

FLUDEOXYGLUCOSE F18- fludeoxyglucose f18 injection
Houston Cyclotron Partners LP dba Cyclotope

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Fludeoxyglucose F18 Injection safely and effectively. See full prescribing information for Fludeoxyglucose F18 Injection.

Fludeoxyglucose F18 Injection

Initial U.S. Approval: 2005

----- **DOSAGE FORMS AND STRENGTHS** -----

Multiple-dose glass vial containing 0.74-18.5 GBq/mL (20-500 mCi/mL) of Fludeoxyglucose F18 Injection and 4.5 mg of sodium chloride in citrate buffer (approximately 16 – 17 mL volume), for intravenous administration (3).

----- **ADVERSE REACTIONS** -----

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

To report SUSPECTED ADVERSE REACTIONS, contact CYCLOTOPE at 1-713-747-5686 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Revised: 8/2012

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FULL PRESCRIBING INFORMATION

3 DOSAGE FORMS AND STRENGTHS

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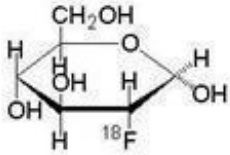
6 ADVERSE REACTIONS

Hypersensitivity reactions with pruritus, edema and rash have been reported in the post-marketing setting. Have emergency resuscitation equipment and personnel immediately available.

11 DESCRIPTION

11.1 Chemical Characteristics

Fludeoxyglucose F 18 Injection is a positron emitting radiopharmaceutical that is used for diagnostic purposes in conjunction with positron emission tomography (PET) imaging. The active ingredient 2-deoxy-2-[¹⁸F]fluoro-D-glucose has the molecular formula of C₆H₁₁¹⁸FO₅ with a molecular weight of 181.26, and has the following chemical structure:



Fludeoxyglucose F 18 Injection is provided as a ready to use sterile, pyrogen free, clear, colorless citrate buffered solution. Each mL contains between 0.740 to 18.5 GBq (20.0-500 mCi) of 2-deoxy-2-[¹⁸F]fluoro-D-glucose at the EOS, 4.5 mg of sodium chloride in citrate buffer. The pH of the solution is between 4.5 and 7.5. The solution is packaged in a multiple-dose glass vial and does not contain any preservative.

11.2 Physical Characteristics

Fluorine F 18 has a physical half-life of 109.7 minutes and decays to Oxygen O 18 (stable) by positron decay. The principal photons useful for imaging are the dual 511 keV "annihilation" gamma photons, that are produced and emitted simultaneously in opposite direction when the positron interacts with an electron (Table 2).

Table 2: Principal Emission Data for Fluoride F18

Radiation/Emission	% per Disintegration	Mean Energy
Positron (β^+)	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)

The specific gamma ray constant (point source air kerma coefficient) for fluorine F 18 is 5.7 R/hr/mCi (1.35×10^{-6} Gy/hr/kBq) at 1 cm. The half-value layer (HVL) for the 511 keV photons is 4 mm lead (Pb). The range of attenuation coefficients for this radionuclide as a function of lead shield thickness is shown in Table 3. For example, the interposition of an 8 mm thickness of Pb, with a coefficient of attenuation of 0.25, will decrease the external radiation by 75%.

Table 3: Radiation Attenuation of 511 keV Photons by Lead (Pb) Shielding

Shield Thickness (Pb) mm	Coefficient of Attenuation
0	0.00
4	0.50
8	0.25
13	0.10
26	0.01
39	0.001
52	0.0001

For use in correcting for physical decay of this radionuclide, the fractions remaining at selected intervals after calibration are shown in Table 4.

Table 4: Physical Decay Chart for Fluoride F18

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

* Calibration time

16 HOW SUPPLIED / STORAGE AND DRUG HANDLING

Fludeoxyglucose F 18 Injection is supplied in a multi-dose, capped 30 mL glass vial containing between 0.740 – 18.5 GBq/mL (20 - 500 mCi/mL), of no carrier added 2-deoxy-2-[F 18] fluoro-D-glucose, at end of synthesis, in approximately 16 - 17 mL. The contents of each vial are sterile, pyrogen-free and preservative-free.

NDC 47584-001-01

Store the Fludeoxyglucose F 18 Injection vial upright in a lead shielded container at 20° to 25°C (68° to 77°F); excursions permitted to 15-30°C (59-86°F) [See USP Controlled Room Temperature].

Distribute, 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.

The expiration date and time are provided on the container label. Use Fludeoxyglucose F 18 Injection within 12 hours from the EOS time.

Manufactured and distributed by:
 Cyclotope
 Accelerated Medicine
 8285 El Rio Suite 160
 Houston, TX 77054
 USA

Label for Container Closure System: 30 ml Vial

NDC# 47584-001-01	Multiple-Dose Vial
Fludeoxyglucose F 18 Injection	
20 mCi/mL to 500 mCi/mL @ EOS*	
Sterile, Non-pyrogenic	Diagnostic - For Intravenous Use Only
Date	Lot #
Exp.	(Expires 12 hour(s) after EOS*)
Each ml contains:	Store at 20° to 25°C (68° to 77°F) (see insert).
0.74 GBq to 18.5 GBq (20 mCi to 500 mCi) of no-carrier added Fludeoxyglucose F 18 (2-deoxy-2-[18F]fluoro-D-glucose) @ EOS* and 4.5mg of sodium chloride in citrate buffer.	Store upright in a shielded container.
Do not use if cloudy or if it contains particulate matter.	Aseptically withdraw and handle doses.
*EOS = End of Synthesis	[18F] Half-Life = 109.7 minutes. Calculate correct dosage from date and time of calibration.
CAUTION: RADIOACTIVE MATERIAL	Manufactured by: CYCLOTOPE 8285 El Rio suite 160 Houston, TX 77054



R_x ONLY

Label for Lead Pig Container

NDC# 47584-001-01

Multiple-Dose Vial

Fludeoxyglucose F 18 Injection

20 mCi/mL to 500 mCi/mL @ EOS*

Activity @ EOS*: Total mCi Volume ml
Concentration mCi/ml

Sterile, Non-pyrogenic
Calibration (EOS*) Time
Calibration Date

Diagnostic - For Intravenous Use Only
Exp. Date/Time
Lot #
(Expires 12 hour(s) after EOS*)

Each ml contains:

0.74 GBq to 18.5 GBq (20 mCi to 500 mCi) of no-carrier added Fludeoxyglucose F 18 (2-deoxy-2-[18F]fluoro-D-glucose) @ EOS* and 4.5mg of sodium chloride in citrate buffer.

Do not use if cloudy or if it contains particulate matter.

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CAUTION: RADIOACTIVE MATERIAL

Store at 20° to 25°C (68° to 77°F) (see insert).
Store upright in a shielded container.
Aseptically withdraw and handle doses.
[18F] Half-Life = 109.7 minutes. Calculate correct dosage from date and time of calibration.



Manufactured by: CYCLOTOPE
8285 El Rio suite 180
Houston, TX 77054

R₁ ONLY

FLUDEOXYGLUCOSE F18

fludeoxyglucose f18 injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:47584-001
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FLUDEOXYGLUCOSE F-18 (UNII: 0Z5B2CJX4D) (FLUDEOXYGLUCOSE F-18 - UNII:0Z5B2CJX4D)	FLUDEOXYGLUCOSE F-18	500 mCi in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47584-001-01	16 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product	12/08/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203665	12/08/2011	

Labeler - Houston Cyclotron Partners LP dba Cyclotope (118258354)

Establishment

Name	Address	ID/FEI	Business Operations
Houston Cyclotron Partners LP dba Cyclotope		118258354	positron emission tomography drug production(47584-001)

