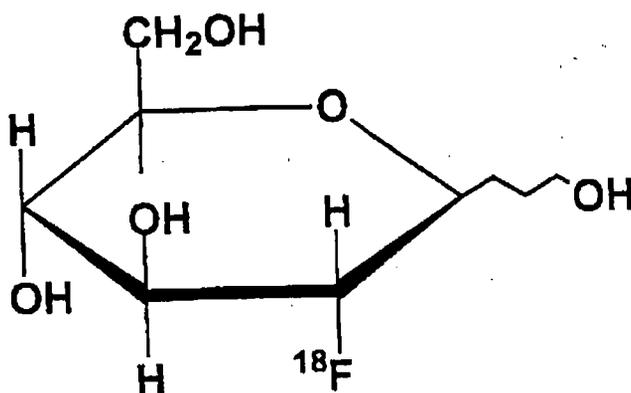


**Fludeoxyglucose F18 Injection [<sup>18</sup>F] FDG**  
**Diagnostic - For Intravenous Administration**

**DESCRIPTION**

Fludeoxyglucose F18 Injection is a positron emitting radiopharmaceutical containing no-carrier added radioactive 2-deoxy-2-[<sup>18</sup>F]fluoro-D-glucose that is used for diagnostic purposes in conjunction with Positron Emission Tomography (PET). It is administered by intravenous injection.

The active ingredient 2-deoxy-2-[<sup>18</sup>F]fluoro-D-glucose, abbreviated [<sup>18</sup>F] FDG, has a molecular formula of C<sub>6</sub>H<sub>11</sub><sup>18</sup>FO<sub>5</sub>, with a molecular weight of 181.26 daltons, and has the following chemical structure:



Fludeoxyglucose F18 Injection is provided as a ready to use isotonic, sterile, pyrogen free, clear, colorless solution. Each milliliter contain between 148 to 1480 MBq (4 – 40 mCi) of 2-deoxy-2-[<sup>18</sup>F]fluoro-D glucose at the end of synthesis (EOS), and 9 mg of sodium chloride. The pH of the solution is between 5.5 to 7.5. The solution is packaged in a multiple-dose glass vial and does not contain any preservative.

**PHYSICAL CHARACTERISTICS**

Fluorine F18 decays by positron ( $\beta^+$ ) emission and has a half-life of 109.7 minutes. The principal photons useful for diagnostic imaging are the 511 keV gamma photons, resulting from the interaction of the emitted positron with an electron (Table 1).

**Table 1. Principal Emission Data for Fluorine F18**

Radiation/Emission	% per Disintegration	Mean Energy
Positron ( $\beta^+$ )	96.73	249.8 keV
Gamma ( $\pm$ )*	193.46	511.0 keV

\*Produced by positron annihilation

From: Kocher, D.C. "Radioactive Decay Tables" DOE/TIC-i 1026, 89 (1981).

### EXTERNAL RADIATION

The specific gamma ray constant for Fluorine F18 is 6.0 R/hr/mCi (0.3 Gy/hr/kB) at 1cm. The half-value layer (HVL) for the 511 keV photons is 4.1 mm lead (Pb). A range of values for the attenuation of radiation results from the interposition of various thickness of Pb. The range of attenuation coefficients for this radionuclide is shown in Table 2. For example the interposition of an 8.3 mm thickness of Pb, with a coefficient of attenuation of 0.25, will decrease the external radiation by 75%.

**Table 2. Radiation Attenuation of 511 keV Photons by Lead (Pb) Shielding**

Shield Thickness (Pb) mm	Coefficient of Attenuation
0	0.00
4.1	0.50
8.3	0.25
13.2	0.10
26.4	0.01
52.8	0.001

For use in correcting for physical decay of this radionuclide, the fractions remaining at selected intervals after calibration are shown in Table 3.

**Table 3. Physical Decay Chart for Fluorine F18**

Minutes	Fraction Remaining
0	1.00
15	0.909
30	0.826
60	0.683
110	0.500
220	0.250
440	0.060

\*Calibration Time

## CLINICAL PHARMACOLOGY

### General

Fludeoxyglucose F18 Injection is a radiolabeled analog of glucose that is rapidly distributed to all organs of the body after intravenous administration. After background clearance of Fludeoxyglucose F18 Injection, optimal PET imaging is often achieved between 30 to 40 minutes after administration.

### Pharmacokinetics

In 4 healthy male volunteers, receiving an intravenous administration of 30 seconds in duration, the arterial blood level profile for Fludeoxyglucose F18 was described as a triexponential decay curve. The effective half-life ranges of the three phases were 0.2-0.3 minutes, 10-13 minutes with a mean and standard deviation (STD) of  $11.6 \pm 1.1$  min, and 80-95 minutes with a mean and STD of  $88 \pm 4$  min.

Within 33 minutes, a mean of 3.9% of the administered radioactive dose was measured in the urine. The amount of radiation exposure of the urinary bladder at two hours post-administration suggests that 20.6% (mean) of the radioactive dose was present in the bladder. See the Metabolism Section for additional clearance times.

### Metabolism

Fludeoxyglucose F18 Injection is transported into cells and phosphorylated to [ $^{18}\text{F}$ ]-FDG-6-phosphate at a rate proportional to the rate of glucose utilization within that tissue. [ $^{18}\text{F}$ ]FDG-6-phosphate presumably is metabolized to 2-deoxy-2- [ $^{18}\text{F}$ ]fluoro-6-phospho-D-mannose ([ $^{18}\text{F}$ ]FDM-6-phosphate).

Fludeoxyglucose F18 Injection may contain several impurities, e.g., 2-deoxy-2-chloro-D-glucose (CIDG). Biodistribution and metabolism of CIDG are presumed to be similar to Fludeoxyglucose F18, and would be expected to result in intracellular formation of 2-deoxy-2-chloro-6-phospho-D-glucose (CIDG-6-phosphate) and 2-deoxy-2-chloro-6-phospho-D-mannose (CIDM-6-phosphate). The phosphorylated deoxyglucose compounds are dephosphorylated, and the resulting compounds, (FDG, FDM, CIDG and CIDM) presumably leave cells by passive diffusion.

FDG and related compounds are cleared from non-cardiac tissues within 3 to 24 hours after administration. Clearance from the cardiac tissue may require more than 96 hours. Fludeoxyglucose F18 that is not involved in glucose metabolism in any tissue is excreted unchanged in the urine.

## Pharmacodynamics

Fludeoxyglucose F18 is a glucose analog that concentrates in cells that rely upon glucose as an energy source, or in cells whose dependence on glucose increases under pathophysiological conditions. Fludeoxyglucose F18 is transported through the cell membrane by facilitative glucose transporter proteins and is phosphorylated within the cell to [<sup>18</sup>F]FDG-6-phosphate by the enzyme hexokinase. Once phosphorylated it can not exit until dephosphorylated by glucose-6-phosphatase. Therefore, within a given tissue or pathophysiological process, the retention and clearance of [<sup>18</sup>F] FDG reflect a balance involving glucose transporter, hexokinase and glucose-6-phosphatase activities. When allowance is made for the kinetic differences between glucose and FDG transport and phosphorylation (expressed as the "lumped constant" ratio), Fludeoxyglucose F18 is used to assess glucose metabolism.

In comparison to background activity of the specific organ or tissue type, regions of decreased or absent uptake of Fludeoxyglucose F18 reflect the decrease or absence of glucose metabolism. Regions of increased uptake of Fludeoxyglucose F18 reflect greater than normal rates of glucose metabolism.

In cancer, the cells are generally characterized by enhanced glucose metabolism partially due to (1) an increase in the activity of glucose transporters, (2) an increase rate of phosphorylation activity, (3) a reduction of phosphatase activity or, (4) a dynamic alteration in the balance among all these processes. However, glucose metabolism of cancer as reflected by Fludeoxyglucose F18 accumulation shows considerable variability. Depending on tumor type, stage and location, Fludeoxyglucose F18 accumulation may be increased, normal or decreased. Also, inflammatory cells can have the same variability of uptake of Fludeoxyglucose F18.

In the heart under normal aerobic conditions, the myocardium meets the bulk of its energy requirements by oxidizing free fatty acids. Most of the exogenous glucose taken up by the myocyte is converted into glycogen. However, under ischemic conditions, the oxidation of free fatty acids decreases, exogenous glucose becomes the preferred myocardial substrate, glycolysis is stimulated, and glucose taken up by the myocyte is metabolized immediately instead of being converted into glycogen. Under these conditions, phosphorylated Fludeoxyglucose F18 accumulates in the myocyte and can be detected with PET imaging.

Normally, the brain relies on anaerobic metabolism. In epilepsy, the glucose metabolism varies. Generally during a seizure, glucose metabolism increases. Interictally, the seizure focus tends to be hypometabolic.

### Urinary Excretion

Fludeoxyglucose F18 is cleared from most tissues within 24 hours, and can be eliminated from the body unchanged in the urine. Three elimination phases have been identified in the reviewed literature. An early elimination phase (0.2-0.3 minutes) and two late phases ( $11.6 \pm 1.1$  min and  $88 \pm 4$  min or  $4.21 \pm 1.09$  and  $50.08 \pm 14.62$ ). Within 33 minutes, a mean of 3.9% of the injected dose was measured in the urine of normal subjects. Within two hours of administration, a mean of 20.6% of the injected dose was found in the bladder.

### Plasma Protein Binding

The extent of binding of Fludeoxyglucose F18 to plasma proteins is not known.

### Pharmacokinetics in Special Populations

Extensive dose range and dose adjustment studies with this drug product in normal and special populations have not been completed. In pediatric patients with epilepsy, doses given have been as low as 2.6 mCi.

The pharmacokinetics of Fludeoxyglucose F18 in renally-impaired patients have not been characterized. Fludeoxyglucose F18 is eliminated through the renal system. Care should be taken to prevent excessive and unnecessary radiation exposure to this organ system and adjacent tissues.

The effects of fasting, varying blood sugar levels, conditions of glucose intolerance, and diabetes mellitus on Fludeoxyglucose F18 distribution in humans have not been ascertained. Diabetic patients may need stabilization of blood glucose levels on the day before and on the day of the [ $^{18}\text{F}$ ]FDG study.

### Drug-Drug Interactions

Drug-drug interactions with Fludeoxyglucose F18 have not been evaluated.

## CLINICAL TRIALS

**Oncology:**<sup>1</sup> The efficacy of Fludeoxyglucose F18 in positron emission tomography cancer imaging was demonstrated in 16 independent literature reports. These studies prospectively evaluated the sensitivity and specificity of Fludeoxyglucose F18 for detecting malignancies. All these studies had at least 50 patients and used pathology as a standard of truth to compare the results of Fludeoxyglucose F18 readings. The studies encompassed a variety of cancers: non-small cell lung cancer, colo-rectal, pancreatic, breast, thyroid, melanoma, Hodgkin's and non-Hodgkin's lymphoma, and various types of metastatic cancers to lung, liver, bone, and axillary nodes. The doses in the studies ranged from 200 MBq to 740 MBq with a median and

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<sup>1</sup> See \_\_\_\_\_ FIR \_\_\_\_\_.

mean dose of 370 MBq.

In these studies the patients had a clinical reason for the evaluation of malignancy (e.g., the patients had an abnormality identified by a prior test and were seeking a diagnosis, or the patients had an existing diagnosis of cancer and were having further work-up or monitoring). None of these studies evaluated the use of Fludeoxyglucose F18 in routine population screening in which healthy, asymptomatic people are tested for purposes of cancer early detection. The efficacy of Fludeoxyglucose F18 PET imaging in cancer screening, including its ability to decrease cause-specific mortality, is unknown.

Fludeoxyglucose F18 PET imaging sensitivity is restricted by the biologic variability of cancer glucose utilization found in individual patients, with different cancers (See Clinical Pharmacology and Pharmacodynamic Sections). In the reviewed studies, the sensitivity and specificity varied with the type of cancer, size of cancer, and other clinical parameters. Also, there were false negatives and false positives. A negative Fludeoxyglucose F18 PET imaging result does not preclude the diagnosis of cancer and further work-up is indicated. Also, a positive Fludeoxyglucose F18 PET imaging result cannot replace biopsy to confirm a diagnosis of cancer. There are non-malignant conditions such as fungal infections, inflammatory processes, and benign tumors that had patterns of increased glucose metabolism that give rise to false-positive examinations.

**Cardiology:**<sup>2</sup> The efficacy of Fludeoxyglucose F18 for cardiac use was demonstrated in ten independent literature reports which, in general, shared the characteristics summarized below. The studies were prospective and enrolled patients with coronary artery disease and chronic left ventricular systolic dysfunction of a mild to moderate degree. The patients were scheduled to undergo coronary revascularization with either coronary artery bypass surgery or angioplasty. Before revascularization, patients underwent PET imaging with Fludeoxyglucose F18 and perfusion imaging with other diagnostic radiopharmaceuticals. Doses of Fludeoxyglucose F18 ranged from 74-370 MBq (2-10 mCi). Segmental left ventricular wall-motion assessments of asynergic areas made before revascularization were compared to those made after successful revascularization to identify myocardial segments with functional recovery. Segmental wall motion assessments were made blinded to the results of metabolic/perfusion imaging, and PET image analyses were quantitative.

Left ventricular myocardial segments were predicted to have reversible loss of systolic function if they showed Fludeoxyglucose F18 accumulation and reduced perfusion (i.e., flow-metabolism mismatch). Conversely, myocardial segments were predicted to have irreversible loss of systolic function if they showed concordant reductions in both Fludeoxyglucose F18 accumulation and perfusion (i.e., matched defects). Diagnostic performance measures such as sensitivity, specificity, positive predictive value, and negative predictive value were calculated. None of the studies prospectively determined the degree to which mismatch, or the location of mismatch,

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<sup>2</sup> See \_\_\_\_\_ FR \_\_\_\_\_.

is associated with improvements in global ventricular function, clinical symptoms, exercise tolerance, or survival.

Findings of flow-metabolism mismatch in a myocardial segment suggest that successful revascularization will restore myocardial function in that segment. However, false-positive tests occur regularly and the decision to have a patient undergo revascularization should not be based on PET findings alone. Similarly, findings of a matched defect in a myocardial segment suggest that myocardial function will not recover in that segment, even if it is successfully revascularized. However, false-negative tests occur regularly, and the decision to recommend against coronary revascularization or to recommend a cardiac transplant should not be based on PET findings alone. The reversibility of segmental dysfunction as predicted with Fludeoxyglucose F18 PET imaging depends on successful coronary revascularization. Therefore, in patients with a low likelihood of successful revascularization, the diagnostic usefulness of PET imaging with Fludeoxyglucose F18 is limited.

**Epilepsy:**<sup>3</sup> In a prospective, open label trial, Fludeoxyglucose F18 was evaluated in 86 patients with epilepsy. Each patient received a dose of Fludeoxyglucose F18 in the range of 185-370 MBq (5-10 mCi). Demographic characteristics of race and gender are not available. The mean age was 16.4 years (range: 4 months - 58 years; of these, 42 patients were < 12 years and 16 patients were < 2 years old). Patients had a known diagnosis of complex partial epilepsy and were under evaluation as surgical candidates for treatment of their seizure disorder. Seizure foci had been previously identified on ictal EEGs and sphenoidal EEGs. In 16% (14/87) of patients, the pre-Fludeoxyglucose F18 findings were confirmed by Fludeoxyglucose F18; 34% (30/87) of patients, Fludeoxyglucose F18 scans provided new findings. In 32% (27/87), Fludeoxyglucose F18 scans were not definitive. The influence of these findings on surgical outcome, medical management or behavior is not known.

Several other studies comparing Fludeoxyglucose F18 scan results to subsphenoidal EEG, MRI and/or surgical findings supported the concept that the degree of hypometabolism corresponds to areas of confirmed epileptogenic foci.

The safety and effectiveness of Fludeoxyglucose F18 Injection to distinguish idiopathic epileptogenic foci from tumors or other brain lesions that may cause seizures have not been established.

## INDICATIONS AND USAGE

Fludeoxyglucose F18 Injection is indicated in positron emission tomography (PET) imaging 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.

Fludeoxyglucose F18 Injection is indicated in positron emission tomography (PET) imaging in patients with coronary artery disease and left ventricular dysfunction, when used together with

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<sup>3</sup> See NDA #20-306.

myocardial perfusion imaging, for the identification of left ventricular myocardium with residual glucose metabolism and reversible loss of systolic function.

Fludeoxyglucose F18 Injection is indicated in positron emission tomography (PET) imaging in patients for the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures.

## WARNINGS

None known

## CONTRAINDICATIONS

None known

## PRECAUTIONS

### General

Use in patients with diabetes or hyperglycemia has not been well studied. It is recommended that patients be normoglycemic when undergoing PET imaging with Fludeoxyglucose F18 Injection.

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides. (See Drug Handling Section)

## INFORMATION FOR PATIENTS

To minimize radiation absorbed dose to the bladder, adequate hydration should be encouraged to permit frequent voiding during the first few hours after intravenous administration of Fludeoxyglucose F18 Injection. This may be achieved by having patients drink at least an 8 oz. glass of water prior to drug administration. To help protect themselves and others in their environment, patients should take the following precautions for 12 hours after injection: whenever possible a toilet should be used and should be flushed several times after each use and wash hands thoroughly after each voiding or fecal elimination. If blood, urine or feces soil clothing, the clothing should be washed separately.

**Diabetic Patients:** [<sup>18</sup>F] FDG transport into cells may be effected by fasting or by blood glucose changes associated with diabetes mellitus. Diabetic patients may need stabilization of blood glucose levels on the day before and on the day of administration of Fludeoxyglucose F18 Injection.

### **Carcinogenesis, Mutagenesis, Impairment or Fertility**

Studies with Fludeoxyglucose F18 have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

### **Teratogenic Effects: Pregnancy Category C**

Animal reproduction studies have not been conducted with Fludeoxyglucose F18 Injection. It is not known whether Fludeoxyglucose F18 Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, Fludeoxyglucose F18 Injection should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

### **Nursing Mothers**

It is not known whether Fludeoxyglucose F18 Injection is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Fludeoxyglucose F18 Injection is administered to a nursing woman.

### **Pediatric Use**

The safety and effectiveness of Fludeoxyglucose F18 Injection in pediatric patients with epilepsy is established on the basis of studies in adult and pediatric patients. In pediatrics, the recommended dose is 2.6 mCi. The optimal dose adjustment on the basis of body size or weight has not been determined.

The safety and effectiveness of Fludeoxyglucose F18 for the evaluation of malignancy or for the identification of left ventricular myocardium with reversible loss of systolic function in pediatric patients below the age of 16 years have not been established.

See Clinical Trials Section.

### **ADVERSE REACTIONS**

The Fludeoxyglucose F18 Injection safety database for epilepsy included of 374 patients. Of these, 245 were male and 105 were female. For 24 patients, gender was not specified. The mean age was 47.8 years (range under 2 to over 65 years). Eighteen patients were between the age of 0 and 2 years; 42 patients were between the ages of 2 and 21 years old; 213 patients were between 21 and 65 years old and 98 patients were older than 65 years and the ages of 3 male patients were not specified. A racial distribution is not available. In this database, adverse drug reactions that required medical intervention were not reported. In a small, 42 patient subset of the 374 patients studied, 4 patients had transient hypotension, 6 had hypo- or hyperglycemia and 3 had transient increases in alkaline phosphatase.

Reviews of the oncology and cardiology literature did not reveal reported adverse reactions.

## DOSAGE AND ADMINISTRATION

The recommended dose of Fludeoxyglucose F18 Injection for an adult (70 kg) is 185-370 MBq (5-10 mCi), as an intravenous injection for studies of malignancy, cardiology, and epilepsy.

In general, Fludeoxyglucose F18 Injection should be administered after patients have fasted for 4-6 hours. For cardiac use, Fludeoxyglucose F18 Injection may be administered either to patients who have fasted or to patients who have received a glucose load. (See Patient Preparation Section)

The optimum rates of administration and upper safe dose for Fludeoxyglucose F18 Injection have not been established. The time interval between doses of Fludeoxyglucose F18 Injection should be long enough to allow substantial decay (physical and biological) of previous administrations.

The final dose for the patient should be calculated using proper decay factors from the time of the end of synthesis (EOS), and measured by a suitable radioactivity calibration system before administration. See decay factors in Table 3.

**Patient Preparation:** Blood glucose levels should be stabilized before Fludeoxyglucose F18 Injection is administered. In non-diabetic patients this may be accomplished by fasting 4-6 hours before Fludeoxyglucose F18 Injection. Diabetic patients may need stabilization of blood glucose on the day preceding and on the day of the Fludeoxyglucose F18 Injection.

For cardiac imaging, administration of Fludeoxyglucose F18 Injection to fasting patients limits the accumulation of Fludeoxyglucose F18 to ischemic myocardium. This may make localization of the ischemic region difficult because the surrounding myocardium will not be well-visualized. Conversely, administration of Fludeoxyglucose F18 Injection to patients who have received a glucose load (e.g., 50-75 grams, 1-2 hours before Fludeoxyglucose F18 administration) allows the surrounding, non-ischemic myocardium to be seen and facilitates localization of ischemic areas.

**Imaging:** Optimally, it is recommended that positron emission tomography (PET) imaging be initiated within 40 minutes of administration of Fludeoxyglucose F18 Injection.

Static emission scans are acquired after 30-100 minutes from the time of injection.

## OVERDOSE

Overdoses of Fludeoxyglucose F18 Injection have not been reported. See Radiation Dosimetry Section for related information.

## DRUG HANDLING

Fludeoxyglucose F18 Injection, like other parenteral drug products, should be inspected visually for particulate matter and discoloration before administration, whenever solution and container permit. Fludeoxyglucose F18 Injection preparations containing particulate matter or discoloration should not be administered. They should be disposed of in a safe manner, in compliance with applicable regulations.

Aseptic techniques and effective shielding should be employed in withdrawing doses for administration to patients. Waterproof gloves and effective shielding should be worn when handling the product.

The contents of each vial are sterile and non-pyrogenic. To maintain sterility, aseptic technique must be used during all operations involved in the manipulation and administration of Fludeoxyglucose F18 Injection.

The current Reference Listed Drug (RLD) states that Fludeoxyglucose F18 should be used within 8 hours of the end of synthesis (EOS).

As with any other radioactive material, appropriate shielding should be used to avoid unnecessary radiation exposure to the patient, occupational workers, and other persons.

Fludeoxyglucose F18 Injection, like other radioactive drugs, must be handled with care and appropriate safety measure should be used to minimize radiation exposure to clinical personnel. Care should be taken to minimize exposure to the patient consistent with proper patient management. Radiopharmaceuticals should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radionuclides, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

## RADIATION DOSIMETRY

The estimated absorbed radiation doses (rem/mCi) to a 1-year (9.8 kg), 5-year (19 kg), 10-year (32 kg), 15-year (57 kg), and a human adult (70 kg) from intravenous injection of Fludeoxyglucose F18 are shown in Table 4. These estimates were calculated based on human<sup>4</sup> data and using the data published by the International Commission on Radiological Protection<sup>5</sup> for Fludeoxyglucose F18. The dosimetry data obtained and presented in this table show that there are slight variations in absorbed radiation dose for various organs in each of the age groups. These dissimilarities in absorbed radiation dose are understood to be due to developmental age variations (e.g., organ size, location, and overall metabolic rate for each age group). The

<sup>4</sup> Jones, S.C., Alavi, A., Christman, D., Montanez, I., Wolf, A.P., and Reivich, M. (1982). The Radiation Dosimetry of 2-F-18 fluoro-2-deoxy-D-glucose in Man. *J. Nucl. Med.* 23, 613-617.

<sup>5</sup> ICRP Publication 53, Volume 18, No. 1-, 1987, page 76.

identified critical organs (in descending order) across all age groups evaluated (i.e., newborn, 1, 5, 10, 15 year(s) and adults) are the urinary bladder, heart, pancreas, spleen, and lungs. The absolute values for absorbed radiation in each of these organs vary in each of the age groups.

Table 4. Estimated Absorbed Radiation Doses (rem/mCi) after intravenous administration of 2-deoxy-2-[18F]fluoro-D-glucose, Fludeoxyglucose F18 injection.

Organ	Newborn (3.4 kg)	1-year old (9.8 kg)	5-year old (19 kg)	10-year old (32 kg)	15-year old (57 kg)	Adult (70 kg)
Bladder Wall <sup>2</sup>	4.3	1.7	0.93	0.60	0.40	0.32
Heart wall	2.4	1.2	0.70	0.44	0.29	0.22
Pancreas	2.2	0.68	0.33	0.25	0.13	0.096
Spleen	2.2	0.84	0.46	0.29	0.19	0.14
Lungs	0.96	0.38	0.20	0.13	0.092	0.064
Kidneys	0.81	0.34	0.19	0.13	0.089	0.074
Ovaries	0.80	0.8	0.19	0.11	0.058	0.053
Uterus	0.79	0.35	0.19	0.12	0.076	0.062
LLI wall	0.69	0.28	0.15	0.097	0.060	0.051
Liver	0.69	0.31	0.17	0.11	0.076	0.058
Gallbladder wall	0.69	0.26	0.14	0.093	0.059	0.049
Sm Intestine	0.68	0.29	0.15	0.096	0.060	0.047
ULI wall	0.67	0.27	0.15	0.090	0.057	0.046
Stomach wall	0.65	0.27	0.14	0.089	0.057	0.047
Adrenals	0.65	0.28	0.15	0.095	0.061	0.048
Testes	0.64	0.27	0.14	0.085	0.052	0.041
Red Marrow	0.62	0.26	0.14	0.089	0.057	0.047
Thymus	0.61	0.26	0.14	0.086	0.056	0.044
Thyroid	0.61	0.26	0.13	0.080	0.049	0.039
Muscle	0.58	0.25	0.13	0.078	0.049	0.039
Bone Surfaces	0.57	0.24	0.12	0.079	0.052	0.041
Breast	0.54	0.22	0.11	0.068	0.043	0.034
Skin	0.49	0.20	0.10	0.060	0.037	0.030
Brain	0.29	0.13	0.09	0.078	0.072	0.070
Other Tissues	0.59	0.25	0.13	0.083	0.052	0.042

<sup>1</sup> MIRDOSE 2 software was used to calculate the radiation absorbed dose. Assumptions on the biodistribution based on data from Gallager et al. (JNM 18:10,990-996) and Jones et al. (JNM 23:7,613-617).

<sup>2</sup> The dynamic bladder model with a uniform voiding frequency of 1.5 hours was used.

**HOW SUPPLIED**  
NDC 60326-511-18

Fludeoxyglucose F18 Injection is supplied in a multi-dose, septum capped 30 ml glass vial containing between 148 – 1480 MBq/mL (4 – 40 mCi/mL) of no carrier added 2-deoxy-2-<sup>[18F]</sup>fluoro-D-glucose, at end of synthesis, in approximately 16 mL.

This radiopharmaceutical is licensed by the Illinois Department of Nuclear Safety for distribution to persons licensed pursuant to Section 330.260(a),(b),(c) for Radioactive material specified in 32 Ill. Adm. Code 335.4010, as appropriate, or under the equivalent licenses of an Agreement State or Licensing State.

**STORAGE**

Fludeoxyglucose F18 should be stored upright in a lead shielded container at controlled room temperature.

Storage and disposal of Fludeoxyglucose F18 should be in accordance with the regulations and a general license, or its equivalent, of an Agreement State or a Licensing State.

**EXPIRATION DATE AND TIME**

The expiration date and time are provided on the container label. Fludeoxyglucose F18 should be used within 8 hours from the time of the end of synthesis.

Caution: Federal Law Prohibits Dispensing Without Prescription

Manufactured by:  
Distributed by:

PETNet Pharmaceutical Services, Inc. at  
The Methodist Medical Center of Illinois  
221 N.E. Glen Oak Ave., Peoria, IL 61636

**LABELING**

IMMEDIATE CONTAINER

VIAL/LEAD PIG

**Fludeoxyglucose F18 Injection  
Diagnostic-For Intravenous Administration**

Lot# \_\_\_\_\_ Expiration Date/Time: \_\_\_\_\_ / \_\_\_\_\_  
(12 hours after EOS\*)

Calibration: Date: \_\_\_\_\_ Time: \_\_\_\_\_ (EOS\*)

Activity Concentration: \_\_\_\_\_ mCi in \_\_\_\_\_ mL @ EOS\*

Each mL contains 148 – 1480 MBq (4 – 40 mCi) of no carrier added 2-deoxy-2-[<sup>18</sup>F]fluoro-D-glucose @ EOS\* and 9 mg of sodium chloride. Caution: Federal Law Prohibits Dispensing Without Prescription. Store upright in a shielded container at controlled room temperature. Do not use if cloudy or contains particulate matter. <sup>18</sup>F Half-life = 110 min. Calculate correct dosage from date and time of calibration. Manufactured by PETNet Pharmaceutical Services, LLC. (radioactivity caution statement and symbol)

EOS = End of Synthesis