



[¹⁸F] Fluorodeoxyglucose

([¹⁸F] FDG) Solution

for Diagnostic Use

Pharmaceutical Form

Solution for injection. Clear, colourless or slightly yellow solution.

Availability, Calibration and Expiry

Glucotracer is produced 3 times a day, from Monday to Friday.

	Calibration Time*	Expiry*
Run A	9H50	14H00
Run B	12H50	17H00
Run C	15H50	20H00

*CET

Activity Concentration

5 mCi/mL (185 MBq/mL)
at calibration time.

Vial and Container

Glucotracer is supplied in crimped 20 mL multi-dose vial, colourless glass. One vial contains 2 to 10 mL of solution, corresponding to 10 to 50 mCi (370 to 1850 MBq) at calibration time.

Order Deadline

At noon, the working day before delivery.

Storage

Do not store above 30°C.
Store in the original package.

Delivery Service

At MDS Nordion, we know that physicians and patients absolutely depend on reliable and timely supply. Carefully managed transportation logistics ensure products reach their destination on time.

NAME OF MEDICINAL PRODUCT: Glucotracer QUALITATIVE AND QUANTITATIVE COMPOSITION: 1 ml solution for injection contains 185 MBq [¹⁸F]-fludeoxyglucose at the date and time of calibration. The activity per vial ranges from 185 MBq to 1850 MBq. PHARMACEUTICAL FORM: solution for injection, clear, colourless or slightly yellow solution. DIAGNOSTIC USE: ONCOLOGY Glucotracer is indicated for imaging in patients undergoing oncologic diagnostic procedures describing function or diseases where enhanced glucose influx of specific organs or tissues is the diagnostic target. The following indications are sufficiently documented. DIAGNOSIS: characterisation of solitary pulmonary nodules, metastatic cervical adenopathy of unknown origin. STAGING: head and neck cancers including assistance in guiding biopsy, primary lung cancer, including detection of distant lung metastases, Oesophageal cancer (staging for oesophageal cancer by FDG-PET may be indicated when cancer remains in doubt after completion of a standard diagnostic workup using endoscopic ultrasound-fine needle aspiration, including conventional imaging), recurrent colorectal cancer, malignant lymphoma, malignant melanoma (Breslow >1.5 mm or lymph node metastasis during first diagnosis – regarding metastases in the brain and coincidence cameras). MONITORING OF THERAPEUTIC RESPONSE: malignant lymphoma, head and neck cancers. DETECTION IN CASE OF REASONABLE SUSPICION OF RECURRENCES: glioma with high grade of malignancy (III or IV), head and neck cancers, thyroid cancer (non-medullary): patients with increased thyroglobulin serum levels and negative ¹³¹I whole body scintigraphy, primary lung cancer, colorectal cancer, malignant lymphoma, malignant melanoma. CARDIOLOGY In the cardiologic indication, the diagnostic target is viable myocardial tissue that takes -up glucose but is hypo-perfused, as it must be assessed beforehand using appropriate blood-flow imaging techniques: evaluation of myocardial viability in patients with severe impaired left ventricular function who are candidates for revascularisation when conventional imaging modalities are not contributive. NEUROLOGY In the neurologic indication the interictal glucose hypometabolism is the diagnostic target: localisation of epileptogenic foci in the presurgical evaluation of partial temporal epilepsy. POSOLOGY AND METHOD OF ADMINISTRATION: the recommended activity for an adult weighing 70 kg is 100 to 400 MBq (this activity has to be adapted according to the body weight of the patient and the type of camera used), administered by direct intravenous injection. Only few clinical data are available for patients aged less than 18 years concerning safety and diagnostic efficacy of the product. Therefore, the use in oncologic paediatrics has to be carefully weighted. The activity administered to children and to adolescents is a fraction of the activity recommended for adults. The injection must be intravenous in order to avoid irradiation as a result of local extravasation, as well as imaging artefacts. The emission scans are usually started 45 to 60 minutes after the injection of [¹⁸F]-fludeoxyglucose. Provided a sufficient activity remains for adequate counting statistics, [¹⁸F]-fludeoxyglucose-PET can also be performed up to two or three hours after administration, thus reducing background activity. If required, repeated examinations can be carried out at short notice. CONTRA-INDICATIONS: pregnancy, hypersensitivity to the active substance or to any of the excipients. UNDESIRABLE EFFECTS: undesirable effects after the administration [¹⁸F]-fludeoxyglucose have not been observed to date. Since the administered substance quantity is very low, the major risk is caused by the radiation. Exposure to ionising radiation can lead to cancer or development of hereditary defects. Most examinations involving nuclear medicine involve levels of radiation (effective dose) less than 20 mSv.

MARKETING AUTHORIZATION NUMBERS: Belgium 1550 S1 F12 – France: 564 460-1 – The Netherlands: RVG30437 – Luxembourg: 1331-04090012 – Germany: 59605.00.00

Fluorine 18 Decay Table Half-Life: 109.77 minutes

MINUTES:		0	6	12	18	24	30	36	42	48	54
HOURS	0	1.00000	0.96280	0.92699	0.89250	0.85930	0.82734	0.79656	0.76693	0.73840	0.71094
	1	0.68449	0.65903	0.63451	0.61091	0.58819	0.56631	0.54524	0.52496	0.50543	0.48663
	2	0.46853	0.45110	0.43432	0.41816	0.40261	0.38763	0.37321	0.35933	0.34596	0.33309
	3	0.32070	0.30877	0.29729	0.28623	0.27558	0.26533	0.25546	0.24596	0.23681	0.22800
	4	0.21952	0.21135	0.20349	0.19592	0.18863	0.18162	0.17486	0.16836	0.16209	0.15606
	5	0.15026	0.14467	0.13929	0.13411	0.12912	0.12431	0.11969	0.11524	0.11095	0.10682
	6	0.10285	0.09902	0.09534	0.09179	0.08838	0.08509	0.08193	0.07888	0.07595	0.07312
	7	0.07040	0.06778	0.06526	0.06283	0.06050	0.05824	0.05608	0.05399	0.05198	0.05005
	8	0.04819	0.04640	0.04467	0.04301	0.04141	0.03987	0.03839	0.03696	0.03558	0.03426
	9	0.03298	0.03176	0.03058	0.02944	0.02834	0.02729	0.02627	0.02530	0.02436	0.02345
	10	0.02258	0.02174	0.02093	0.02015	0.01940	0.01868	0.01798	0.01732	0.01667	0.01605
	11	0.01545	0.01488	0.01433	0.01379	0.01328	0.01279	0.01231	0.01185	0.01141	0.01099

The half-life values stated are as of time of publication. MDS Nordion values may vary.

ref: internal report

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